Locating Ethics: capacity building, ethics review and research governance across Asia

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Research ethics has become integrated into what it means to conduct good science. This thesis is about the nature of that integration, which I argue is not neutral, carrying with it ideas of duty, moral obligations, organisational mechanisms, and processes of monitoring. For developing countries to participate in global research, the pre-requisite of ethical review has necessitated a growth in capacity building exercises.

The chapters aim to elucidate ethnographically the activities and implications of 'capacity building' activities in biomedical research ethics, through following the trainings, assessments and networking of the Forum of Ethics Review Committees of Asia and the Pacific (FERCAP), a Non-Governmental Organisation. The work provides a critical reflection on the spread and uptake of ethics, contributing particularly to literatures in medical anthropology, organisational studies, and development anthropology. Drawing on material from ethnographic fieldwork with the NGO in Sri Lanka, Thailand, the Philippines, Taiwan and mainland China over 12 months between March 2009 and November 2010, it advances an argument that the uptake of ethics through forms such as the Ethics Review Committee implicates social relations in new forms of management, with the moralities assumed to be part of ethics attaching to varied understandings of obligation, accountability, trust and personhood. Central to the analysis is the exploration of the co-existence of standardisation with practices of differentiation within the activities of FERCAP, a tension explored through a theoretical framework informed by attention to fractal imageries replicated across the settings of research.

Locating Ethics

Capacity building, ethics review and research governance across Asia

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List of Illustrations

Abbreviations

Ethics Review Committees are known by many names:

EC	Ethics Committees (Sri Lanka)
ERC	Ethics Review Committees (Europe)
REC	Research Ethics Committees (UK, WHO, Thailand)
IEC	Institutional Ethics Committee (USA)
IRB	Institutional Review Boards (USA, Philippines, Taiwan)
IRB	Independent Review Boards (USA)
REB	Research Ethics Boards (Canada)

EC is a shorthand used most frequently in FERCAP's presentations; IRB is used more by American commentators and countries which orient their ethics review procedures towards the American model. For this reason, I have preserved the different usages throughout the text, rather than choosing a common term.

Key Acronyms

FERCAP: Forum of Ethics Review Committees of Asia and the Western Pacific

SIDCER: Strategic Initiative in Developing Capacity in Ethical Review

TDR: Tropical Disease Research, an arm of the WHO

WHO: World Health Organisation

GCP: Good Clinical Practice

SOP: Standard Operating Procedure

WIRB: Western IRB

AAHRPP: Association for the Accreditation of Human Research Protection Programs

Statement of Copyright

Acknowledgements

This work bears many debts. Some I here acknowledge and repay with thanks, others I hope to keep open, in the knowledge that happy debts give sustenance to continued relationship. Since I do not name the committees I observed, I cannot name all those with whom I spoke during this research. Nonetheless, all are thanked for allowing me to participate, watch and ask questions. I thank particularly Dr Cristina Torres and Dr Juntra Karbwang for their support and openness. I hope those who so generously opened their working lives to me will find something in the resulting text of interest.

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For H.

Chapter 1: Introduction

I want to begin by recounting a conversation that occurred at a Bangkok lunch table during a training workshop on Good Clinical Practice (GCP) and Research Ethics. Our plates were almost cleared and Cristina, the speaker, was reporting a recent discussion she had had with an American academic:

> They asked me, 'How are you going to do a system when you don't have any laws?' And I said, 'Have you never heard of moral force?' If a group of people believe something strongly enough, you don't need laws. I think that is what we're doing. You need to be strategic.

'And what is "moral force"?' I asked.

> You get the leaders in different countries to be with you. That kind of force. I think we're happy to meet the doctors, because they're leaders in their respective countries. That kind of moral force can be powerful as well if you can convince important people. We're not a human rights program, that would work with the masses and make them agitate for regulation. We're trying to create a duty based ethics, if you don't do your duty then you're not a good professional. We're not working with patient groups. Our audience are the doctors, academics, regulators.

Conducted within the International Science and Bioethics Collaborations (ISBC),[1] a tri-university anthropological study of collaborations in biomedical science across Asia, this doctoral research was tasked with examining capacity building of research governance in developing country settings. It takes Ethics Review Committees as the locus of that governance. Cristina, with whom I shared lunch that day in Bangkok, is the coordinator of a regional Non-Governmental Organization (NGO) called the Forum of Ethics Review Committees of Asia and the Pacific (FERCAP), who became the focus of the study. Her comments above have come to form one of the key conversations structuring my analysis of the Forum's work. FERCAP's principal activity is capacity building in ethics review through trainings, networking, Surveys and an annual conference. Positioning myself in this regional NGO for 12 months of fieldwork, I followed their activities across several of the Asian countries they work in. Though the research is 'multi-sited', the faces at each site have been largely familiar as it is *they who move*, surveying, training and conducting meetings. I followed.

The American academic's question betrays a sense of absence in the face of the project of 'doing' a system: where are the laws? Over the course of the following chapters, I explore the various

[1] ESRC Res 062-23-0215.

implications of Cristina's rich response. Through both the ethics committee and the dissertation we find repeated the tensions between different forms of governance. As the following chapters demonstrate, claims to independence, the consideration of different viewpoints, a commitment to evidence and 'objectivity' are all tools used within and upon ethics. Cristina's invocation of the concepts 'moral force' and 'duty based ethics' provide a way in to conceptions of ethics which themselves have a long history in anthropology (Durkheim 1995[1912, 1992[1957]). She positions herself and her organisation clearly: the capacity she wishes to build is that of professionals, 'doctors, academics, regulators.' Her conversation also reveals the questioners preoccupation with a 'system', law and regulation. It is between these two poles that this thesis stretches. Can one type of behaviour — the conduct of clinical trials — be governed through another: the ethical assessment of proposals? In the growth of ethics committees, we see the growth of and in FERCAP, an 'institution' of governance. In the study of governance through ethics, and the governance of ethics itself, I am led to questions that those who serve on, and train ethics committees ask: how does one convince, compel, or force others into a particular way of acting?

Many of the questions I ask in the text seem elementary: what is an ethics committee? What makes ethics committees necessary, desirable and possible? How do ethics committees make decisions? In order to begin to answer these questions, 'committee' and 'ethics' must be disaggregated and put back together again; the form (Riles 2001) of this form of governance, and the people who exercise it, carefully examined. Ethics is a contemporary companion to audit and other fixtures of regulatory life. The research constitutes an investigation into the introduction of ethics review committees to Asian settings, and the chapters of this thesis have two aims: to explore the ethics review committee as a form of decision-making, and to explore its consequences.

The recent collection *Social Knowledge in the Making* summarizes neatly the background to my approach, borrowing from Science and Technology Studies (STS) and Legal Anthropology a 'turn to practice' in the study of social knowledge, 'the overdue arrival of social knowledge practices as a central topic for empirical investigation' (Camic, Gross and Lamont 2011:13). I add to this practice based study of social knowledge Annelise Riles' observation that 'behind and within objects are theories and behind theories are objects' (2011:68), evident in my attention to the material manifestations of 'ethics'. I combine the interest of STS scholars in 'showing how specific relations between human and non-human agents are drawn into the business of sustaining the

image of an external, objective order of being — the networks that sustain the practices and indeed the notion of modern science' (Edwards et al. 2007:4) with the interest of anthropologists, looking 'at how connections are made and unmade between persons, on what terms and with what effects (ibid).

The collection on social knowledge in the making contains an essay by Laura Stark on Institutional Review Boards (IRBs) in the USA, for whom '[s]tudying evaluation as a social process offers an opportunity [...] to explore the practice of statecraft and to consider its effects on knowledge production' (2011a:250). She is writing in an environment where 'the state' is active through the committees she studies. She can speak of coercive power, and cite laws upon which committees can rely. Indeed, in speaking of IRB members assessment of risks and safeguarding of participants rights, her board members 'say that they do these things because they are moral imperatives and also because they are the law' (2011b:9). Part of what makes her research compelling is that it adds IRBs to a broader consideration of what she terms "declarative bodies" (Stark 2011a:233) through whom state power is issued, such as 'data-and-safety monitoring boards, funding panels, editorial boards and film rating committees' (Stark 2011a:233). Her concern is that these 'expert groups [...] are empowered by governments to make decisions without consulting citizens' (2011a:233). But it is precisely the ability of committees to become 'declarative bodies' (2011a:233) which is at stake in my material. The question posed to Cristina by the American in my opening vignette makes a little more sense. 'How can ethics be done in the absence of law', s/he is asking. How do committees gain their authority? Upon what grounds are they able to claim direction over the work of colleagues?

Noting the capacity of models to travel, Simpson argues that 'the current proliferation of codes of ethics and the ethics committees that are needed to realise these as forms of practice across the developing world' illustrates this mobility, 'a kind of institutional and conceptual penchant to create templates that pass virtually undetected across international frontiers' (2012:156). This research was based in Asia, but its focus is on an activity and phenomenon with distinctly Euro-American origins. In addition, members of FERCAP have received fellowships and training from Western IRB, in Olympia, Washington[2]. They have been fellows of the Global Forum on Bioethics in Research, and are in regular contact with the WHO-TDR. I have spent more time learning about the regulatory systems of the USA and Europe than anticipated, since

[2] The fellowship program, established in 2002, an initiative by the Western IRB, in Olympia Washington, in collaboration with the WHO, Middleton Foundation for Ethical Studies and NIH university of Washington. It allows for international fellows to spend six months in Olympia working with WIRB.

understanding the expectations and problems that these systems face in their 'native' environments, I might better understand how FERCAP are approaching ethics. As Simpson remarks, '[t]he question of who is building capacity and for what purpose becomes contested and challenged in ways that are not apparent in First World contexts' (2012:157). This thesis is about what becomes apparent as ethics committees are established and instiutionalised in Asia, and ethics becomes professionalised.

I therefore cannot begin where Stark does, since her concern with experts, empowered committees, involved governments and the enforcement of laws to protect human subjects in research emanates from a particular setting. This Introduction serves to provide an ethnographic view on my different starting point. I use presentations given at two events during my fieldwork to frame both the organisation I worked with and my approach to their work. The first, a Regional Collaborative Workshop, opens onto the contemporary concerns of members and the need FERCAP serves. I then turn to the FERCAP annual conference as a site from which to view the world of clinical research, looking at who is present, listening, imagining, affected, compelled, and persuaded, considering the events as opportunities to observe world-making.

A Regional Collaborative Workshop

In 2009, on my third day of fieldwork, a workshop took place in the Medical Faculty of Colombo University, Sri Lanka. Designated a '*Regional Collaborative Workshop*' in the ISBC research proposal, it had been arranged through the work of ISBC colleagues at Durham and members of the Colombo medical faculty. Held the day before the Sri Lankan Medical Association (SLMA) annual conference, the invited speakers from across the region each gave a summary of their concerns and experiences around the workshop's title: *Ethical Issues in International Collaboration*. The workshop was my first encounter with members of FERCAP, the regional forum I would go on to study, and it demonstrated the expansion of problems considered to be within the scope of ethics committees. As an entry point for fieldwork it was a rich ethnographic event, its collaborative formation constituting what Marcus (2008:52) would call a 'para-site.' We — UK based researchers — had provided funds and worked with Sri Lankan counterparts to invite speakers around a theme which would not only be of interest to us as part of research, but also to them. As a ground for my analysis of FERCAP's capacity building work, I take the presentations

of speakers from the day which afford insights into concerns, both in practice and the literature surrounding the ethics of international research and capacity building efforts.

Dr Vasantha Muthuswamy, the speaker from India, was FERCAP's founding secretary. She presented that day on the large number of research studies being proposed for and carried out on India's 'diverse population' as a result of international collaborations. 'We will make ethics as a major activity to see that we will take part in international collaboration on our own terms, without compromising the rights of any our population,' she told the audience. Taking examples from genetic research she moved from the consideration of the ethics of presenting a Hindi speaker with a thirty-page informed consent form in English, to the management of a situation where current technologies make possible research that was not conceivable at the time original human tissue samples were collected. The list of things to consider within the meeting was long, and went all the way to publication.

> Our major concern is that generated information may produce ethnic disharmony without realising this, if some information is published without looking at that, it may cause havoc to the whole community and the country. So the results have to be well examined before they are being published.

In that sentence, we left behind the patient in the clinic with their thirty page informed consent document and displaced them with the question of how many samples were really required, or whether there was a collaborative agreement in place for the material transfer of samples. The view of the layperson moved aside as the expert on Material Transfer Agreements (MTAs) spoke. We then began a deliberation on what proposed research will do 'for India', moving from empathy with a potential participant, from immediate physical harm to bodies, to judgement of the measure of harm to a 'whole country'. While these are all different orders of knowledge, our audience experienced no whiplash. We followed the presentation through. 'Learning to think ethics requires thinking of many things,' Vasantha told us.

Dr Muthuswamy's talk demonstrated the encompassment of ethics, not only the use of the term but the way it can be used to reframe, reconfigure. The encompassment is perhaps not surprising. In order to be *seen* to be ethical, there is always more one could have thought of: having thought of it becomes evidence of an 'ethical' stance. Not only is it ethical practice to consider the 'social' or 'legal' aspects of a proposed piece of research, it becomes a game of ethical one-up-man-ship to extend the reach of this arm. Particularly in countries without legislation on the conduct of biomedical research, or governments that run 'public consultation', conjuring 'the public' as something to be consulted, ethics must stand on its own. One set of American powerpoint slides

circulating (Emmanuel 2008) listed three 'tiers' of consideration: 'Must consider how the research will improve the health of: i) Participants in the research, ii) the Community where the research is conducted, iii) The World'. As we watched the presentations at the Regional Collaborative Workshop, the concept seemingly expanded, covering more and more ground. At the time, this appeared

> to leave the work of ethical review in a state of perpetual insufficiency: an ever widening remit, not enough committees, not enough scrutiny, not enough trained people and not enough public participation (Simpson et al. 2010:113).

The next speaker, Dr Hemantha opened by comparing his country with the others gathered. 'Unlike some neighbouring countries, for Sri Lankans, international collaboration is a new field and brings new challenges,' he said. 'As ethicists we need to be prepared to meet these challenges.' The first slide up was a definition of collaboration, which he used to make a contrast between collaborative work that seeks to build something in common, and collaboration that is considered a betrayal. He commented that we often only think of the positive side of collaboration, of all there is to be gained: 'We must never forget there is a negative side as well.' Switching slides, he showed the audience an image of shaven-headed women being paraded through the streets of Second World War France. 'These women were collaborators,' he said. Then:

> I fear this. I fear this. If something goes wrong, we could be paraded around in the press. We have to be acutely aware we could be accused of colluding in exploitation. New colonialism, sweatshops.

I repeat his presentation delivery because it gives us pause. Capacity building may come through collaborative scientific enterprise, but ethical review must balance desires to further a national science arena against the fears outlined above. The word 'collaboration' contains the potential for a switch. Are the relations (and what they bring) welcome? Who decides? This ambiguity is replicated in the research being carried out: science and health can be portrayed as development and progress, but this is a vulnerable image. The language of ethics can be employed to make the shift. The *accusation* of being unethical can stop research; researchers can be evicted (see Simpson 2012). While international collaborative research was thought to bring technologies both material and practice based (Sariola and Simpson 2011), such opportunities present challenges: who will be responsible for decisions about ethics? The task falls to ethics review committees. In this thesis, I trace FERCAP's capacity building of ethics review committees in the way that one might trace a disease, a medical practice or a trial. Before I do, however, it is worth looking at why ethics committees are being focused upon now, and what they are responding to.

Attracting and Deflecting Research

The theme of International Collaboration at the Regional Collaborative workshop was of interest to both the ISBC team and local researchers. Collaboration is a contemporary mode of research favoured by 'knowledge economies.' As Konrad (2012:6) writes, the:

> widely held assumption among leaders of OECD countries [...] that economic growth depends on science-driven technological innovation [...] has resulted in numerous decisions by governments all over the globe to commit investments in science and technology as part of national or cross-national collaborations in innovation.

Similarly, the Royal Society's report on '*Knowledge, networks and nations*' (2011) highlights the changing landscape of scientific research, focusing on the growth in collaboration (see also Wagner and Leydesdorff 2005). Several of my interviewees felt that to build research capacity, research had to be going on: 'research capacity building happens at the high end,' said one Ethics Committee member in Sri Lanka, 'and how many randomised drug control studies are coming through?' He identified improvements in both finance and Sri Lanka's 'academic status' as benefits, saying 'it is easy for a local set up to hang onto the tail and move on, dragged up and be integrated.' The workshop touched upon the 'fine line' walked by ethics committees in developing world settings: 'too restrictive [...] impeding scientific and economic development' or 'excess permissiveness [...] complicit in abuse, injustice or exploitation in research' (Simpson et al. 2010:114). These concerns were echoed in my interviews with ethics committee members in Sri Lanka. For example:

> Say the USFDA approved a test of doing some genetic study and they wanted to use Sri Lanka as an area to do research. They would want to know the credibility of the hospital. If we say "no" [and] take the safe route, then that technology and knowledge could come to Sri Lanka ten years from now. Whereas if we are progressive, if we can take Sri Lanka forward, [we will be] zooming on to the next level.

While emphasis is placed on the export of Euro-American trials to other countries (Angell 2005), the growth in research comes from the confluence of many agendas. Studies of academic, industry and corporate relationships have led to models such as University-Industry Research Relationships (UIRR, see also MacKenzie 2004), 'Mode 2' (Gibbons et al. 1994, Nowotny et al. 2001), 'helical' relations (Etkowicz et al. 1998, Etzkowicz and Leydesdorff 1997, 2000, see also Baber 2001) and

'academic capitalism' (Slaughter and Rhoades 2004, Mirowski and Sent 2008).[3] Research ambition is not limited to the West (e.g. Sunder Rajan 2005). At a Regional Workshop on Capacity building in Ethical Review in Bangkok in 2009, Professor Priom Kamolratanakul, President of Chulalongkorn University[4] in Thailand announced that:

> One of the ultimate goals of Chula is to become a fulfill[ed] research university. Regarding to that respect, besides conducting international standard level of researches, performances of the Ethics Committees need to meet international standard[s] as well. Fortunately, main Ethics committees of Chula, the medical school's and the Health science group [...] have been recognised by SIDCER/FERCAP (Kamolratanakul 2009:36).

Changes in University administration, expectations and pressures (Shapin 2008, Croissant and Smith-Doerr 2008) mean that universities and researchers in developing countries are keen to host research. 'People can't do research just based on their own curiosity anymore', commented one university lecturer I interviewed in Sri Lanka:

> There are other reasons to do it. It is becoming an institutional necessity. Something has come at the right time and that is the move towards 'publish or perish'. We have to have publications in ICI recognised journals.

Not all institutions were moving in this direction though, as several researchers and interviewees complained that the research quality, even that required for promotion in the universities was still quite poor:

> It is seniority based hierarchy, and it's [position] based on time spent, or I say, wasted. Time spent in a place is the most recognised and you could even have the position if you had not published anything [...] You don't perish, you prosper!

As such, changes in institutional recognition procedures, while approved from above, were being changed from below. 'The old ones aren't going to do this', remarked a lecturer, 'they're already high up.' Dissanayake et al. (2006) reported that the number of institutional Ethical Review Committees (ERCs) in Sri Lanka 'increased rapidly... due to the requirement of ethical review being mandatory for presentation and publication of research.' As Dingwall puts it,

> an important export route for the IRB model has been the control of access to scientific publication. Unless biomedical research has been approved by an IRB-type body, it cannot be published in any major journal. Most leading research countries, and many lesser ones,

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[3] Croissant and Smith Doerr (2008:704) draw attention to the critique leveled at these models from scholars. Grundmann (2004) points to the apparent 'free flowingness' of knowledge, missing the embeddedness and relationality of people and materials. Pestre (2000) criticises their presentist ahistoricism and MacKenzie notes (2004) the implications of models which get taken up outside the academy (see also Nowotny et al. 2003).

[4] Commonly abbreviated to "Chula."

> have installed such systems in order to maintain their access to the international scientific community (Dingwall 2007:788).

Thus sites of biomedical research are linked now not only by experimental practices, but also by particular forms of what could be called ethical practice.

Capacity building and FERCAP

In 2003, the Lancet reported mobilization of capacity building in research ethics, with the European Group on Ethics (EGE)'s announcement that 'fundamental ethical rules applied to clinical trials in industrialised countries must be applicable elsewhere':

> Collaborative trials must involve local scientists from the host country from the earliest stages of research protocol development "to develop a culture of collaboration" and to harness "knowledge of local conditions and traditions". Research protocols must be evaluated by ethics committees from "all involved countries", said the report. But since local ethics panels are commonly lacking in poor countries, EHC "strongly supports EU initiatives" to build local committees in host countries, which should be considered as a priority in terms of "capacity building" (Bosch, 2003:579).

Prompted particularly by the turn of the century increase in multi-sited and 'collaborative' trials, the Lancet's was one of many calls for improvements in 'local' ethical capacity (Eckstein 2004). The Nuffield Council on Bioethics (2002, paragraph 8.22) recommended that all research should have 'dual ended' review, meaning review in both the sponsoring country and the countries where the research will take place ('hosts'). Nuffield's 2008 overview also notes that the Council for International Organizations of Medical Sciences (CIOMS) (2002) 'does not necessarily require host countries to have a distinct, fully functioning REC, although representatives from the host countries should be involved in the ethical review process' (2008:490). More recent documents put the need for a 'local' ethics committee more strongly:

> A clinical trial should not take place in a country in the absence of a review by an Ethics Committee in that country. If such a committee does not exist it should be established as a pre-requisite before the trial takes place (EMA 2012:17).

Through the 'local' of two-ended ethical review, there is a recognition that while the bodies of 'elsewhere' may become (can be imagined as) part of the assemblages of international medical research, the social worlds may not. The problem with having trials reviewed 'elsewhere' (here the elsewhere is not the elsewhere of the 'local', whose capacity is to be built, but the West understood as elsewhere), as one WHO employee told me, was that 'those people in Geneva', even if they were 'very good' and even if they meant well, could not tell how research would be 'locally' received. Although guidance exists (e.g.. Fitzgerald et al. 2003), most I interviewed felt

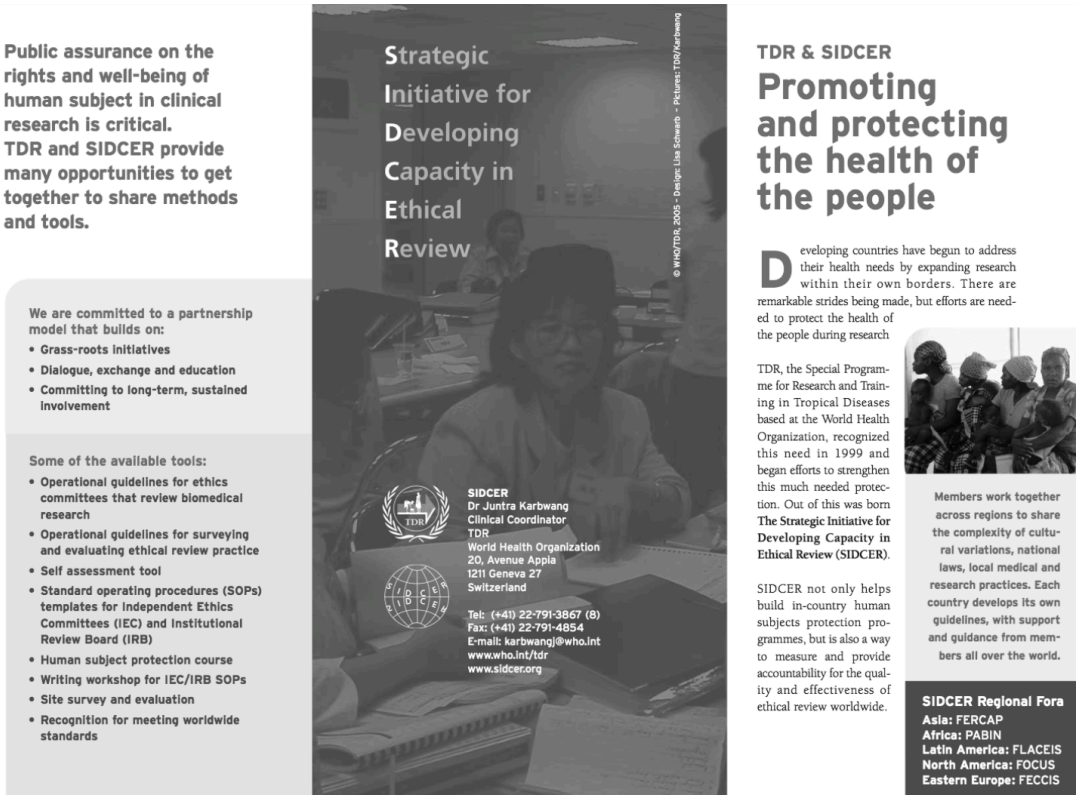

Figure 1: SIDCER Pamphlet.

that no matter what their scientific and ethical expertise, committees abroad did not have the 'local knowledge' required to make a decision, or to make it on behalf of people in (any part of) Asia, for example. Capacity building is pitched as the solution, through which ethics can be taught 'locally', 'local' committees established, and standards met.

Juntra Karbwang, one of my key interlocutors, was the coordinator and a co-founder of the Strategic Initiative in Developing Capacity in Ethical Review (SIDCER). The initiative was established to help countries help themselves as they establish biomedical research arenas; its aims are described in its promotional documents (Figure 1). Speaking about the initiative and its intended effects, Juntra commented that

> Review *has* to come from within the country. Rather than use England, 'the competent one' or Geneva, why not harness capacity? When we are in Geneva, we say we want this to change. In Geneva we say, it has to be like this, but how do we know what is acceptable? We *imagine* these will be the issues.

Like Juntra, others who wish to see capacity describe the form it must take. Nancy Kass of Johns Hopkins University has argued that

> short workshops cannot effect a sustained impact on their own [...] Without sustained local presence, it is unrealistic to imagine that ethics training ultimately will have much impact.

> And to state the obvious, it is both impractical and inappropriate for that role to be served by a transient professional from the outside (Kass, cited by Eckstein 2004)

There is even the suggestion that short term training may reinforce existing disparities (see Ulrich 2011, Shrum 2005, Wagner et al. 2001). Juntra reframes her point, emphasising not the inadequacy of review inspired by distance, but the inadequacy of the current inequalities in review capacity. She leverages her position as an experienced Thai researcher against her job and colleagues in the WHO:

> Why use Geneva? The power stays with [Geneva]. [Geneva] thinks you're not good enough to have power, and then they never share it, so nobody else ever tries. Once you assume [other countries] don't know how to do review…[she shrugs]. I say [other countries] do, and [Geneva] says, 'What evidence do you have?'

In response to these challenges and issues, Juntra has been instrumental in establishing regional branches for SIDCER, of which FERCAP is the most successful. An indicator of its capacity building profile is its recent citation by The European Medicines Agency, which lists FERCAP's work as a key initiative in its recent report on the ethical and GCP aspects of clinical trials

Table 3. *FERCAP Initiatives in Support of Ethical Review Systems*

Ethical review system goals	FERCAP initiatives
Protection for research participants	*Human Participant Protection Course* (HPPC)
Consistency and cooperation	*Standard Operating Procedure* (SOP) *Development Course*
Highest attainable quality in science and ethics	*SIDCER Recognition Program*

Figure 2: Objectives and Initiatives box (Torres 2011)

conducted outside the EU (EMA 2012:14). As a network of persons, institutions and events, its primary activities are: trainings, surveys and conferences (Figure 2).

The Survey, which I discuss in Chapter 2, implements the SIDCER Recognition program, a three day assessment in which groups of FERCAP surveyors visit ethics committees, review them, make recommendations, and if the standards are met, award them a certificate of recognition. The hoped for effects are laid out in this Strategy Diagram (Figure 3).

In the following section I focus on one of these activities, the annual conference, as a way of describing FERCAP's priorities and concerns as they play out through presentations, break-chats and trainings. I draw on ethnographic material from my visits to the 9th conference in Chiang

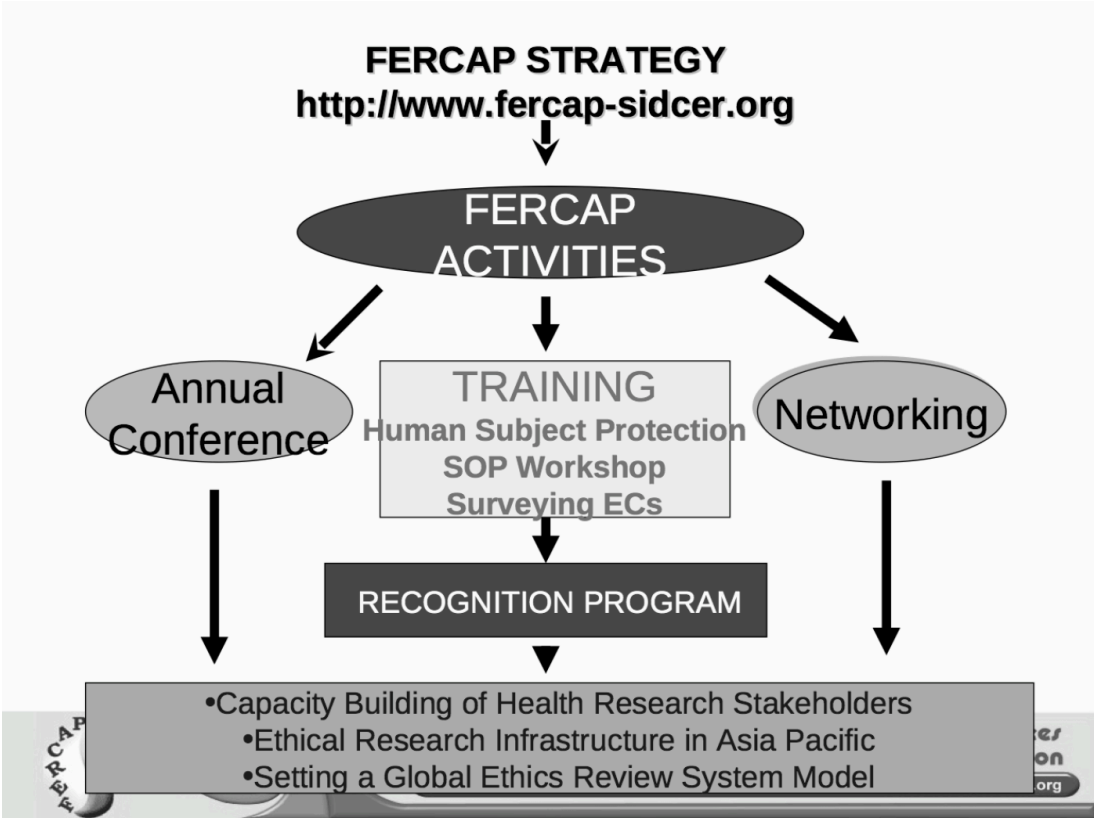

Figure 3: FERCAP Strategy Diagram

Mai in 2009, and the 10th in Shanghai in 2010 as well as archived materials from previous years. To understand Cristina's response to the question asked in the opening vignette, it is essential to also address the world the question comes from (Haraway 1996:440). At the Conference, the links between the world Stark studied in the USA and the committees trained by FERCAP in Asia become more visible, and the way these links are conceptualised become part of the way I establish my approach to the topic.

Thinking Conference

Conferences are familiar to the point of banality for academics. From time to time, anthropologists have turned their attention to their own ritual gatherings — and those of others — in order to analyse what it is that compels people to travel large distances, meet, and discuss. Anthropologists of policy, expertise and the character of knowledge in contemporary institutions and organisations have found themselves conducting fieldwork at conferences, listening to papers being given and break-time conversation shared (Gross and Fleming 2011, Schwegler 2008, Fortun

2001, Shore and Wright 1997, Gusterson 1996, Helmreich 2000, Sunder Rajan 2006, for historical attention see Mead and Byers 1968).

The Annual Conference is FERCAP's key annual event, where people speak from podiums to colleagues gathered from across Asia. For the observer, it provides a glimpse of the organisation's self descriptions, the images that constitute its imaginary of place within an international arena. At the Conference, FERCAP describes itself both to itself and to international guests. It needs to draw a convincing image, and 'to create the conditions of trust under which their representations will hold conviction' (Strathern 2006:189). The FERCAP Conferences I attended during fieldwork in Chiang Mai, northern Thailand (November 2009) and Shanghai, China (November 2010), were held, as Conferences usually were, in a vast single room of a large, chain hotel. Banners detailing the title, venue, dates and sponsors were strung up on vast boards; rows of chairs placed in equally spaced lines. An annual event since 2000, the Conference brings together FERCAP members from around the region, and past titles of the FERCAP Conference give us a sense of the priorities of the meetings: 'equity and responsibilities' (2004), 'roles, responsibilities and relations' (2006), 'developing quality systems 'transparency and accountability' (2007) 'ethics of responsibility' (2007, also 2008) 'developing leadership' (2009) 'towards good practices and integrated systems' (2009) 'networking and alliance building' (2010) 'innovation and integration' (2011), and in 2012 'ethnicity, culture, religion and ethical research'. The invited guests — international speakers from US NIH, EMEA, regulatory bodies, European Universities and the WHO-Tropical Disease Research arm — speak alongside researchers and ethics committee members from the Asia-Pacific region. All are called upon as 'stakeholders' — physicians, researchers, manufacturers and governments, national health authorities and ethics committees — to work together towards human subject protection.

In what follows, I begin by examining the 'macro-structuring' (Callon and Latour 1981) active in the Conference through presentations and images. Macro-structuring is the term given by Callon and Latour to the work and techniques by which both actors and analysts structure realities, their point being that each act of definition can be regarded as a negotiated achievement when the 'large' and 'small' are not pre-assumed. Before I start, I want to emphasise that claims of 'fragmentation' originate and circulate within the field; they are a description generated by the field itself, not my analysis or claims. I will revisit the point below in a section on Vocabulary, but because of the similarity the terms have with language anthropologists have used to describe 'world systems' (Wallerstein 1974) and fragmented realities (Tyler 1986, Clifford 1986), I repeat

the point for emphasis. Part of the challenge of an ethnographic account of this kind is that the language used to describe the world by those with one whom works resembles (even takes on) certain of the problems of the history of anthropological and sociological thought.

The Cloth: Systems and Fragments

At the 2008 FERCAP Conference in Bangkok, Dr Koski, chair of the SIDCER advisory board and ex-director general of the Office Human Research Protection (OHRP) in the USA, projected this slide to his audience.

> The individuals and entities engaged in human research constitute a matrix of overlapping roles and responsibilities that together serve to ensure that the duties are satisfied. This matrix is like a finely woven silk cloth. A single broken thread causes a defect, a single defect spoils an entire cloth. A single hole can result in disaster, a single disaster can shred the fabric of trust. It is our duty to protect not just research subjects, but to protect the integrity of science itself.

What is this image of a cloth? What can it tell us? (Douglas-Jones, forthcoming). Adriana Petryna's research (2007, 2009) on the spatial mobility of the clinical trials industry shows an 'outsourced world' (2007:290) whose scope and reach is vast, but largely unknown (Sim and Detmer 2005). The growth of multi-centered clinical trials and contract research organisations (CROs) mean that not only is information being generated in many different places by many different people, but the sites of responsibility and oversight seem confused and overwhelming (Etkowitz and Leydesdorff 2000; Nowotny et al. 2002; Ong and Collier 2005). Petryna writes as an American who has researched this outsourcing, but at the FERCAP conference, we begin at what are imagined as the further reaches of these networks. For both analysts and researchers, finding a vantage point from which to view the research process — from the study design to the subject recruitment, data collection and analysis, preparation of report manuscripts creation of strategies for data dissemination and publication (Lemmens 2006) — seems impossible. In Koski's image, the system is imagined in such a way that any point in it — the committee, the standards, the people, the personalities, the institutions — could be 'broken.'

Clinical Trials

When FERCAP presents its program to committees, it describes a world in which trials happen. It is not just that the world contains clinical trials, but that the trials are composed from research done in different parts of the world. 'The same trial being done in Asia, we see it in being done in Africa, in the West. No matter where,' they say, 'the concern is about quality of research.' At a cancer centre in southern China, Cristina explained:

> Basically we work in an environment where clinical trials are globalizing. In your cancer centre, you're doing some of the global trials. I have visited many countries in Asia. Cancer clinical trials are most frequent and popular, and I see the same design being adopted — indication that clinical trials are globalized — one protocol done in different countries all at the same time.

Contemporary biomedical research has the objective of producing a very specific kind of knowledge. The clinical trial, preferably a double blind, randomized control trial (RCT), has become the "gold standard" of medical research; the technique considered to produce the 'best' evidence (Williams and Garner 2002, see also Marks 1997). As Kelly and Geissler remark,

> The RCT provides a statistical framework to interpret the merits of new drugs against the biases of patients and doctors[...] The method can be understood as part of a general epistemic shift across the sciences to practices that privilege objectivity and disinterestedness, the particular objectivity of the RCT is defined by the needs of the market place (2011:4).

Some voices from my research attest to the changes brought about by the RCT and the effects they have had on their practice. Evidence, and the nature of it, is at the center of their experiences:

> This is the thing about presenting evidence. You have to compare it with something else, and there comes this question of double blind trials. Or 'class one evidence.' You have to have a control group, individual patients as per random number and you have to do away with bias on the trial. As a result, class one evidence is very hard to come by, nearly impossible.

Ecks (2008:S80) argues that 'the rise of EBM [Evidence Based Medicine] can be interpreted as one more phase in a systematic devaluation of immediate visibility as a reliable source of scientific evidence,' and he goes on to make the rather astonishing claim that '[d]octors are trained to believe more in statistical evidence than in what they observe in clinical practice' (2008:S80). Jesse, a researcher with whom I had lunch in Bangkok, repeated this feeling:

> In the old days they did not stress RCTs. Now we have realised to make results reliable, [we need to] make sure groups are equal, that there are control and test groups. But placebos are hard to get. You need a package of something of the same colour, the same size, you need to order them and get someone to make them for you. It's more difficult than in the old days, when you said [to the patient] 'I'll give you this' and not give the full information.

The research conducted in institutions in Asia is shaped by the changing expectations of ethics review committees. Cristina reminds her audience at the Cancer Center that:

> Because of [the globalization of clinical trials] it becomes more important that standards are harmonized and there's some assurance that no matter where the trial is held there's some harmonization of standards. All, no matter where, the concern is about quality of research

> and the clinical trial and to talk abut quality you need some kind of oversight, monitoring. That monitoring at the lower level is being done by the EC.

Jesse had found this to be the case in her field. 'IRBs want a good methodology,' she said.

> No more observation. You have to do a RCT, give a participant information sheet, explain the risk. But this is different, and it's hard because the patient may not want to know. In the old days, they didn't want to [know]. 30 years ago, the doctor may not want to tell the patient that they have cancer, because the patient could be sad. That was the ethical thinking of the doctor. But now if he wants to do a trial, he has to prepare an information sheet. The education level of the patient may be low. They may be very frightened.

The difficulty of conducting an RCT led some to claim 'lower classes' of evidence were being produced. According to one of my interviewees, a practicing researcher in Sri Lanka:

> Evidence itself can never be absolute. Unless it is double blind, controlled and free of bias [...] In the past, where you compared something with virtual zero, then a trial was very easy. There's the famous example — what is the ethics of a parachute? If you jump with a parachute, your chance of survival is very high. If you jump without a parachute, your chance of survival is very low. But to prove the parachute is a useful entity, one has to do a double blind to be absolutely ethical. Well, to be scientific.

In his extraordinary example lies a switch: to be ethical, to be scientific. An essential means by which this relationship is negotiated and in which it is contained is Good Clinical Practice, or GCP.

Good Clinical Practice

At the 2010 Shanghai FERCAP conference, Dr Robert Ridley, then-director of WHO-TDR, linked 'ethics' with a turn of the millennium campaign to build capacity in Good Clinical Practice (GCP): 'one of the logjams that inhibited GCP was the lack of appropriate ethical review.' GCP is the result of the cooperation between the regulatory authorities of Europe, Japan and the United States (the International Conference on Harmonisation, ICH), working with the pharmaceutical industry to develop international guidelines for:

> a more economical use of human, animal and material resources, and the elimination of unnecessary delay in the global development and availability of new medicines whilst maintaining safeguards on quality, safety and efficacy, and regulatory obligations to protect public health (ICH 2005).

ICH define GCP as:

> an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and wellbeing of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible (ICH 1996:1).

A 20th anniversary booklet celebrating the value of ICH-GCP for regulators contained an account from Toshiyoshi Tominaga, of the Pharmaceuticals and Medical Devices Agency Japan. It gave the story of how Japanese GCP was developed, publicly and contentiously, with consensus forged by the Japanese working group experts and opinion leaders. Tominaga's narrative ends on April 1st, 1997, the day when Japan was able to 'generate globally usable clinical data' (ICH 2010:14). This 'usability' was intended for regulators, such as Fergus Sweeney, a European GCP working group member who presented to the FERCAP conference in 2010:

> Sitting in Europe, I rely on data coming mostly from countries in other parts of the world. But if I was to change places, and set up in China, the Philippines, in Africa, the USA or Argentina, wherever I sit as a regulator I have data coming from somewhere else. We think it's very important to set out a network. It's very hard for an inspector to inspect 5 different countries [and] it would be impossible to inspect every clinical trial outside Europe. But we receive more and more trials coming from outside Europe. We need a system, we need to network between competent authorities, get some transparency and knowledge of and between different systems.

GCP was about harmonising the regulations and guidelines for drug development, to provide a unified standard to facilitate the mutual acceptance of clinical data by the regulatory authorities. It was, at the outset, focused 'on input by industry — the technical submission requirements for pharmaceuticals for human use' (ICH 2010:2). The submitted information was collated in a 'consistent harmonized format' which was named the 'Common Technical Document' and this standardised format, it was hoped, would 'relieve pharmaceutical companies of the time, workforce and financial burdens of assembling a submission for on DRA and then having to reformat it for another.' The Common Technical Document became electronic, and was widely celebrated:

> Seasoned regulatory affairs hands recall with a mix of bemused nostalgia and frank horror the days before the electronic Common Technical Document - or to be more exact, the days, nights, months, weekends and holidays spent by sleep-deprived regulatory staff to build an NDA for the FDA then deconstructing and reformatting it for EU submission [...] The eCTD has changed all that [...] and the world is better off' (ICH 2010:10)

Petryna writes that the US FDA took an active role in establishing the International Conference on Harmonisation[5] and GCP and it 'began to actively promote the globalisation of clinical trials, declaring that the search for sites and sources of data is part of its mandate to determine the safety and efficacy of new drugs' (2009:37). She provides the backstory to Ridley's ethics logjam:

[5] In addition, ICH E5 (1998: 9, 14) encourages sponsors to address ethnic factors of 'Asians, Blacks and Caucasians' in early phase clinical trials, prompting further trial internationalisation.

> [m]any countries that had already tailored their patent laws according to the provisions of the TRIPS Agreement also signed on to the ICH GCP. They were eager to attract new investments and participate in the booming production of global pharmaceuticals. As ICH-GCP members, they began the costly work of setting up national agencies that could standardise and monitor the conduct and performance of trials in their territories. Countries were required to create ethical review boards to ensure the rights and protections of patients (2009:37).

In the rush to adopt GCP, which they hoped would 'attract new investments,' countries set up ethics review boards. But this quickly became a sticking point: Ridley told the Conference in Shanghai that WHO-TDR recognised 'a need to develop some documentation to facilitate the creation of ethical review committees, and how those committees might operate.' These documents are known as '*The Silver Book*' (2000) and '*The Blue Book*' (2002), entitled '*Operational Guidelines for Ethics Committees that Review Biomedical Research*' and '*Surveying and Evaluating Ethical Review Practices*' respectively (Figure 4).

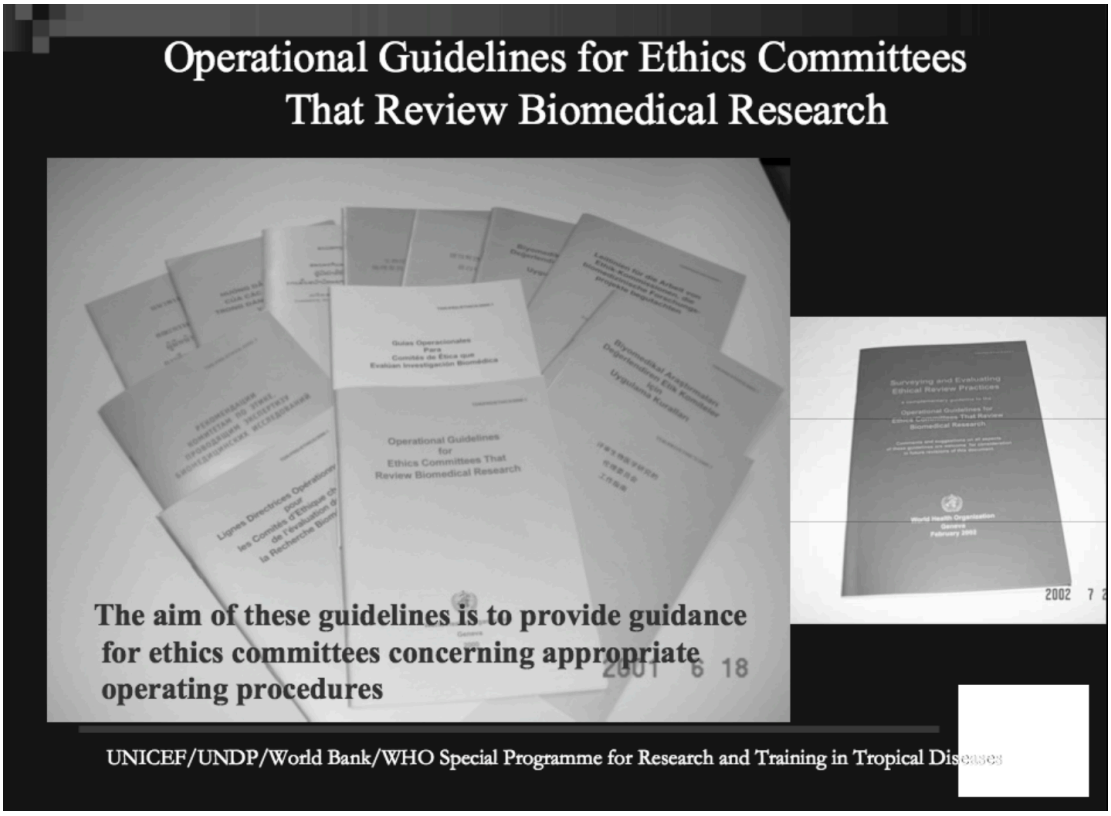

Figure 4: Multiple translations of the Silver Book on the left. Blue Book on the right.

The books are published by the World Health Organizations's Tropical Disease Research arm (TDR), which, according to its Business Plan (2008-13), saw itself in a 'stewardship role for

infectious diseases research' (TDR 2008:2). Philanthropic support, the document states, 'while well meant' has resulted in 'fragmentation' with 'knowledge on priority needs [...] becoming blurred as different research constituencies define priorities from their own specific perspective' (TDR 2008: 6). TDR's Plan writes of a 'need for a global information platform to facilitate effective collaboration among all stakeholders in order to avoid fragmentation and to enhance effective utilization of available resources.' In line with this spirit, in 2009, SIDCER and FERCAP came up with a shared vision of 'a global network that fosters an integrated and sustainable ethical review system toward quality culture in health research' (FERCAP 2009, Navarro and Na-Bangchang 2011).[6]

GCP is a measure against which research matters; it also claims the entanglement of scientific and ethical knowledge in the same document. The debate over nature of this entanglement has increased in recent years, as in 2008, the USFDA declared that clinical trials performed outside of the US only had to comply with GCP, not the declaration of Helsinki (DHHS 21 CFR part 312). In the academic and professional debate which followed, Goodyear et al. argued that

> despite assurances by the FDA, GCP is not an ethical code, but a procedural regulatory manual based on the regulatory frameworks of the US, Japan and Europe. Thus it is a description of existing procedures (2009: 1559).

The USFDA has also come under strong criticism from academics, who see the GCP guidelines — 'abetted by a rhetoric of universal human rights' that steps into ethics and ethics review — turning Research Ethics Committees into 'mechanisms for creating 'open' worldwide markets in pharmaceuticals and clinical devices' (Abraham and Reed 2002 cited in Dyer and Demeritt 2009: 53). This arena provides perhaps another forum for studies of the co-imbrication of economics and morality (e.g. Bornstein 2003, Coleman 2005).

GCP describes two-fold quality systems: quality control and quality assurance (Bhatt and Pradhan 2008:15), the former checking and testing for quality, the latter designing and planning a process or system which will result in the desired outcome. Comparing the Belmont Report with GCP, a FERCAP trainer said: 'Those were principles. These are procedures. GCP is the common language.' At the 2010 FERCAP Conference, Sweeney reminded attendees that:

> It's not regulators from another part of the world which can ensure the patients are protected [...] Therefore we want to reach out more and build and extend our relationships with regulators in all parts of the world. In every case the trial must receive positive opinion, or approval from an ethics committee with appropriate jurisdiction for the

[6] I pay closer attention to the notion of quality culture and the use of language in Chapter 7.

> investigator sites for the trials concerned. And your contribution to that is enormous. You are the people who can make that happen.

In planning how to 'make that happen', models are actively discussed, and are understood to move between places. As one 2009 conference attendee mused while thinking over the possible implications for his country of a Dutch presentation, 'Foreigners show us different systems.' I turn now to one of these 'systems' and the means of its circulation.

The Warning of Coast

International speakers invited to the FERCAP Conference sometimes presented national versions of their 'system.' The tale told here was repeated at several surveys and trainings during my research but I heard it first from Leslie, an employee of the US Food and Drug Administration (FDA) whose first job had been in the Philippines as a paediatrician. Her affinity with the region and support of FERCAP's work led her to present at the FERCAP general conference in Chiang Mai, in November 2009. Her talk detailed what she called a 'sting' operation, conducted by the US Government Accountability Office (GAO) earlier that year. Speaking nine months after the 'sting' occurred, Leslie's topic was 'Conducting IRB inspection for better Human Subject Protection, from the USFDA perspective'. She specified her concern with how 'we', the USFDA, view ethics review outside the USA:

> The public must have confidence in the whole research enterprise. IRBs should fully understand the scope of their responsibilities. We will be looking at paperwork outside the US and we are looking into having a more active role outside the US. If one component is weak or fails then there are ripples in the whole system.

Weak components and system-wide ripples echo the language of Koski, and the story she told was part of another kind of rippling. Emerging from doubts of the GAO regarding the operation of IRBs, the 'sting' had been commissioned by the House Committee on Energy and Commerce's subcommittee on Oversight and Investigations. It had two parts. In the first, fake IRBs were successfully registered with the Department of Health and Human Services despite listing members such as 'April Phuls,' 'Timothy Wittless' and 'Alan Ruse.'

The second part involved a fake trial proposal, sent to three commercial IRBs. The fake drug was a surgical adhesive gel, called 'Adhesiabloc', supposedly developed by a company called Device Med-Systems. According to the trial protocol, a litre of 2.5% Adhesiabloc gel was to be poured into the abdominal cavity of post-operative female patients, to aid healing. The non-existent investigator, a Dr Jonathan Q. Kruger, had a four-page CV and was supplied with a fake Virginia medical license,

which had an expiry date of 1991. Two of the three commercial IRBs rejected the trial outright, on the basis of patient risk. The third however approved it with minor changes. This IRB's name was Coast. In the minutes of the meeting, the committee stated the trial was 'probably very safe' (Walton and MacDonald 2009).

At this point accounts vary, but five months later, prompted either by a letter from the GAO panel or by a 'routine audit,' Coast made two announcements in quick succession. In the first, Coast stated they believed the trial of Adheisiabloc to be fraudulent, and warned against enrollment of patients. In the second, they indicated that trial was actually part of a government 'sting' operation,' and did not in fact exist. Coast responded to FDA warnings by agreeing to 'voluntarily halt aspects of its clinical trial oversight operations' (Mundy *Wall Street Journal* 2009) and for a time, it seemed the company were hoping to return to business in a new incarnation: sweeping overhauls were undertaken, 'to ensure maximum protection for human subjects,' a new board chair and new board members were to be put in place. 'Coast IRB is changing everything,' said Chief Executive Dan Dueber:

> Within the next 30 days this company will be completely different, operated by different people, relying on different standard operating procedures, even having a different name (Mundy, *Wall Street Journal* 2009).

A congressional hearing ensued. Rather than defend his own company, Chief Executive Dueber took the approach of insisting that the GAO were the criminal party. No human subject participant had been harmed, he argued, since *there was no trial*. The GAO, on the other hand, according to Dueber, had violated state and federal criminal laws in perpetrating the sting. 'The question confronting me, and which I hope will occur to you' he said at the hearing, 'is whether this committee and the GAO have lawful authority to defraud an innocent party to prove a political point' (Mansell 2009). Asked why he hadn't done background checks on the research site (a strip mall in Clifton, Virginia) or the PI (with his expired medical license), Dueber said it never occurred to him that anyone would develop a study that was not real. In the aftermath of the hearing Coast decided to close entirely, citing loss of key customers. Dueber conceded that his committee had been 'duped': 'had we started from a premise of skepticism rather than trust, we would not have been' (cited in Dove 2009). Officials concluded that the 'sting' had raised 'serious questions not only about the specific IRB involved in this investigation but with the entire system for approving experimental testing on human beings' (Stupak, Chair of the Oversight and Investigations Subcommittee, cited in Mansell 2009).

It becomes clearer now why Koski, an American commentator, in thinking of clinical research is concerned with the potential for fragmentation. The many official bodies, committees and government agencies listed in this story, and the manner in which the law becomes involved, only begin to cover the American 'Human Subject Protection' system and biomedical research arena. The story is about IRBs as part of a system of checks on research, and the 'sting' reveals their potential inadequacy. When Leslie began her presentation, she told us that it would 'echo some of the themes about the interconnectedness and interrelatedness of us all, in this global research enterprise.' I suggest that it did more than echo themes; it *participated* in relating the US sting story with Asian concerns. Traveling with Leslie to the FERCAP conference in 2009, and around the world through forwarded emails, industry circulars and discussions, the story of how Coast closed down was not confined to American territory.[7]

For researchers in Asia, it carried in itself another story. Despite the domestic response to the American sting operation being far from approving, and the FDA regularly coming under criticism for being under-resourced and "lacking teeth", it matters that there is a 'system'. Some months after Leslie's presentation Cristina referenced the Coast scandal as she explained to me the role she saw FERCAP playing in the region:

> In the US, they have money from government and they have a system. Here, that system doesn't exist yet. The US have a good system to check and balance. If the EC is not good, then they'll close them down. And funding will be stopped as well. Funding for that research, for the whole institution. You sign a Federal Wide Agreement (FWA) and it means you'll comply with all the regulations. So if you [institution] don't support the EC, they'll be stopped, because you didn't comply. That's why its so effective in the US — they have control. If you're not compliant...They have a good system. In Asia, we don't have that.

By 'system', I took Cristina to be referring to the range of government, legal and institutional powers invoked by Leslie in the Coast sting story. For many of the countries Cristina worked in, however, being seen to have sufficient capacity in ethics review was a prerequisite for attracting research to their shores[8], as a means of increasing local competence and knowledge. With a greater number of trials conducted as 'multi-sited' studies over the last two decades, sponsors and funders also look increasingly for sites with a certain degree of 'capacity'. Ethics has come to form an important part of this capacity, and its development is not always at the behest of governments or public concern. Rather, committees often undertake this through their own initiative, with the

[7] To be clear, it is not the system itself which circulates as yet, even though the US FDA is in the process of opening offices in Asia for monitoring trials. Rather, what travels is the idea, the promise and the desirability of such 'systems.'

[8] Recognition, provided through the Survey, was an important part in this. I discuss it in Chapter 2.

support of FERCAP and its networks. Indeed, comments during my fieldwork indicated that advances in ethics committee capacity were often seen as being ahead of national programs. As a coordinating trainer Thailand laughingly said,

> Now, ethics committees are more advanced than the regulatory bodies! In the Philippines, they're happy [that we run trainings] as they'll learn from us how to inspect! We have to build little by little. Build ethical review system first. From there, link the system as a whole. FERCAP conference brings in dialogue among stakeholders. That's the aim of FERCAP — to have a a research system. Not only ethics committees, that's only part. [The] ethics committee is our entry point.

Ethics committees are the entry point for both FERCAP and GAO: where for FERCAP they are a building block towards establishing a future system, to GAO they are the weakest link of a system that is already taken to exist. Both rely on an imaginary of a whole system, currently operating in a way that is — in some respect — inadequate. In one sense, the GAO's sting 'uncovered' the possibility of inadequate review, as a hidden potential of the system. As Gregory Kutz, the Managing Director of Forensic Audits and Special Investigations (FSI) put it in his testimony to the Subcommittee: 'The IRB system is vulnerable to unethical manipulation, particularly by companies or individuals who intend to abuse the system or commit fraud, or who lack the aptitude or qualifications to conduct and oversee clinical trials' (Kutz 2009:4). In Coast's view however, the GAO sting represented a potentially illegal overstepping of its jurisdiction. Dueber's comments indicate that in attempting to prove the fallibility of the system, which would in turn provide the necessary political pressure for reform towards a more 'trustworthy' system, the sting — a fraud perpetrated by the system against itself — had in fact created a new layer of mistrust. As he said, before evaluating scientific and ethical merit, the starting point of Coast should have been not trust, but doubt in the very existence of researchers and drugs. From Cristina's standpoint outside the US, both Dueber and Kutz speak of a system that already exists, illustrating how the parameters that underpin the story have yet to be established in Asia. To detect inadequacy is to detect the potential for a failure with potentially damaging consequences: trust is both a function of being able to measure the conditions, and left implicit as an outcome. To speak in Koski's terms, Cristina handles threads from which to make a cloth, whereas in the US these threads can be frayed and need to be protected. What separates the two is a difference in temporal orientation: towards a future cloth, or the protection of an existing one. The conference provides a forum in which members of FERCAP can raise concerns, and it makes the need for the organisation more evident; as one commentator on the above debate said,

> In developing countries, we don't have laws and regulations. It is important that we advocate, so a regulatory authority can be set up. The initiative has to come from us. We cannot wait for [governments] to recognize the importance of an ethical regulatory system.

But we have reason to be cautious about the framing of research provided by Leslie. The 'sting' was conducted with accountability in mind, and in her language we find resonance with Dr Koski's concern for the trust of the public. It is a concern which frames much discussion on ethics and science in Euro-American settings, a theme I will go on to develop in Chapters 4 and 5. For now, I look at some of the ways members of FERCAP frame their work not in relation to science or publics, but to bioethics and research ethics.

Not doing Bioethics

It would be easy to regard research ethics as a part of a larger project on bioethics. FERCAP's trainings are peppered with bioethics stories, examples and issues, a litany of historical examples with which I became familiar over the course of research. The stories that circulate are largely Euro-American; they tell of people, please, dates and diseases. Edward Jenner, England 1796, small pox; Major Walter Reed, Cuba, 1900s, yellow fever; 1932-72 Alabama, the Tuskegee Syphilis study; 1943, Josef Mengele, Auschwitz.

As I became familiar with FERCAP's work however, I observed the distinction they make between bioethics and their own activities. Take, for example, Cristina's comment that:

> [FERCAP's] approach has made it possible to operationalize the basic ethics principles of autonomy, beneficence, and justice in the review of health research and translate them into tools, such as checklists and assessment forms to assist the EC/IRB members in reviewing protocols, consent forms, and related documents. (Torres 2011: 49)

While I was speaking to a researcher about bioethics organisations and activities in the region, he commented on the style of reasoning he had observed in encounters with bioethics organisations: 'In the moral dilemma approach, when something is resolved, they introduce another factor so another dilemma emerges. But research ethics needs to be solution oriented.' His example was the preparation of a curriculum that had been drawn up for a collaborative course between the University of the Philippines, Manila, and the Fogarty International Centre on Bioethics.

> There was a lot of discussion. [Fogarty] wanted a course on "moral dilemmas" and they said it was a "skills" course! Doctors in the course said, 'This is a never ending discussion!' Suppose someone is run over by a car. Who is responsible? The driver. Suppose the pedestrian is drunk? Well, both. But say the driver... And you keep adding to the issue. It

> goes on and on. The medical doctors, they said, 'There is no resolution to the issue!' That was the "skill" they learnt. It is a very different approach.

That bioethics was a 'very different approach' to research ethics was a repeated sentiment throughout my research. One interviewee remarked that the divergence led to bioethicists condemning the work of FERCAP as that of 'clerks': meaning, in her interpretation, that to bioethicists FERCAP were not 'really' engaging with bioethical issues. In turn, this meant that engagement with explicitly 'bioethics' networks was not a priority for FERCAP. Few considered this a great loss, since the attempts of certain FERCAP members to bring in bioethicists had led to blank faces and reportedly confused clinicians. Another interviewee illustrated for me the systems she implicitly understood to be at work in the region through an event involving American and Chinese bioethicists and members of FERCAP.

> Some Harvard fellows[9] also work with us. That's when it gets complicated. Bioethicists in China, they are philosophers. So they think we belong to one group. When you do training they put us together, with the bioethics lectures. We had a session on Standard Operating Procedures, management of Serious Adverse Events.... and then the Chinese philosophy people talked about principles. They were talking about "there is no objective reality," the deconstruction movement. I know what it is, because I'm coming from a social science background, I've been exposed to these things at the University, about radical sociology, but can you imagine doctors listening to that! How can you tell which drug is more effective if there is no objective reality?! Meiji was doing the translation for me and I asked her what they were talking about and she shook her head and said, 'I cannot translate this, I do not know how to.' She is a very smart medical doctor. But she will just stop doing the translating and say, 'I don't know how to translate that.' Even she gets confused.

The work of training ethics review committees can at times be aided by being viewed as 'part' of bioethics. In the examples of international involvement with groups like the US NIH Fogarty, Harvard program or UNESCO Bioethics offices, brief, sometimes tense alliances are formed. Researchers trained abroad return, collaborations are set up. However, as these narratives suggest, these events also reaffirm FERCAP's distinctness. As Cristina put it:

> What is the point of talking about these things when we're talking about research ethics? For us, the guidelines are there. For us, what is more important is for us to be able to operationalise those guidelines. If a new issue comes up and they can incorporate it into the guidelines, we can follow it and start implementing.

When I pushed this point with Cristina, she said that FERCAP worked to take the tension between bioethics and research ethics away. One way in which this would be achieved by reframing ethics as a part of a quality system:

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[9] Graduates of the Harvard School of Public Health Program on Ethical Issues in Global Health Research.

> If it is unethical it cannot be quality research. I think that makes us different from other bioethics groups, because we focus on a system and ask [about] the role of the stakeholders. It's not about moral dilemmas or conformism. We say what's there and how we apply the ethics. Because that is what is lacking in Asia. The system. And we've established that niche.

Cristina's definition of the system and its link with quality recalls Fujimura's definition of a 'standardized package' (1992). Unlike the perhaps more familiar concept of boundary objects (Star and Griesemer 1989, Bowker and Star 1999), standardized packages are robust enough to change local practices (Guston 2000:29), something which is clearly FERCAP's intent. They are both 'a theory and a standardized set of technologies' that together make it possible 'to locally concretize the abstraction in different practices to construct new problems' (Fujimura 1992: 169, 179, cited in Riles 2011:70). This thesis is an exploration of what it looks like to roll out ethics as such a package, with attention to the politics of the differentiating work of standards and the technoscientific expertise needed for their efficacy (Busch 2011). Though I argue that the "ethics" conducted and advocated by FERCAP is not one single thing, it does aspire to standards, and standardization, through its recognition program. The effects of these aspirations I explore in the chapters to come.

Since I have made it clear that FERCAP members believe they are 'not doing bioethics' perhaps I should also make it clear that I am not either. Although a recent empirical turn in bioethics research is resulting in the use of various social scientific approaches, with bioethicists seeking to bridge the gap 'between ethics as presented in bioethics, and the way in which ethical reasoning takes place in the clinic' (Hedgecoe 2004:121, see also Goldenberg 2005), in the arena FERCAP defines as research ethics, the opposite seems to be occurring. FERCAP's drive is towards more formalized, structured, assessable formulas. Nonetheless, both moves can be rendered in the same language of evidence: evidence for how bioethics operates 'on the ground' and evidence for research ethics as having an effect. I take this pervasiveness up in Chapter 7.

Research Communities and Advocacy

If FERCAP are not 'doing bioethics' then what are they doing? The group established its self-described 'grass-roots' ethos at its first seminar in 2000, when, writes a founding member:

> we noted that working with government will be very difficult and very slow because of too much red tape. So instead of working with government, we chose to start from scratch and create our own organization starting with the participants of the seminar (Chokevivat 2011:7).

At the 2009 Conference, Juntra described the FERCAP approach as 'bottom up', saying it was like a family. She described members eating together: 'we don't want people to [just] have a meal, we say 'let's cook together,' not 'you will eat now, and this is what you will eat and this is how you will cook.' The common effort and direction encapsulated in Juntra's metaphor is echoed in another FERCAP member's statement about the organisation's values, which uses the metaphor of a house to explain that involvement in FERCAP is about more than just self-improvement, or improvement for one's own country. 'If you have your house nice, you cannot just be happy with that,' she said.

> You need to think about what is around it. Are the streets tidy, is there trash? If you are just here to talk about yourself, that is not the way, that is not the attitude... You need to care about it all, the universe.

Caring here translated to inter-regional support, the universe made equivalent to the 'family region,' and took the form of visiting for training, surveys, and a shared distribution of costs which took into account each country's ability to pay. This is described in the *FERCAP@10* anniversary booklet as the value of equity, 'shown in [FERCAP] being accessible to both developed and developing countries and in [FERCAP's] socialized costing of programs' (Torres 2011:50). Taiwan, posed against Cambodia, can pay, 'but Cambodia at the moment, TDR supports. Our philosophy is to help them help themselves,' said Juntra during the 2009 Conference. As a Taiwanese conference delegate put it,

> for us, [funding ethics committees is] not a big deal, but for them it is. Delegates from poorer countries have their flights to conference paid by Korea and Taiwan. They ask for money from [pharmaceuticals] because you need sponsors, whether countries or companies. America can't understand that.

I rarely saw financial issues discussed, particularly since I did not attend FERCAP's steering committee meetings. The network has been supported by annual project grant applications to WHO-TDR, receives institutional contributions for trainings, the use of FERCAP modules and the Survey. It also collects institutional fees from recognised committees, of which there will be over 100 in 2012. Annual conferences, however, provided an opportunity for evaluating funding mechanisms, sustainability of the network, and models of payment. During a 2009 conference discussion on how to finance FERCAP in the future, one delegate did not think the idea of "family" was enough. He suggested FERCAP seek out wealthy donors, who could gain tax exemptions or fame from supporting ethical review:

> Many people want to do something for FERCAP [...] We're an international organisation, we can change our idea, [get] NGO tax-free donations. Some of our people want to do that

> because they can create their own dignity. Obama, he [might] put $1000 in FERCAP because he is going to have Peace Prize!'

Juntra considered a donation model unsustainable, and returned to the idea of a house to explain her reasoning:

> Do you want to be on the first page of a newspaper, or just want to keep doing [this], sharing same values? This [work] is not only for our country. Our house is really nice, but it's not a good environment for the house. I don't think FERCAP wants millions…maybe better to think "OK, we have activities, how can we maintain our activities?"

In the view of its leaders, the organisation aims not at profit but at sufficiency. It simply wants to continue doing what it is doing, and do it better. This modesty of aim was reflected in the attitudes towards the roles countries wanted, and were encouraged to take. FERCAP encouraged delegates 'not look at themselves' but look at 'someone else.' Cristina took countries with 'more advanced economies' as examples of this shift in attitude:

> In the beginning, it was different, it was about "my" interest. "I don't want to share." Now, they have a different perspective…[T]hey were like that, now they want to host the conference. They want to help those less fortunate to them.

When I asked how this shift had occurred, Cristina was very aware of how the phrasing of her requests affected others. 'You adjust the language,' she said. 'You ask them what they want their role to be.' She had suggested to some of the Korean delegates that perhaps their role was one of leadership, because they were coming from an advanced economy and had resources. 'And then they are happy,' she said, 'they can help others.' I pressed this point of attitude with Juntra later:

> When you're in the same room talking about the same thing, then there are unfortunates in the room, you ask, could I contribute to make it better? They feel proud. The minute you help others, its hard to explain. Happiness that comes from that is hidden until you experience it. In the old days, they had an agenda in mind. Even now, people do. For example, let's say your country is helping another country. You've got an agenda, you're wondering what you'll get out of it. If you do something without expecting what you're going to get, if you get it, you know what it feels like. If you do it because you feel like it's the right thing, because you want to contribute, you get more back. You have to experience it. I like to train people, to see them advance in their career - that gives me happiness. At that moment, I just try to help them, and then in the future they will become something. The minute you say "I do it because of this or because of that," you lose that.

Why do Cristina and Juntra liken their organisation to a family? Drawing on kinship, Juntra is accessing the implicit assumptions of 'relatedness': 'predicated on the absorption of difference by commonality and togetherness' (Viveiros de Castro 1999:S80). This foregrounding is visible when principal investigators, often cast in an antagonistic relationship with ethics committees, become *extensions* of the committee. They become 'members of the family': 'don't say they are your client,

without them FERCAP would not exist! They are part and parcel' (see Chapter 2). During questions at the 2009 conference one IRB chairperson stood up and argued that thinking big was difficult, because sometimes it was the researchers who seemed very 'big'. Some of them were 'even up for a Nobel' he said:

> Sometimes [they] act before IRB. They're not...they think we are strong a big rock. So regulation - between researchers to IRB member - sometimes doesn't work. Difficult to make them understand why IRBs trying to protect human subjects.

Different countries described different tactics to engage researchers. In stepping up to their leadership role, Korea became host for the 2011 conference. At the 2010 conference, a Korean delegate had gone to great effort to present the transition that she and a colleague had prompted

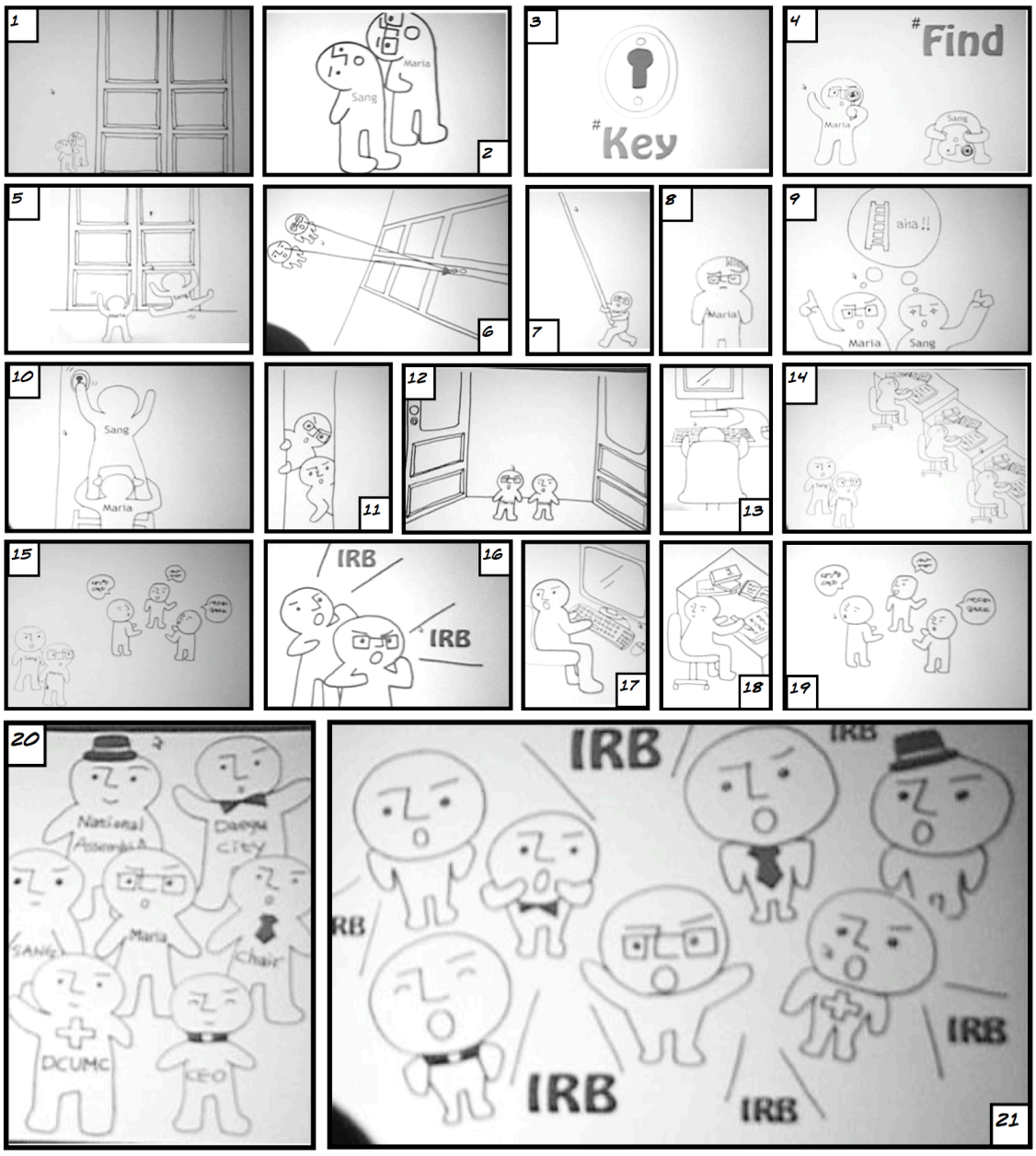

Figure 5: Stills from South Korean Animation at FERCAP Conference 2010.

through illustrating their achievements in an animation (Figure 5). Against the music to *Totoro*, a popular Japanese anime, the presenter narrated the struggle:

> Here is the door [1]. The door is really a difficulty. If you don't overcome this difficulty, I can't work on the IRB. So at that time my friend Sang is coming. Everyone told me she is a very good doctor in Emergency Medicine. She is coming to me. And we are trying together: how to open this door? [2] Its difficult. We have to find the key: key is the main solution of opening the door, of overcoming difficulty [3]. Now, we find the key, but the door is really really big [6]. So we don't know how to reach the keyhole. We can't reach. So we have to find a way: what is a good way to reach they key [hole]? We try over and over again [7, 8]. We are cooperating together, but we get a ladder and the key open the door [10]. We open the door, wow! [11] But when we open the difficulty another difficulty is in front of us [12]. At that time nobody is interested in us. Every time we shouting, they are indifferent. They are just doing their job. They are just in front of their computer [13]. Writing some document [14]. They are talking among themselves [15]. But we never stop here. We have to overcome. We are shouting "IRB", "IRB" over and over again [16]. At that time we try and speak about the meaning of IRB. Protection! Why we have to do? With our effort, they try to understand what IRB is [17, 18, 19]. At first we are just the two, but every persons are getting together and they are shouting together so it is possible to make them understand why human protection subject is so important for developing medical [20]. And what is the right way and they really understand [21]. I don't think they can understand it fully but they are trying.

By telling this story the presenter managed to convey, with indirect criticism, the 'deaf ears' upon which calls for ethical review fell, and how ethics had successfully been brought to the attention of new actors. A Chinese delegate agreed:

> In the early times [...] most of them say 'We don't have support from the institution, nobody notice[s] we are there.' And then they say the investigators don't listen, they just come to say 'Could you just stamp on this letter?' But nowadays when I visit the IRB those members feel really honoured to be IRB members.

There are a great number of institutional and interpersonal dynamics involved in 'changing' an institution's approach to ethics, and changing individual researchers. Both could be the subject of the advocacy work conference delegates were encouraged to undertake (c.f. Keck and Sikkink 1998, Rushton and Williams 2011). As Cristina put it, 'we must advocate for the values we believe in. Other parts of the system do not respect the same values [...] Advocacy is very important, so is the sharing of values.'

The point at which FERCAP had arrived on its 10th anniversary in 2010 meant that in the annual November conference in Shanghai, Robert Ridley, Director of the Special Programme for Research and Training in Tropical Diseases (TDR), could say that '[f]rom very small beginnings,

[FERCAP] has now developed into almost an institution. The number of representatives here from different countries across the region', he continued, 'is testament to that. I've been asked to talk about FERCAP in TDR's product development activities. However, FERCAP has now got so big and so large that I think it's also appropriate to talk about how TDR can fit into FERCAP's activities'.

Ridley's opening line suggests the 'child' is outgrowing the 'parent', or at least becoming so 'big' as to require a reconsideration of the current relationship. Through its own 'organisational charts' or 'organograms,' FERCAP provides family trees worthy of African Structural Functionalists (figure 6). These charts are a favoured method of positioning an organisation, committee or group 'in relation' to other groups, mark FERCAP's perceived (and given) place in the world (Callon and Latour 1981).

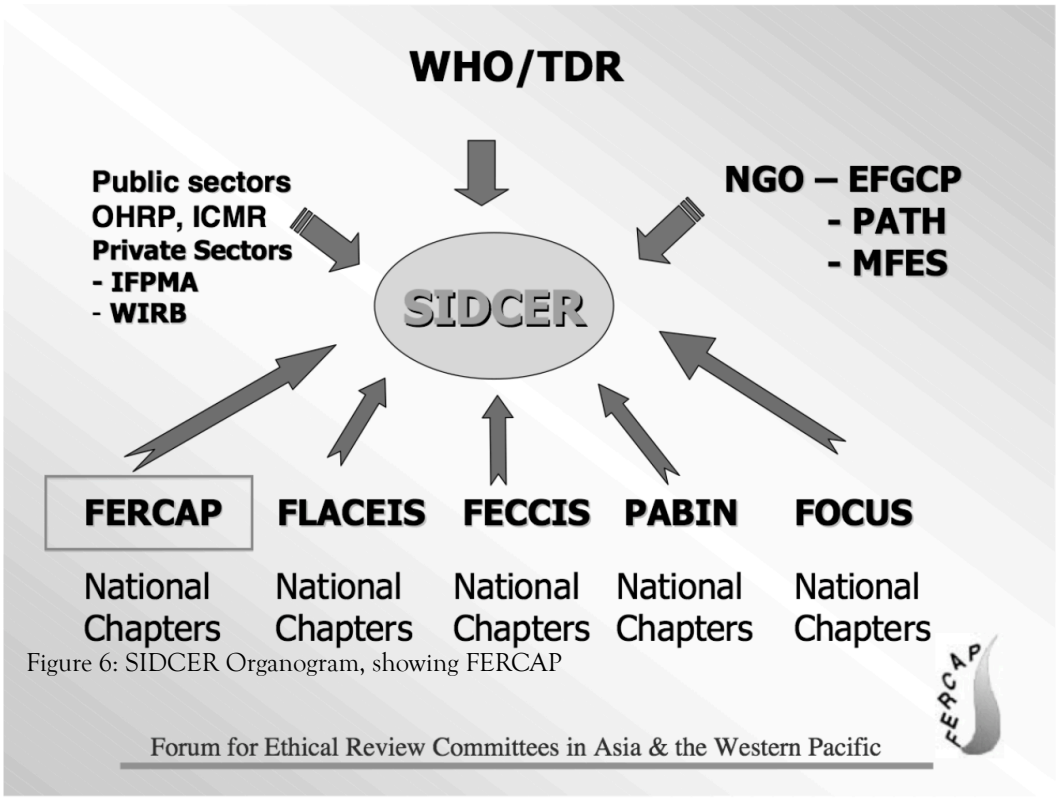

Figure 6: SIDCER Organogram, showing FERCAP

Taking FERCAP as the ego, there is the parent (SIDCER) and grandparent (TDR) and great-grandparent (WHO). We find siblings across (PABIN, FLACEIS, FOCUS and FECCIS), children (NAREC) and grandchildren down (FERCIT (Thailand), CIDCER (China), FERCSL (Sri Lanka), KAIRB (South Korea), FERCI (India) etc). A project of the Strategic Initiative for Developing

Capacity in Ethical Review (SIDCER), FERCAP is compared with its 'siblings', the other four regional fora.

Drawing on Koski's image of a finely woven silk cloth I have explored how the language of systems and fragments permeates the research arena of which FERCAP thinks and enacts itself as part of. The conference as an ethnographic site allows the display of attitudes, priorities, connections and relations imagined. It also hints at how these images have effects, how they move people, and move with people.

Strathern sets up the markers by which the movement of knowledge may be detected, for we can never see the movement itself, she writes. 'What we stop to describe is at rest itself; however many places it has come from, we give it a singular location in the moment of reflection' (2004: 17). Leslie's story of Coast's demise was just that, a story told to a specific group of people at a specific conference. These people then carried it with them as they returned to their countries, hospitals and institutes. Leslie's concern, with the Coast story, was to emphasise how the research conducted in Asia is vitally important; she insisted on the 'interconnectedness and interrelatedness of us all.' The planning that constitutes 'capacity building for research ethics' is the planning of connections-to-be (Strathern 2004: 15), both equipping committees and members to make their own judgements, and ensuring that research sponsored from abroad remains 'acceptable' to those authorities (EMA, FDA) who will eventually review and 'accept' the scientific data.

FERCAP's conferences are designed to bring together 'stakeholders' from the various sectors, having 'representatives from national health authorities, ethics committees, researchers, research participants, academic institutions, pharmaceutical industry sharing their ideas and experiences', 'educating' them on their roles and responsibilities, 'empowering' them (FERCAP 2008 and 2011 Conference Agendas). There is a sense in the documents produced by FERCAP that the conference helps hold these Koski-an "threads" together. Here Koski's image has further claim on our attention. It reveals a habit of scaling, the microcosmic into the macrocosmic and the reverse (see Chapter 5). Koski aims to addresses himself to both to the 'micro' and 'macro' when he draws on the image of a single broken thread, to both committee members and 'science'. He does so, however, in a way which recalls the unsettling of these scales in the work of Callon and Latour (1981) where both people and objects challenge presumed scalings:

> At other times actors who had always defined themselves and had always been defined as micro-actors ally themselves around a threatened district, march to the town hall and enroll dissident architects. By their action they manage to have a radial road diverted or a tower that a macro-actor had built pulled down [...] A tiny actor becomes a macro-actor, just like in the French nursery rhyme: 'The cat knocks over the pot, the pot knocks over the table, the table knocks over the room, the room knocks over the house, the house knocks over the street and the street knocks over Paris: Paris, Paris has fallen!' (1981: 295-296, cited in Jensen 2007: 846)

Koski's broken thread repeats the nursery rhyme, but instead of Paris, we find the feared destruction of 'public trust' (see Institute of Medicine, USA, 2001). This fusion of trust, ethics and science requires attention. Although Dr Koski's intent is to contextualise ethics within wider systems of product development and biomedical research, his slide itself needs contextualization. In his presentation, Koski discusses the trust that is spoken about by medical regulators, by 'publics,' by governments. It is a trust that at its mention, is always lacking or about to be absent; a vulnerability or fragile future (Strathern 2005b) rolled out in a display of socially robust knowledge (Nowotny et al 2001). But what are these 'gaps', and how is ethics to bridge them? Dr Koski's image builds from a 'single broken thread' towards a shredded 'fabric of trust.' Trust is widely acknowledged as a contemporary problem and Alberto Corsín Jiménez has recently pointed to the way it has become entrenched not only in political but also sociological discourses: 'Everyone', he says, 'is talking about trust' (Corsín Jiménez 2011:177). He is, too, in his paper, but his intention is not to add to the growing literature which takes trust as its organising device, replacing 'class' or 'gender' to spin stories of the consequences of its absence. His interest lies in the reasons for its political salience. Dr Koski is part of Corsín Jiménez's 'everyone', speaking in his presentation about the trust that medical regulators worry about, the trust in science feared lost by 'publics' and the trust sought by governments (Johnson et al. 2008). Ethics is thought to work in the 'gaps' between the threads, to rebuild and reassure. This mode of thinking about ethics I revisit in Chapters 4 and 5.

One of FERCAP's challenges is to sustain something that looks like the unified systems towards which Koski leans. It does this largely through appeals to standards, 'good practice' and the display of knowledge of regulatory affairs abroad. Here I have been concerned with the environment that FERCAP imagines for itself, and has had imagined *for* it. As Star (1991:52) writes, 'power is about *whose* metaphor brings worlds together, and holds them there'. I argue that the images that I have discussed are inherited imaginaries, endorsing and emphasising a systemic approach to ethics. If the act of imagining oneself as part of a system can itself be regarded as a

capacity, then it is one that the Conference surely shores up. When Cristina Torres describes her job as FERCAP coordinator (2011:44) she says her travel in the region showed her

> the urgency of the work to build an ethical review infrastructure that we could promote. I soon realized that FERCAP's unique role was to develop and advocate for a systems approach in ethical review.

Consequently, her definition of capacity building was:

> getting people to do their thing correctly. Doing what is expected of them. [Learning] what they need to ask, how to review a [biomedical research] protocol. It's being able to fulfill your role. Capacity is always specific to a role. You have to define, like each person has his role in society. You cannot be good for all, you do a specific role.

I return to her discussion of roles, systems and capacity in Chapter 5 since it applies both to individual members being a part of FERCAP, and FERCAP as a part of international research. Their imaginings and descriptions make it, and have effects. To be a part, as ethics is perceived to be, is not only to belong but to be part *of* some other image: the fracture references the complete. The conference is a means of *holding steady* this reality. Hence the surprise of this speaker's colleague: 'My friend came with me to the FERCAP conference, and they ask 'Who is, where is FERCAP', and I have to explain that it is only one full time person!'[10] The conference is a site at which FERCAP's reality can be generated, as in Riles's summary of a network as 'a set of institutions, knowledge practices and artifacts thereof that internally generate the effects of their own reality by reflecting on themselves' (2001:3). But, Latour cautions,

> these panoramas [...] have to be studied very carefully because they provide the only occasion to see 'the whole story' *as a whole*. Their totalizing views should not be despised as an act of professional megalomania, but they should be *added,* like everything else, to the multiplicity of sites we want to deploy (Latour 2005:189).

The 'whole' which I have depicted in this introduction I will not sustain across the chapters to follow; I will show instead how it is made, adding the images at the conference to the 'multiplicity of sites' from my fieldwork. As Latour also says, '[panoramas] allow spectators, listeners and readers to be *equipped with a desire for wholeness and centrality* [...] However much they trick us, they prepare us for the political task ahead (Latour 2005:189). What is so powerful in these panoramic images is that they nicely solve the question of staging the totality, of ordering the ups and downs, of nesting 'micro', 'meso' and 'macro' into one another. They also clearly delineate roles. The talk of fragments, just as much as the talk of systems, is a tool for imagining.

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[10] Cristina Torres is FERCAP's full time employee. She is assisted by the current Research Fellow Arthur (Atoy) Navarro.

Research Questions

George Marcus claims that 'classic anthropological ethnography, especially in its development in the apprentice project/dissertation form, was designed to provide answers, or at least data, for questions that anthropology had for it' (Marcus 2008: 52). 'Nowadays', he continues, 'anthropology itself does not pose these questions [...] thus it is a contemporary burden of projects of anthropological research — and especially apprentice ones — to identify these question-asking domains' (Marcus 2008: 52). In a field already thick with its own commentators, what role exists for extended ethnography or slow anthropological analysis? I opened the thesis in a way which outlined some of the themes it will address; here I detail questions that run throughout. I suggest that while the International Science and Bioethics Collaborations (ISBC) project identified a question-asking arena — the challenges of international collaboration in scientific research — the questions it has posed within that 'question asking domain' serve questions that anthropology itself continues to have; material gathered on the ISBC project and for this doctoral research contributes to longstanding debates within the canon, and that which is anthropological need not — despite utilitarian research environments — be relegated as secondary to the interests of other domains.

I began my study with a strong interest in how ethics committees make decisions, not dissimilar from that of Stark (2011a, 2011b), or Lamont's (2009) work on the deliberations of academics. The research shares with Stark (2011a, 2011b) a concern with what happens inside ethics committee rooms, a common interest in the creation and sustaining of 'the image that members have reached a legitimate decision' (Stark 2011a:233). Although attempts to get closer to decision-making took me elsewhere,[11] an interest in 'how disparate evaluators reach collective agreement' (Camic, Gross and Lamont 2011:19) remains a question in this text. However, ethics committees have a claim on the making of another kind of knowledge. Stark puts it plainly when she writes that '[w]hen researchers look beyond the administrative burden of IRBs, they find that IRBs are consequential because they affect how researchers go about creating knowledge - and, as

[11] I did collect material from ethics review committee meetings I was present at in Sri Lanka, Taiwan, the Philippines, Thailand and China, mostly in my capacity as a trainee Surveyor. I do not bring the material together to produce an analysis of decision-making practices in this thesis however, in part because of the resources that would be required for translation but more significantly because my focus shifted during research and analysis towards how participants in committees describe and experience the problems of decision-making (Chapters 3, 4 and 5).

a result, the *kinds of things that are knowable*' (2011a:234, emphasis added). This is something I explore in the chapters to come.

Ethics

The starting point of any good ethnographic analysis must be an examination of the categories by which people live their lives. The rapidly proliferating language of ethics (Simpson 2012: 153) is the category under examination here. I explore the formation of the concept through its articulation in 'formal and informal practices, where and by whom it is contested, [and] how it reasserts itself in the face of challenges to its integrity or meaning' (Jasanoff 2005:19). Throughout the thesis the way in which 'ethics' is used, called upon and summoned is examined, the edges and limits of its reach explored. At a most general level, this inquiry addresses the question of the concept of ethics as it is employed in the governance of biomedical research. How has it been brought in to the making of good science, what is its given role? More specifically, the thesis asks what ethics is for the members and participants in the Forum for Ethics Review Committees in Asia and the Pacific. Who gets written in to what ethics is to be? What are the social relationships that ethics inscribes, how does it intervene on the social, what are its tools, what counts as an accomplishment?

Though the conceptual centering work of ethics is powerful (it links transparency and accountability, takes on the languages of human rights, efficiency, economic use of resources, quality, even justice in its promises to check the strong and protect the weak), ethics review committees have been accused of being *unethical*, both within medicine and law. In this pitch of one 'ethics' against another, academics in the USA have challenged Ethics Review Committees as unconstitutional, using First Amendment concerns (Lerner 2007) and issues of censorship[12] (Hamburger 2004, 2007; Weinstein 2007a, 2007b; Bledsoe et al. 2007; Menikoff 2007; Katz 2007). The effect of an IRB on 'how researchers go about creating knowledge' comes from their attention to methodology, as 'IRBs might suggest changes to researchers' site selection, sample size, recruiting methods or interview questions' (Stark 2011b: 74), rarely approving research without requiring some changes to the proposal. Stark writes that

> IRB members suggest (read: require) changes that a researcher could make to the proposal that would result in the board's approval [...] This coercive power to change research is quite

12 [T]he act of inspecting some form of expression - anything from a scientific finding or a political opinion to a work of art - in order to suppress or delete elements alleged to be harmful, offensive, or immoral (Bledsoe et al. 2007:596).

> effective since getting approval is the ultimate goal for researchers who submit protocols (2011a:234).

It is worth reflecting on Stark's comment with an eye to literatures in the history of science. Recounting Shapin and Schaffer's analysis of scientific life in the 1600s, Haraway writes that '[e]xperimental philosophy — science — could spread only as its materialized practices spread. This was not a question of ideas, but of the apparatus of production of what could count as knowledge' (Haraway 1996:430; Shapin and Schaffer 2011 [1985]:25). 'Ethics' is on the move; as a result of its integration into the *making* of science, not merely its affirmation, its materialized practices too must spread. While the question of what an ethics committee is in the USA is largely solved (Stark 2011b), their establishment in Asia is ongoing.

What is an ethics committee?

Initial questions on how (and why) ethics decisions were apparently being taken in the 'same' way in different places led me to questions on why it was that the *committee itself* was the form of choice for making these decisions. Indeed, what *was* the committee as 'a form' (Riles 2001)? An ethics committee is a group of people but the idea of it is more than the instantiation of it at any given time. Was this one of the qualities that allowed it to move? Another way of asking why the ethics committee is enjoying such proliferation is to ask "what are the problems to which the ethics committee is a solution?" My overview of the spread of biomedical research and GCP above provides some direction, but there are further answers.

As Dr Muthuswamy's concerns at the Regional Collaborative Workshop illustrate, ethics committees are a form of managing biomedical research and the consequences of the knowledge it produces. Strathern describes 'a particularly Euro-American oscillation between the condition of knowing through investigation (research) and the condition of asking what is to be done with that knowledge (management)' (2006:195). If, as I am suggesting, ethics committees embody this oscillation, how does this play out in Asia?

How does ethics work as governance?

Ethics committees have become a point through which all research must pass. In studying the implications of this development, I have sought to understand what kind of control they are thought to have over research and how this is enacted. FERCAP's capacity-building concern with 'how to get people to do things' — to run good ethics committees, to encourage ethics activity in their institutions, to educate researchers in ethics, to protect human subjects — reveals, with a little shift, a double sided question.

First, how to get *people*, to do things. Ethics appears as a solution to a failed science, an ethics of 'research' whose practitioners, after Nuremberg, cannot be entrusted to their professions or consciences. These rules made by persons, it was hoped, would make persons made by rules. However, it would not do to follow what Laidlaw (2002), Zigon (2006) and Robbins (2004) all attribute to a Durkheimian legacy: a reduction of morality to social norms. In distinguishing the work of FERCAP from bioethics, my interviewees did remark that the guidelines were 'already there,' that the work they did was implementation, or operationalisation. Nonetheless, in attention to the language of training sessions and conference I am brought to ask how and why actors are invited to 'make themselves into subjects of esteemed qualities or kinds' (Faubion 2011: 3), how an ethics of the self intertwines with the ethics of review committees and trials. FERCAP itself asks how and why people behave the way they do (cf. Howell 1997; Malinowski 1926); the form of its capacity building exercises gives an insight into what people are imagined to be, in order that they can be changed, inspired and governed. My attention to the making of particular types of people is one part of showing, as Shapin does 'how and why people and their virtues matter to the making and the authority of late modern bodies of technological knowledge' (2008:3). He points out that in order to give an account of why personal virtue "*still matters*" he must also give an account of "why it is so widely said that it does not matter" (2008:13).

There is also the question of the kind of governance which FERCAP's implementation of the SIDCER recognition program establishes. Are we looking at members of an organisation concerned with standards for the collective sentiment of protecting the human subject, or with the trials and research that SIDCER recognition could bring? Though the answer cannot be exclusively either, in this question we see rewritten a division between Malinowski and Radcliffe-Brown, who, Kuper writes, did not agree on sociological theory: 'In his *Essay on the Gift*, in 1925, Mauss rewrote the *kula* ethnography in terms of Durkheimian collective sentiments. Malinowski in turn recast reciprocity as a matter of enlightened self-interest' (2005:48). Cristina's response to the question posed by the American academic in the opening vignette of this thesis — No, we don't have the kind of systems or law that you'd recognise but we have 'moral force' — recalls debates common in 20th century anthropology, as researchers interested in the dispute settlement and judicial systems of peoples they studied focused on principles of social control (Colson 1953) to discern how societies were governed.

With this, we move to the second side of the question: 'how to get people to *do* things', with the emphasis on getting them to do something, what we tend to call governance. 'Late modernity', write Shapin, 'is supposedly marked by the extension of impersonal means of control to ever new domains, ultimately bringing all of social life under the sway of impersonal reason' (2008:9). He remarks that

> [i]t would be convenient to be able to tell a story of linear transition from [...] a sacred to a secular world, from trust-in-familiar-people to anonymous trust in impersonal standards and faceless institutions; from virtue to institutional control as a solution to problems of credibility and authority (2008:17).

However, as his circumspect tone indicates, this is not the case. In the chapters that follow I explore FERCAP's standardisation agenda (Chapters 2, 3 and 6) alongside its reliance on 'familiar people,' asking how the two successfully coexist. This is not to say the FERCAP program has no struggles with authority. Entities such as FERCAP, non-governmental organisations between government and state, prompt questions about their sources of legitimacy (Keck and Sikkink 1998; Irwin 2008). They also prompt contestation over epistemic authority: who should set the standards, should they enable or constrain? Who should do this kind of recognition? While it has come to be agreed that governance over biomedical research is needed, the question of how it can be both effected and enforced varies. I explore the variety of answers given in the text.

Where is Ethics?

Where does one look for ethics? Who decides? By what criteria? Ong (2010: 13), suggests that

> [i]nstead of proceeding from a position of moral certitude to make judgements about particular ethnographic situations or seek to remedy them according to a universal set of ethics, an anthropology of ethics is necessarily about locating ethical practices, that is, tracking ethical configurations where "ethicalizing" processes and decisions take place.

Capacity building in research ethics — "ethicalizing" — takes place in rooms, around tables. The thesis examines these sites. It also considers the form of the committee, an 'ethical configuration.' What kind of politics inhere in it; what does it assume? The ethics committee is one of several contemporary spaces of deliberation into which 'society' is thought to enter, converse with, and engage science. Consensus conferences, round tables and public consultations are, argues Weingart (2008), the outcome of academic debates on the democratization of expertise. He cites the House of Lords *Science and Society* report (2000) which followed the UK's BSE (mad cow disease) crisis, and the European Union's white paper on democratic governance (2001). In light of these developments, Strathern (2005) cautions us against the abstraction of 'society', arguing

that it produces the concept of 'science' in 'contradistinction to itself,' de-socialising 'science and technology' in the process:

> it encourages the idea that all 'science' need now is that it does useful things 'for society.' It could even prompt people to equate ethics committees and government commissions with society's studied opinion. But above all, the invocation of 'society' summons the fragility of measurement: what will count as society, whose views will figure? (Strathern 2005b: 476)

The question of who counts is central to this inquiry. I reflect on the convenience of reifications such as society and the individual, the political tools of science, and the problems to which audit and oversight appear as solutions. Many research ethics committees in developing countries work in the absence of national ethics committees. Governments and scientists do not conduct the kind of public consultation or polls with which analysts of Euro-American science studies are becoming familiar (Nowotny et al 2001). I pay attention to what and how knowledge are displayed in the committee, the articulation of these positions, and the making of the 'view' from which members of an ethics committee can speak.

In asking where ethics is located, the question of where differences are located also arises. Difference is a problematic category for bioethics: the Nuffield Council on Bioethics recommends a 'duty of respect' which 'implies a duty to be sensitive to other cultures' (2002:50). Simpson (2004a, 2004b) asks 'to which cultural differences' is this sensitivity to be directed? FERCAP works between countries pre-conceived as 'different' through their legal systems, research cultures and 'cultures'. How are these difference managed (Wastell 2001) by this system–in–the making? FERCAP must manage the central authoritative texts of GCP, WHO, CIOMS, etc, and at the same time, strive to honour sensitivity to 'local difference' (Nuffield 2002). FERCAP comes to be a context in which these things can be worked out, and how it does so is an ethnographic question I explore in this thesis.

Methods

This was fieldwork organised around the aeroplane, as I traveled to the various sites of FERCAP activity in the region. Planning from a calendar .pdf[13] emailed to me by Cristina, I spent 4 months

[13] Portable Document Format is a formal open standard known as ISO 32000, viewable on any platform.

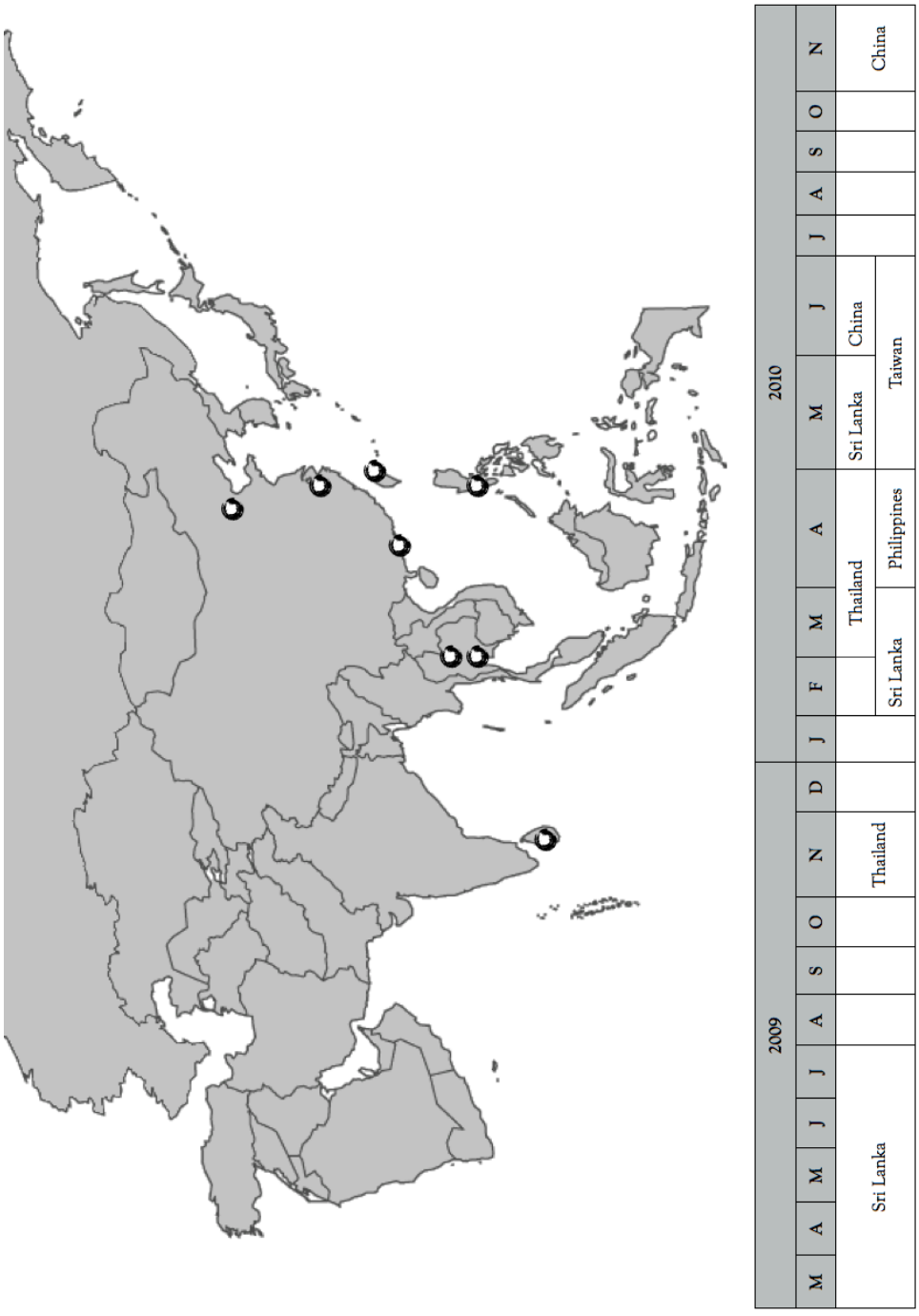


Figure 7: Fieldwork Map, March 2009 – November 2010.

at the offices of the Colombo Medical Faculty Ethics Review committee, Sri Lanka and for each of the subsequent 15 committees with which I had contact, either observed their activities through the FERCAP Survey, met members at trainings or solicited interviews through contacts. The field based research consisted of six months in Sri Lanka (March – July 2009, February – March and May 2010) resulting in contact with four committees; a month in Thailand (March – April 2010) largely interview and workshop based, contact with one committee; 3 weeks in the Philippines (April 2010) contact with three committees; 3 weeks in Taiwan (May – June 2010) contact with four committees; and just over a month in China (June 2010 and November 2010) contact with three committees (Figure 7). In arranging the time by country, the impression is one of disjointedness. While there was a great deal of unfamiliarity over the course of the 'following', my facility with the activities I was observing and participating increased. I met the same people over and again. Interactions with one key informant ran like this: March 2009 Colombo; November 2009 Chiang Mai; March 2010 Bangkok; April 2010 Manila; June 2010 Beijing, Shanghai and Guangzhou, November 2010 Shanghai. We became more familiar with one another, and as I trained, I saw trainings, surveys and lectures repeated. A core group of four or five members of FERCAP showed up regularly at events, trainings and meetings but I knew people as they knew one another — through surveys, trainings, conferences. At certain points, this forced me to raise a question much like that which Candea asks for his Corsican village: 'how is one to ground one's knowledge in intimacy, when people's intimacies only stretch so far?' (2010: 22).

As a participant observer, I was a trainee, a Surveyor, an interviewer. It was requested that, as an observer of the workings of the network, I provide a form of feedback. I produced a commentary on some of the metaphors the group used to describe themselves (Douglas-Jones 2011). Thus, in a study of systems oriented towards improvement, and while immersed in the participant observation role of surveying and critically assessing ethics review committees, one of the difficulties, perhaps, was that of being an ethnographer, not an auditor. Understanding how the critical angle was prized open and how critique was formulated revealed a great deal more about the relationships between surveyors and surveyed than simply coming to a detailed understanding of the process of critique. As with anthropologists who work with development, there was a double-think required to get around the promise of the 'good' contained within promise of the capacity building sessions in which I participated. Improving the system in the hope of providing 'better human subject protection' is difficult to disagree with, but it was not disagreement that would — in the end — allow an externality to the rhetoric. While the role of auditor or surveyor

wonderfully naturalised extensive note-taking, as Strathern pithily put it, 'ethnography does not measure accomplishments in the hopes of improving the system' (2003a: 309).

While the scrutiny of audit provided a foil for ethnographic attention (as long as I could divine the difference), my data collection seemed to resemble the increasing multi-sitedness of clinical trials. Similarly, collaboration as a problematic was written into this research from the outset. Cast as a research topic, methodology, and the form of the ISBC project's operations, it coloured both practice and analysis, a concept in vogue both in the anthropological academy (Marcus 2008, Lassiter 2005, 2008, Reddy 2008, Holmes and Marcus 2008, Lowe 2007, Konrad 2012) and within the bioscientific world (Glasner 1996, Hackett 2005, Royal Society 2011, Wagner 2001, 2002a, 2002b, Parker et al. 2010, Halliday 2010, Hackett 2005). The way in which the project was set up might lead one to a conclusion that the whole picture gathered by nine anthropologists would (necessarily) be greater, clearer, more accurate, than the picture gathered by one alone, were she to set out on the same task. As the collaborators in the Matsutake Worlds Research Group (MWRG hereafter) confirm, collaboration in multi-sited research seems simple, to the point of obviousness:

> To the extent that the sites are different from each other, expertise and commitment are necessary to study each site, and this is most easily accomplished with more than one researcher on board. Multiple researchers can carry the burden of multiple languages, area studies and histories in the study (MWRG 2009:198).

However, they note, the danger is that in the collection and deployment of these multiple expertises, the method might be 'mistaken for a division of labour' (MWRG 2009:198), with analyses compiled to generate, 'add up to a coherent whole' (MWRG 2009:198) as is the ambition in multi-sited clinical trials.

But neither the ISBC project nor my fieldwork were cases of methodological mimicry, with the imagined outcome being a larger sample size, more perspectives, resulting a greater view on the 'whole' work of the organisation under study.[14] It is not my contention that a single site would be 'insufficient for capturing the complexities of social systems,' (MWRG 2009:197) nor is it a quantitative 'adding on' of sites. What I must also do is insert some doubt as to the 'view' achieved from this multi-sited approach. Indeed, it was the proliferation of these knowledge

[14] Ideas passed formally and informally, knowledge about field sites gained different degrees of circulation. It is not possible to read back from the outputs of the ISBC the successes and impasses of our conversations, since as the project's PI once put it '[t]he kinds of communities formed by the circulation of knowledge in the course of producing an artifact, a product, can only be imperfectly gleaned from the product itself' (Strathern 2004:21, see however Law 2002).

practices of research, and their assumptions, which interested me. The problem was one of gaining critical purchase on such ideas.

So how is one to study such an object? Would it not be simpler were I to say that in the addition of sites, I had gained many more perspectives upon the (single) phenomenon, that my regard could be classed not as local, not as national but as regional? This is a hierarchy, with associated scales. The complaint an examining anthropologist might have of a regional claim — that it would be 'too general', also fails the point: it is no more general at this fictional place called the 'regional' than it would be in a single ethics committee room in Sri Lanka. I could fill a thesis with each, and progress no further than the assumption that the 'global' is necessarily more complex than the local. That in invoking complexity, in relying on the scaling effect of the global in the minds of the western anthropologist, the complexity of the global (imagined as large) must necessarily be greater than the local (imagined as small). Actor Network Theory has prepared the way, and, more recently, provided ancestors with whom one can battle Durkheimian legacies in revisionist re-matches. Tarde, recently revived ancestor remarks that

> [i]t is always the same mistake that is put forward: to believe that in order to see the regular, orderly, logical pattern of social facts, you have to extract yourself from their details, basically irregular, and to go upward until you embrace vast landscapes panoramically (1999: 114, cited in Latour 2002:124).

Wanting to avoid the idea that FERCAP was indeed an object of a certain (regional) size that articulated differently in the various countries in which it operated (for that would be to reproduce a global/local binomial) I wanted my activities to question the concept of context as a tool used by FERCAP and through this, make ethnographic the question of how FERCAP organised 'object' and 'context'. One effect of the scaling and organisation of description in writing is to locate 'the field' in geographic coordinates, comments Leach, arguing that: 'a descriptive and explanatory strategy that outlines how meaning systems are built upon particular social-organizational bases, which themselves rely upon certain material conditions, makes obvious sense to us' (2006: 149).

While this research is, in the classic sense, an arrangement of a number of sites, it is so because the work of FERCAP is itself multi-sited. I do not describe the research done as the 'gathering of different perspectives' — a gathering neither conceived of as representative nor as complete. Indeed, it is as a *result* of the way in which the trope of 'perspective' is used by research ethics committees that I take the approach I do. How persuaded am I by FERCAP's models, how can I read their frames (Marcus 1986, Strathern 1987)? I could have portrayed FERCAP as abstract, a

structure emerging from relationships that I as an anthropologist would be able to observe first hand. But it could equally serve as the explanation for the meetings of those people: it describes, stands for, their activities and meetings. Indeed, FERCAP's representation of itself is much like what a 20th century British Social Anthropologist would have produced. The privileging of 'concrete, observable relationship over the abstraction of structure is most evident in the legacy of kinship studies' (Munro 2005: 225-226). I intend to show how the social life of the organisation is made to hold, how people become interested, the reasons they give for their continued interaction with one another.

The form of questions I was able to ask developed and my sensitivity to recurring and important issues within the concerns of the network grew as time passed. I was, at each point, explicitly provided with a different country's "perspective", the multi-sited work connected through the organization, watching when cultural difference was inserted or asserted to signify disconnection. To return to the significance of this 'objectification' of comparison for my methodological approach, it becomes necessary to state again what might otherwise seem obvious: that the object of FERCAP exists only because of its multiple contexts, and in fact exists as a relationship between those contexts. As I explored above, the metaphor of the family does its work here, uniting and differentiating at once, with the trope of family forming not the object but the objectification of the relationship. To state it another way, FERCAP both creates and *is* the relationship between contexts, in addition to being an object that appears differently in different contexts.

This formulation allows me ground for thinking through my own movements. My participant observation in the network amounted to 'following', participating through moving. In order to examine FERCAP — an object made up of relationships — I myself had to move, shadow relationships and make my own in so doing. Thus, by configuring here what it was that I did methodologically, I find myself laying foundations for what it is that FERCAP is, with its ontology enmeshed in the method used to 'follow it'. What matters is a lively alignment between object and context, through which I came to understand a need to allow *the making of context* to form the context for my arguments, so to speak.

The strongest argument for this tracing is that things that happen in one place affect things that happen in another place. As Cook, Laidlaw and Mair say for their work on Buddhist practices:

> there is no serious room to doubt what is happening in these different sites profoundly and intricately influences and affects the others, and that some similar processes are at work in different sites. But this does not mean there is one whole of which they are all parts (2009: 50).

They relate, as an opening, a story used in Buddhist texts. Their objective in relaying it is also a methodological and conceptual one — to dissuade anthropologists from looking for complete wholes:

> A king orders all the men in his kingdom who have been blind from birth to be brought together and led before him, each having been partially introduced to an elephant, by each being given just one part of that elephant's body to handle. Those who had felt its head replied that the elephant is like a pot. Those who had held its ear said it resembled a winnowing basket. Those who had held only the trunk likened it to a plough and so on. Then, just like the Brahmins, the blind men began to quarrel. The parable is used within the Buddhist text to warn against trying to reach conclusions about the nature of reality on the basis of only the partial view of the unenlightened (Cook, Laidlaw and Mair 2009:47).

Cook, Laidlaw and Mair recall that multi-sited research seemed to be an answer to the 'partial perspective afforded by a single research site' (2009:47) in the age of global systems. I would suggest that this formulation is itself the result of a particular way of regarding space, one which they seek to upset as their article progresses. Their research topic, an ethnographic description of the teaching and practices of self-cultivation and transformation in new forms of Buddhism across at least three states in Asia, would seem to be a perfect candidate a multi-sited approach. However, in the course of the chapter, they question the usefulness of systems thinking, question why it is that 'accounting for local ethnographic phenomena must involve locating them within an encompassing trans-local 'system' located theoretically at a 'higher' level' (2009:48). This is an assumption implicit in multi-sitedness they wish to step away from: that more perspectives on something will make a more complete whole; be more than the sum of its parts. Their position recalls that of Schneider (2011 [1963]) who, in his rejection of the making (and mending) of anthropological models, wrote that:

> it is too late in the history of the social sciences to think we can go out among societies, and by keeping our eyes open, sort them into their natural classes. It is not possible to operate like those in the story of the blind men and the elephant and hope that if only we can put enough blind men on the elephant we will get a good factual description of the beast - the total elephant (2011 [1963]: 486)

What brings me to compare 1963 and 2009 is not just mention of the elephant; it is the common critique of anthropological aspirations towards a 'total system.' The concerns resemble one another: the world religions/world-systems critiqued by Cook, Laidlaw and Mair in their essay on multi-sited Buddhist ethics, echoes Schneider's challenge to the mysterious location of 'the system' in the work of descent and alliance theorists (Needham in particular). Both are concerned with the mapping and location of explanatory power, suspicious of systematicity. Schneider is critical of Needham's (1962) 'whole concrete entities [and] discoverable [...] perfect crystals' (2011[1963]:

482) asking 'at what level does the system exist?'(2011[1963]:481). He recommends attention to analytical terms. Cook, Laidlaw and Mair also leave us with the question: what if there is no elephant? No such higher level? (2009:48). The recommendation, in this case, may still be attention to analytical terms.

Vocabulary: a framing by description

In research ethics, as I have shown above, emphasis is placed on the need for 'local' review of 'global research.' Such a statement appears self-explanatory. Global research 'summons no further exemplification: it is a macrocosm, a complete image, and requires no theoretical underpinning' (Strathern 1995b:169). In the same way, the local of 'local review' 'points to specificities and thus to differences between types of itself — you cannot imagine something local alone: it summons a field of other 'locals' of which any one must be only a part' (Strathern 1995b: 167). At the same time, the push for global health, particularly the needs of the developing world, is seen to be large. As the Royal Society puts it, 'global approaches' are needed for 'global problems', 'grand challenges [...] which transcend national boundaries' (2011:72, see also Highfield and Lawton 2010).

Anthropologists have been drawn into imagining the 'relation' between the global and the local, as they were to configuring analyses of the 'individual' and 'society'. In her analysis of English kinship, Strathern (1992) argues that the individual person came to be seen as incomplete, needing integration into the whole through socialization and convention. However, she then demonstrates a counter, coexisting and equally totalizing view, that the person was *already* a biological and psychological whole. Otto and Bubandt summarise the position as one of

> two partly incompatible holistic perspectives [which] could not be matched or exchanged, because they only partially overlapped: the individual as part of society and the individual as part of nature. Both perspectives were totalizing, but neither could fully encompass the other, thus positing a contradiction at the heart of modern English holistic perceptions of social relations (2010: 256).

Strathern refuses to allow the phrase 'global and local relations' to lie flat, arguing that they were 'incommensurable from the outset': [w]hatever relationship lies between the two parts, it divides as much as links them, renders them as much disjunct as connected (Strathern 1995b:165).

It is evident that care must be taken with these terms. I pay close attention to the language used in describing the world of clinical research: looking at the effects of organising a world into the 'local' and the 'global', a problem paralleling disciplinary discussions (Kearney 1995, Strathern 1995b). 'The danger in thinking that one can move one's analysis from the larger scale (macro) to the smaller (micro) is just that of being caught in an antinomy like that between 'society' and 'individual,' writes Munro (2005: 262). Instead, I ask what their use tells me about what is going on when people talk about 'local' ethics committees, or 'global' research. There is, at the same time, another question at hand, which is 'how actors engage in a constant deployment of their own scales' (Jensen 2007: 833). Latour agrees that 'framing' is 'what actors constantly do' (2005:186), but does not find mere recognition of it sufficient: for him, if this framing is an activity, contextualization is active, and should be examined. He takes issue with scales, asking:

> does it not make perfect sense to say that Europe is bigger than France, which is bigger than Paris that is bigger than rue Danton and which is bigger than my flat? Or to say that the 20th century provides the frame 'in which' the Second World War has 'taken place'? (2005: 185)

It may be commonsensical, he writes, but this 'common sense' is obscuring 'actors at work in their deployment of scales.' Observing this 'work' is impossible, he says,

> as long as the zoom effect is taken for granted', [since] 'to settle scale in advance would be sticking to one measure and one absolute frame of reference only when it is measuring that we are after; when it is traveling from one frame to the next that we want to achieve (2005: 186).

The scale that I avoid settling in advance is one which casts the local as small, the global as large. Work by Actor Network Theorists that has tried to take this on board has been accused of 'flatness', a denial of existing power inequalities. I would argue rather that by denaturalising taken-for-granted scales of large and small, and their concomitant power attributes, it becomes possible to see how the 'taken-for-granted' comes to be. More than this, we can notice that the near and far are not defined 'in purely spatial terms' (Cook Laidlaw and Mair 2009:69, see also Mol and Law 1994). Jensen, in his work on the implementation of an Electronic Patient Records system in Denmark, notes how the macro and micro structure structured the imagination: the system was 'formulated in political offices (macro) - in order to be disseminated ('rolled out') at hospital wards (micro). Ideas do not come from 'somewhere very *distant, large* and *powerful*' (Jensen 2007: 846). Jensen reminds us that:

> in a fractal approach it is [...] crucial to refrain from relying on a specific prioritized scale from which to evaluate all other actors, for the point is precisely to learn from those others

> about the intellectual, practical and moral scales they work with in order to build social networks and spaces (2008:833).

As Callon remarks in his classic study of the scallops of St. Brieuc Bay, an author 'cannot simply repeat the analysis suggested by the actors he is studying' (Callon 1986: 197).

The challenge here is translation from familiarity. Anthropology's own language, words which — though now out of vogue in contemporary writing — inform how FERCAP describes its world. Viveiros de Castro draws upon Herzfeld to argue that 'the anthropologist and native are engaged in "directly comparable intellectual operations" (Herzfeld 2003:7) and such operations are above all else comparative' (de Castro 2004:2). He suggests that 'a good translation is one that allows the alien concepts to deform and subvert the translator's conceptual toolbox so that the intention of the original language can be expressed within the new one' (2004:23). Strathern (1988: 328-329) points directly at the difficulty as she tries to translate a Melanesian symmetry between the positions of men and women against a 'Western aesthetic' whose conjuring cannot be evaded. The language available to her, she demonstrates, will not permit what she means to be communicated to her reader:

> If I say that men's exchanges are oriented towards their wives' domestic concerns, then the statement will be read as men appropriating those concerns and turning them to their own use. If I say that women's domestic work is oriented towards their husband's exchanges, then this will be read conversely, not as their appropriating men's activities but as being subservient to them. I know of no narrative device that will overcome this skewing, because it inheres in the very form of the ideas in which we imagine men's and women's powers (1988:329)

Sometimes, researchers unwittingly play into anthropological hands, the emphasis on systems promoting paper names such as the 'structure and function' of ethics review committees (Kass et al. 2007, Savelescu 2002; Wenger et al. 2002). This evokes, of course, an earlier era of analysis that it might be tempting to return to for the sheer explanatory capacity and clean lines of systems that work. In finding these terms in bioethics, I find also the debates anthropology had in the twentieth century. I find the patterns of thoughts that provide those concepts with their foundation. Problems borrow framings.

Take for example the location of 'value' when it is 'elaborated as a negotiation between the interests of communities, the protocols of science, the priorities of global health' (Kelly and Geissler 2011:3). In the protection of the human subject, the interests of that individual are caught up against those of 'society', the pharmaceutical industry, even national agendas. But these categories betray a whole to which they are part: the familiar reification of 'society' (Munro

2005:474). Where international biomedical research is framed in such terms, 'the vulnerable' are a category of person that emerge, the language of ethics containing 'women' or those unable to give 'informed consent' as subset of a broader 'society.' It is in these reifications that we come to see bioethics as set upon the 'antinomy between society and the individual' (Strathern 1988a:12), with 'specific interests' (ibid). I ask in this thesis what those interests rely upon, how the categories order thought, and what the ethics promulgated by FERCAP does with them.

The anthropological questions asked of this material, then, must engage the anthropological canon of work on structures, functions and systems by drawing on other languages of description. While it is largely comforting to know that anthropologists have been puzzling over related fields since the inception of the discipline it can also complicate analysis, knowing that the models with which ones interlocutors are working have close 'relatives' in the descriptions and carried out by earlier anthropologists. Wagner reminds us that no transformation is independent, nor are the anthropological modes of analysis that come with it:

> Historical anthropology mirrored the ideology of the late colonial and supraethnic empires of Britain, France, Central Europe and others [...] Systemic anthropology reflected the rational urgency of wartime mobilization and the economic nation state (1981[1975]:107)

His reflections prompt questions of what it is that today's anthropology mirrors. Peter Pels has argued that anthropological attention should be paid to ethics for the way it is used as 'a word to talk about things that anthropologists were used to calling culture and society' (1996:18). In a similar vein of awareness, Molyneux and Geissler remark that:

> debates underline that the concept of research ethics or bioethics, its historical emergence and transformations, and the workings of regulatory frameworks, review boards and concrete ethics procedures, ought not to be taken for granted; rather than being self-evident, they constitute an important subject of ethnographic and historical research (2008: 693).

The work I have undertaken fits Geissler and Molyneux's call that ethnography be enrolled to question in an historical framing these self-evident (and self-justifying) developments. However, what if, in the entanglement Pels suggests, bioethics inherits certain of anthropology's conceptual problems?

I suggest that bioethics has taken on the antinomy between 'society' and the 'individual' that has shaped, and been shaped by, much of the last century's social science. This 'taking on' lies in the form of images and assumptions, conceptualisations and framings of problems. For example, although social science's 'preoccupation' with the 'total relationship between the individual and

society [...] belongs to a (modernist) phase already culturally superseded' (Strathern 1988a:20) the dichotomy lives on in ethics. The language ethics promulgates also contains these assumptions, but 'it would be naïve to imagine that along with the borrowing of constructs goes the borrowing of the understandings that produced them' (Strathern 1995b:154). There is an important analytical distance to be claimed, since 'such borrowings recontextualise the conceptual intent with which the constructs were once used' (Strathern 1995b:154).

Equally, FERCAP's engagement with comparison and difference-making was so familiar, that it might have gone unnoticed ethnographically (e.g.. Miyazaki and Riles 2005). What alerted me, however, was the way in which the moves made by FERCAP echoed so closely the moves that many an anthropologist might make. Within academic bioethics particularly, the role of pointing to differences, exceptions, uniqueness has tended to fall to anthropologists (Marshall 1992, Bosk 2001, Turner 2009). If it is, then, taken as a trope that A is different in some way from B, what emerges is that FERCAP is already dependent on that relationship. Were I, for example, to build an argument that used my ethnographic observations from Thailand and the Philippines to argue that things were done differently in each place, *I would be replicating how FERCAP understand what they do themselves*: the expectation of difference, and a comparison is already incorporated into the practice. Thus, the first, and simplest step is to recognise that my interlocutors are already actively doing something interesting with comparison and differentiation. Perhaps more importantly, any place within the FERCAP network is already 'in' comparison, through a practice that incorporates the presence of difference. It is this which forms a ground for an analysis of the particularity of standardisation which has come to be a key thread in my material, with the repeated question 'what people are comparing things "for"' (Jensen 2011:2). Holisms of anthropological invention, such as the global, local, world system, centre and periphery, society, cannot be uninvented. These concepts are often at work in our own field-sites, not just replicated in our analyses, and we would be remiss if we did not pay attention to how people make them do their work. By paying attention I mean not only close ethnographic observation of the way these concepts are drawn upon, employed in descriptions and arguments, but also taking as much care when writing, so that through observing the language we use, we can see what these concepts are up to, under our noses, perhaps sometimes too close for focus (Brennais 2006, Riles 2006).

I have demonstrated the terminological challenges presented by the material, and some of the strategies I propose to address them, joining what Miyazaki calls a

> long strand of anthropological attention to the parallel between anthropologists' and their interlocutors' ways of analyzing, critiquing, interpreting, knowing, modeling and theorizing (Miyazaki forthcoming, see e.g. Bateson 1958 [1936]; Holmes and Marcus 2008, Leach 1954; Miyazaki 2004, Riles 2000, 2011, Strathern 1988a).

'The work we do with concepts transforms them, and sometimes to the point of displacement' (Strathern 1995b:169, 2011c). This is Miyazaki's stated intent with the concept of 'arbitrage', as he examines its use by Japanese derivatives traders in a Tokyo securities company (forthcoming). He explores how the concept rests on an essential ambiguity, an ambiguity he exploits through the narratives in his chapters. Ethics is the term which comes under scrutiny in this thesis. I have shown its positive connotations ('the ethical'); its hold on the 'good' is such that even critiques of it can seem to provoke its (equally connotation laden) obverse 'unethical'. As for anthropologists working with human rights, it takes an examination of the consequences of the language (e.g. Englund 2006) to realise that the enquiring mind is confronted with a self justifying force. Thus, in order to analyse the role of ethics, and the role given to it by those with whom I worked, there is some work to be done in denaturalising it in order to bring the enterprise of ethics itself under critical examination. Henare et al. remark that Roy Wagner sees the 'encounter between anthropologists' own concepts and those of their informants as a productive one *because* of their divergences' (2007:21 emphasis added). It will pay to remember, however, that it cannot be known in advance how much of the contexts concepts carry within themselves (Wagner 1986), how much of the 'understandings that produced them' (Strathern 1995b:154) will be borrowed along with the words themselves. This a challenge for an anthropology of the contemporary (Rabinow et al. 2008).

Overview of Chapters

In preparing the text, I have chosen events, spaces and moments from the fieldwork that were common to each of the countries where I followed FERCAP. This is not to deny the important differences between the sites but, rather, to leave them aside from the structure of my analysis, in order that they emerge in the narratives of the network itself. Where this occurs (Chapter 6), it is hoped that the reader will have enough exposure to the workings and priorities of the network to understand how my analytic treatment of difference differs from the enrollment of difference within FERCAP.

Contributing to the practice based study of knowledge-in-the-making (Camic et al. 2011), the first two chapters follow ethnographic objects: the survey and the rooms of ethics review committees. Chapter Two takes the Survey, FERCAP's implementation of the SIDCER Recognition Program, as its ethnographic core. While FERCAP employs only Cristina full time, the Survey is a key activity of the FERCAP network and she draws upon volunteers from reviewed and surveyed committees to become Surveyors. I combine close observation of the Surveying and auditing process with the descriptions and reflections of surveyors. The discussion explores the ways in which the social relationships that constitute the survey teams and surveyees are carefully managed using supporting literature on hospitality.

Chapter Three, *The Rooms of Ethics* focuses more closely on the space of ethics. The achievement of 'a room' is a physical requirement for an ethics committee. I pay conceptual attention not only to its symbolic status but also its role in quite literally making the space for ethics. Talked of as a means of expanding the importance of ethics, ensuring recognition of ethics, and being a form of standardising — laboratizing even — ethical review processes, the room is at once a template and a unique space in an institution or hospital that comes under assessment during a Survey. An analysis of what happens in the room, particularly decision making, the problems of conflicts of interest and the art of minute taking lead to a discussion of how we can better understand the social space an ethics committee creates.

Chapter Four develops certain of the tensions in Chapters Two and Three by embarking on an active comparison of the Ethics Committee with a Jury. Here I focus on a comparison made by those in the field and then develop the comparison 'so as to translate' (de Castro 2004:3) the concerns the field comparison originally raised. In what ways is an ethics committee like a jury? How can the answers tell us more about how ethics committees operate in the countries where FERCAP works? In the close of this chapter I also address the question of law and ethics, and the poles of regulation and self-governance that I develop in Chapters Seven begin to emerge in the views of my interviewees.

Chapters Five develops material presented in Chapters Two and Three by focusing closely on the problem of perspectives in the committee. Drawing on descriptions of ideal ethics committees both from interviews and from published material, I analyse how knowledges adhere to both professions and persons. Chapter Six extends the work of 'perspective' from the committee to the organisation, exploring explore how images of plurality, perspective, difference and scale are scaled in turn by the languages of comparison at work in the network. Rather than embarking on a

comparison of the countries where FERCAP works, I aim to illustrate FERCAP's own work of comparison, and provide a view of the politics of the organisation's achievements. The analysis of near and far, large and small, takes inspiration from Mol and Law's work on anaemia (1994), Riles' work on UK/Fijian colonial legal documents (1995) and Jensen's discussion of the macro and micro in Danish healthcare systems (2007).

Chapter Seven takes off from Chapter Four, shifting from ethics committees to the employment of 'ethics' by those involved with committees. I return to the phrase with which this thesis began, 'If you don't do you duty, you are not a good professional' by examining both 'duty' and 'professional'. I look at the creation of a profession of ethics, and the professionalising work that capacity building workshops make possible. What are persons, that they are to be governed? What does an approach of governance through ethics reveal about the assumptions that are made about them? Overall, the turn is towards the narratives that invoke the personal characteristics of those who engage with ethical review, an ethics that is located 'within.' Training involves learning particular ways of seeing, of reading for ethical issues and of self examination for problems of conflict of interest. As a way of drawing together the themes of this final chapter with those of the preceding chapters, I turn to a range of ethics committee members' dreams of the future of ethics.

In my conclusions, I situate the ethics committee as a contemporary witness to good science alongside those written about by historians of science. The ethics committee not only *contains* a bundle of models and imaginings, but is itself a model. The ways in which people involved with FERCAP handle the assumptions of this model is the overarching topic of this thesis.

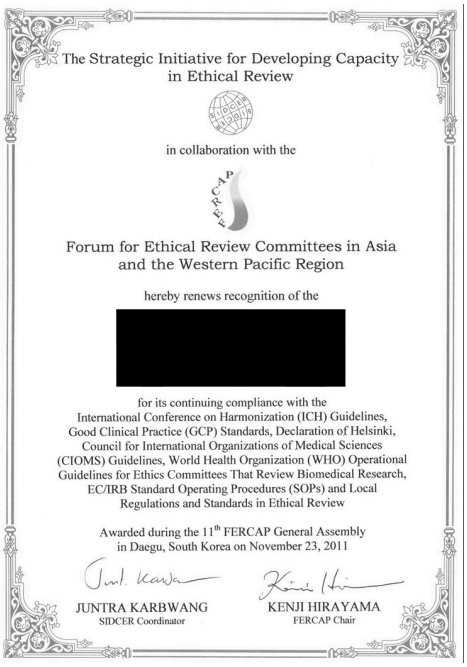
Chapter 2: The Survey

It is late on a sultry April afternoon, and I have joined a group gathered in the ground floor meeting room of the medical faculty at a University in Manila. The windows are tightly closed against the roar of traffic outside, and the air conditioner in the corner is hard at work. Dr Sam, our Lead Surveyor, is standing at the front of the room fiddling with the powerpoint, about to begin his final presentation. He will sum up the findings of the Survey we have been conducting over the past three days. We, his audience, are the members of the survey team, the trainees, local surveyor and international surveyors, and members of the ethics committee that has been under review. His words will be directed at this last group, who are shuffling and whispering amongst themselves. There is a certain amount of suspense: this final meeting, where the findings of the survey team are presented, is a delicate social occasion. The standardised sentence — seen on the closing powerpoint of every survey — seems both recognition and reminder of this: 'The Reason for the Survey: To assist [insert IRB] in reviewing their practices and appraise their performance against the SIDCER criteria for recognition.' Sam begins by listing those who have taken part, the trainees in three groups, each under the guidance of the local, foreign and lead Surveyor. The first fifteen slides list the selected research protocols and meeting minutes that were looked at, the SAE reports considered, and the members of the IRB who were interviewed.

Figure 8: Slide Sixteen of Dr Sam's closing presentation.

Slide sixteen falls between those which document the method of the survey, and its findings (Figure 8). It is a blurry image of a green camouflage-painted helicopter, flying low over the sea. A a rope ladder dangles from its open door. There is a person clutching the ladder, and to its right, a shark is leaping out of the water, its jaws aimed at the suspended figure. Dr Sam has typed in labels for the scene: the helicopter, in a large white font, is FERCAP. In red, the person hanging onto the ladder is the Surveyor, and the shark the ERC/IRB. Will he, the dangling surveyor, the representative of FERCAP, be eaten by the shark of the IRB? Having raised a laugh in the room and dispersed some of the tension, Dr Sam continues with his presentation of the recommendations.

What to make of this moment, and Sam's visual joke? Why is Dr Sam, the apparent authority, portraying himself as in danger? Standing alone at the front of the room delivering the findings of the Survey, he is worried about how the committee he addresses will respond. As this chapter hopes to demonstrate, doing criticism well is difficult, even if one is an invited guest. Humour can help. The placement of his slide, between the technicalities and the results reveals that although during the Survey, it is the IRB that has been under scrutiny, at this point, the surveyor becomes vulnerable to the reaction of the committee. The standardised sentence with which Sam opens emphasises the assistance the Survey intends to offer. A three day review of an ethics committee's activities according to five standards set down by SIDCER in 2005, the Survey is a key FERCAP activity. The Lead Surveyor is always "foreign", a stranger in the country of the IRB. S/he is assisted by a second "International" surveyor, and a "Local" surveyor. Each of these will lead a team in the detailed assessment of the workings of the committee. The international surveyors will be treated as welcome guests, their long hours eased by the hospitality of the committee under survey: tables are laden with water bottles, flowers, fresh fruit and other snacks. A formal meal will often take place on the first or second night, and then, the following day, the work of dissecting the committee (on the guest's terms) begins. Time is found or made for Surveyors to see the cities they are visiting, whether it be the Olympic site in Beijing, the walled city of Santiago in Manila or the markets of Guangzhou. After the three days of Survey and closing meeting, the committee will be left with recommendations to complete. If they comply with the modifications in the agreed timeframe, the committee will be 'recognised' with a glass trophy and certificate (Figures 9 and 10) at the annual conference.



Figures 9 and 10: The trophy and certificate awarded to committees upon recognition. These are presented at the Annual Conference.

I suggest that the ambivalence captured by Dr Sam's summary meeting presentation — the precarious power of the guest, and the potentially volatile vulnerability of the host — stand to be illuminated by a recent resurgence of academic interest in hospitality (Derrida 1997, Herzfeld 1987, Lashley and Morrison 2000, Selwyn 2000, Shyrock 2004, Rosello 2001, Lashley, Lynch and Morrison 2007, Cole 2007, Candea and da Col 2012). A concept that involves 'reciprocity, a tension between spontaneity and calculation, generosity and parasitism, friendship and enmity, improvisation and rule' (Candea and da Col 2012:S1), hospitality serves in the first instance to help us understand Sam's experience. Being a guest, particularly a guest invited to make criticisms — no matter how constructive they may be — is a difficult task. Surveyors are in a precarious position. The success of recommendations, indeed, of the survey program itself, depends on the interaction between the visiting 'Foreign' surveyors and the 'Local' committee members. The latter must accord the former the right — and authority — to make recommendations and suggest corrections. This is a permission granted largely because is is repeatedly said to be done with the intention to improve, to help. But the final meeting, talked of as an opportunity for discussion and feedback, also has the potential to develop disputes if the 'recommendations' are not taken well; that is, if they are taken as criticism. As Selwyn notes, in the celebration of and legitimation of hierarchical structures, hospitality seeks to make 'friends and familiars out of strangers and enemies,' and yet this work also 'serves to draw hospitality's 'twin sister' hostility out of the shadows' (2000:26).

Dr Sam's slide reinforces the uneasy potential in guesthood. Survey guests must be objective outsiders, maintaining their authority to speak and suggest, while softening criticism into 'recommendations', emphasising that they 'come as friends' and 'learn' from the committee they have studied. They are friends one does not necessarily want to see again too soon, however. Again, we are aided by the scope of analysis hospitality offers, as it 'encompasses distant agents; it embeds social transactions in materiality and raises complex questions relating to economy and time' (Candea and da Col 2012: S2). We will see international travel, observe the attention to material detail as Surveyors sift through paperwork, puzzle over the potential of reward, and learn about time: the ambiguities of follow up visits, and the reversals involved in delayed return.

Figure 11: Follow up visit slide from Survey in Manila

Having given the Survey's recommendations, Dr Sam's final slide is a black and white photograph of American soldiers and troops landing from boats, wading through the shallows, sunglasses on, caps jauntily tilted. In the background, a ship, with the word 'FERCAP' superimposed over its hull. A man with binoculars around his neck has been given a yellow speech bubble: 'General, should we return for follow-up visit?' (Figure 11). A follow up visit is only required when committees are significantly deficient. As there are always points to improve, a follow up action plan is always necessary, and evidence of corrections to documents, equipment or work spaces are sent via email to the surveyors. But a return visit denotes more serious shortcomings. As Dr Sam told me shortly after his presentation, in his experiences of surveys in Taiwan, the immediacy of

the result is hoped to bring an equally immediate recognition of success, and any kind of recommendations — the 'follow-up action plan' — can bring the sense of inadequacy and failure. But with principles of continuous quality improvement, 'There is no such thing as a perfect ethics committee,' state the coordinators.

Hospitality, then, affords me a language in which to speak about the survey as friendly support and quality assurance evaluation simultaneously, tracing the ambiguous line of friend and critic that Surveyors must walk. In the first part of the chapter, I discuss the role of "foreign" and "local" surveyors, the guests, the intermediaries and the committee, the hosts. The local surveyor's position is ambiguous, a discomfort described by interviewees, highlighting the tensions between the language of friendship and the dangers of critique. The second part of the chapter explores what constitutes the SIDCER Recognition program, the standards upon which the Survey is based, the observations that take place. What I demonstrate is the mutual investment of the surveyors and surveyees in the recognition program, while relying on means of creating the social separation and 'objectivity' crucial to the program's success.

In the third and final section I turn to the appeal the Survey 'recognition' program has to committees across the region. Why has the program been so successful? Why do committees submit themselves to a voluntary audit? When FERCAP presents the program of 'recognition' to committees, it begins by describing the international research arena which we saw foregrounded during Chapter One. Surveyors voice a key concern:

> The same trial being done in Asia, we see it in being done in Africa, in the West. All, no matter where, the concern is about quality of research. If we are not harmonised, chances are they will not accept the results coming from your country. The objective is to give public recognition to ECs who comply with intentional and national regulations, drive them to the pursuit of excellence and its rewards.

As ethics review committees are trained with a view to their role within this project, as noted above, the image of a 'whole system' provides a context for their operations. That context then becomes the appeal: in becoming hosts to research, they may also gain access to clinical trials, funds, publications. In this shift a scalar slipperiness (Herzfeld 2012:S211) is revealed: hosting surveyors is potentially not far from hosting biomedical clinical trials. In these movements analysts of hospitality are at home (Candea 2012, Shyrock 2012: S28). Cristina outlines below some possible benefits of the recognition program to a committee in southern China who wanted to know more about the Survey:

> It can have impact on an entire research team. You can put the name on your website: I receive queries from sponsors who ask if we want to do research in Thailand; sponsors like assurance that the Ethics Committee is doing their job. [They] ask us if we've visited this Ethics Committee and if we have recognised them. Thats how we do our work. Sponsors would like to have some assurance that the EC is GCP compliant. If its not, it becomes GCP deviation, a violation, therefore they want to make sure that's adequately addressed. So the recognition program becomes important to sponsors as well. So we call it SIDCER recognition program. We're part of this global network. A global initiative called SIDCER, which is a project of WHO TDR — trying to do this in different parts of the world, though we're most popular in the Asia Pacific region.

Attention to the survey as a means of participation allows us to ask what it means to become, as the literature puts it, a 'host country.'[15] 'Compliance' is an essential factor for sponsors, and we can also read it as a measure that a site is hospitable to research: research conducted here can be submitted to regulatory authorities, published and relied upon. Ensuring GCP compliance, to measure oneself against standards and processes, ensures participation. To become hospitable in this sense, then, is to do so on someone else's terms. The point has been made forcefully in discussions of bioethics (Macklin 2004, Farmer 2005). As Candea and da Col write, '[a]cts of hospitality turn people themselves into things, usable, exploitable assets, indexes of other intentionalities' (2012: S10). This is the potentiality of clinical trials.

Movement

Is the Survey an audit? While its audit traits are immediately recognisable with their emphases on documentation, measurement and the need for renewal, the approach taken by FERCAP is distinctive. Surveyors are welcomed as guests, and the language is not one of pass or fail but, in the phrases used by FERCAP surveyors, 'our approach is to help', 'it's developmental'; 'the intention is to make it easy to comply', 'our objective is not to help *us* but to help *you*'.

This section takes the idea of 'help' and reads it against the relationships created through surveys. It details the movement of people across the region as they train and participate in FERCAP's "Surveys," as committees volunteer to submit themselves to peer scrutiny. It draws on observations made during surveys and pre-surveys around the region in my role as a 'trainee' surveyor. The whole of the first day is usually put aside for an 'International Course' on Surveying Ethics Review Committees. In order to take part in the Survey as trainees, and thus earn the right

[15] This is the terminology used by the Nuffield Council on Bioethics, for example (NCOB 2002: 27) but the document places emphasis on enhancing the ability of developing countries to conduct research that is relevant to their needs.

to become Surveyors at a later date, trainees must attend the whole of the first day, and each subsequent day. I have a collection of certificates of attendance, printed in colour on shiny paper, adorned with the logos of FERCAP, WHO-TDR, the institution, bordered with patterns. Surveys proceed by taking the trainees, assigning them to surveyors to create groups and delegating tasks to them. Each group will visit the EC's office, and the entire survey group — including local surveyors, and trainees — will observe the committee meeting. Meetings take place around a table, with the chairperson sitting at the head. Chairs arranged around the outside of the room then provide a second horseshoe of observers, looking (quite literally) over the shoulders of the ethics committee members as they discuss. During research, I kept some, though by no means all, of the hours that the surveyors did, arriving on site by eight, not leaving until nine, ten, sometimes twelve hours later. On days we finished early, there would be homework: the review of a section of Standard Operating Procedures (SOPs). I would sit on hotel beds going through procedural points, one by one. Typical notes from those evenings read as alien poetry, it is difficult to recall accurately the state of mind that produced them:

> Chapter Eight, Page 93: 'inconsistency between 8.1 'special meeting' and 8.3 'emergency meeting' - or rather, is 'emergency meeting' a 'special meeting?; Page 94, 8.3.3.2.2: Possible activities listed are inconsistent with description of Scope. Page 97. Suggest logbook for phone calls.

Back in the institutions, I observed the observers, actively learning techniques of the Survey. A photograph taken by a Surveyor during a Survey in the Philippines captures it well (Figure 12).

Figure 12: A photograph taken by a Surveyor of the author (C) observing a Surveyor (R) interviewing a committee member (L).

Belle, the international surveyor of my team is on the right. The secretary of the committee under survey is on the left. Belle is interviewing her about her role. They face each other. The back of my head falls between them, as I sit in the dialogue, observing the interview. Obscured by my head, a notebook with two columns open is open on my lap. The left contains notes for the survey, the right, field-notes: notes on my notes.

The Survey, while being a learning experience between friends (an event of hospitality between colleagues) is also a badge of quality as suggested above. It indicates hospitality to outsiders, by their own measurements. Bill, a surveyor from South Korea, thought government interest in clinical trials had been a significant factor in the success of the recognition program.

> It started in Thailand, then it moved to Taiwan because the government wanted to get involved in clinical trials, Korea too. And now China. It's in their interest, it's kind of a business, the institutions need to advertise, to put up some accreditation, to show.

This 'show' is written in to the SIDCER initiative, the standards of which are implemented during the Survey:

> SIDCER provides the international community with not only a means to build in-country human subjects protection programs, but also a way to measure and provide accountability regarding the quality and effectiveness of ethical review worldwide (Karbwang Laothavorn 2011:11).

Since outsiders' measurements value greatly the principle of objectivity, the Survey must also achieve a representation of its *own* objectivity. Standards for the Survey were set early in the development of the scheme at a meeting in Olympia, Washington by the SIDCER working group which included Directors of Quality Assurance, Internal Auditors, Quality Assurance Analysts, Directors of Regulatory Affairs.

The Survey is the measure. It has the potential to make hosts of these countries. Bill reflected that as a result of state-level interest and increase in international or multi-sited trials being run, 'people who really care about human subject protection have taken the opportunity to do work - for example FERCAP. It's a very complicated landscape.' The survey relies on the voluntary labour and expertise of members of its network, who have received training in surveying. Cristina, the FERCAP coordinator explained conducting training alongside the survey as 'killing two birds with the same stone', an innovation to 'keep the ball rolling.' 'Whenever we do a survey we train a new group of surveyors, and later on we invite you to join us in some of our trips abroad.' At the dinner of our survey together, Bill told me that his IRB had first been surveyed three years ago.

> We had our renewal two weeks ago. So we're part of the FERCAP family. I do surveys, I've done one in Taiwan, some in Korea and now here. I want to help. That's the spirit of FERCAP. There's give and take. My EC learned a lot from the Surveyors who came.

Bill admitted that finding the time was very difficult, there was a 'lot to balance' and he had responsibilities both at home and work, but he said he would do one a year. FERCAP are very aware that, and I quote from a powerpoint, 'confidence and reliance in the survey process depends on the competence of those conducting the survey.' An excellent SIDCER Surveyor will have:

> excellent human interaction skills, they will be respecting, appreciative and positive. They will have patience and persistence (be stubborn nicely). Active listening. Good memory (along with note taking) System thinking - no assumption, no prompt judgement. Ability to work hard, and long hours. A good team player. The team's ground rules - mutual respect, be objective and observational, share openly and willingly, make it a learning experience, make decision based on evidence and consensus (FERCAP training powerpoint 2009).

International Surveyor

'The rule is that when we survey one country there has to be a foreign surveyor...It depends on their availability, most are medical doctors and find it difficult to join us abroad.' Cristina told me that FERCAP's surveyors are volunteers who have been through two trainings in their own country. They are then invited to be 'local' surveyors or 'foreign' surveyors. Having a 'foreign' surveyor was described as an external quality assurance system: 'It's not *you* saying you are good.' At the opening to a survey in Manila, Cristina explained it to trainees in this way:

> We are from [University], so we say, "We are the best". Do *other* people think you are the best? It has to be validated. So people from outside [University] should audit and check the [University] IRB. So that's the concept and in FERCAP we try and bring in foreign surveyors. We are developing an external quality assurance system, a backup system. We have the rule that the lead surveyor should not come from the same country that is being surveyed. Before we did not even have a local surveyor but now we've accommodated that kind of perspective since we have trained a lot already.

Cristina's phrasing shows us the tension emerging between the auditors' proximity to or distance from the committee under scrutiny. The implicit attribute of the foreign surveyor here is that they are external to the organisation being studied, a (more distant) externality that 'checks'; a view, one that rests on an explicit desire for objectivity. In their introduction to the volume on hospitality Candea and da Col observe that the Chinese language already has terms for precisely

this position: *Keguan*, 'the view from the guest' is used to express the concept of 'objective' or to view things as outsiders would (2012:S6). Sally, a surveyor from Taiwan, considered the Survey an opportunity for committee members to 'get outside of themselves'. 'Maybe people in the IRB are too busy to do a self-audit', she speculated:

> Also, because they are *there*, they cannot see the things that are not correct. They are just in their IRB, they cannot find out what happens, so FERCAP survey maybe helps to find the incorrection [sic].

Simmel's century old discussion of the stranger (1964 [1908]) remains apposite. Candea and da Col note that for Simmel, a visitor organises *within* themselves the 'unity of nearness and remoteness involved in every human relation' (Simmel 1964: 201) (Candea and da Col 2012:S6). The 'organic disconnection' that Simmel uses to describe the social distance is *tied to the distance considered a prerequisite to 'objectivity'*. While I take this linkage up in Chapter 3, for now, I just note that the literal distance that the surveyor has traveled (from her/his country) is tied to the figurative distance, the 'objectivity' so desired for the survey.

The danger of distance, however, is that it reduces the knowledge of the 'local', of the 'complexity of cultural variations, national laws, local medical and research practices and local knowledge' that the fora were set up to accommodate, and SIDCER to unite. Sally considered it an advantage that international surveyors, were 'people from outside the IRB', who 'come with their brand new eyes, have different ideas from different countries and compare to the process in their IRB, and find something.' The other side of that distance, however, was ignorance, an ignorance that could not be seen to overwhelm the advantage lent by their outsider status. Authoritative distance, with the retention of a certain kind of knowledge, was key. Nonetheless, throughout the conversation, Sally stressed that the spirit of the survey had to be one of open-mindedness: 'We want people to feel openminded to do these things not for exam or some kind of very serious audit, that is not the meaning of this site visit.' Dr Sam, whose presentation opened this chapter, framed what Sally had called 'open–mindedness' in the language of culture. He thought arguments made everyone 'grow', and went on to develop a metaphor about FERCAP's role in Asia:

> FERCAP lives in a big house, but sometimes they don't know the other culture is in the other house. Even though the house is big and has everything, [when you are] in [an]other culture you need to change and change your [Survey] regulations, depending on peoples culture. Can't just say everything you're right and other is wrong, it's not the international survey. International survey you say right is right, but FERCAP survey has his regulations. It can be *revised*, depending on your culture. Sometimes, [members of the committee being surveyed] argue with the Surveyors opinion, 'cos the Surveyor is sometimes too considerate about SIDCER Regulations. It's good 'cos all will grow up. FERCAP will become Asia's

> International EC association, cover all of the culture, not just depend on WHO regulations. Sometimes, FERCAP just believes the living room is best and everyone must be the same, but everyone has [their] own house and can go to the living room. The living room is the common regulation, but it is not the only regulation.

Choosing the house as his metaphor, Sam is giving rooms to the countries, and creating the living room as a common space, a metaphoric arena of commonality. It can also be used as a space of compromise. While a person-less objectivity was sought, both Sam's suggestion that the Survey's standards can be revised and Sally's open-mindedness stressed compromise. Though the standards provided an external measure against which the committee was assessed, it became evident to me that the approach FERCAP took with its emphasis on friendship and mutual support meant that few could speak for the standards. 'Is there any answer for this issue,' asked Sally, 'is there a right or wrong?' She offered quorum — the number of people required to be present for a meeting — as an example:

> If they answer quorum is four, and the Survey say it's five, then the IRB is correct, because for them it is four. That kind of thing has a very clear answer. But if the issue is conflict over an idea or culture, for FERCAP it is our opinion, and we just take it out to discuss. It depends then on the IRB.

Here both Sally and Sam are suggesting that the standards are all very well but 'culture' or the 'local' matters. This also contained the potential for excessive externality — where objectivity falls into ignorance and thus to a loss of authority — a danger carefully noted by Surveyors. The lack of knowledge of context which gave objective strength could also be used as a weakness. As Sam put it,

> I believe culture is the most important thing for ethical survey. You can't say 'In Taiwan I'm right'— and use Taiwan thinking and say it is right, if you're in the Philippines. No, you look at what *they* believe is right. That's what is so good about FERCAP, they use the local surveyor and if they say its right, by Philippine regulations, I believe I need to agree with the local surveyor.

But it is all too easy to argue that Surveyors be openminded. Doing open-mindedness is more difficult, and the responsibility for linking the objectivity of the foreign surveyor with the committee's context falls to the Local Surveyor.

Local Surveyor

In her opening of the Survey in Manila above, Cristina calls upon the 'perspective' of a 'local' surveyor; someone to act as an intermediary between the institution being surveyed and the foreign surveyors. Here, 'local' is national, since 'local' surveyors help provide an overview of the 'national context'. As Candea and da Col's collection pointed to the term *keguan,* the view of the guest is countered by *zhuguan*: the subjective view, or the view as host (2012:S6). But it is a criteria of appointment set down by the SOPs of SIDCER that the person who serves as local surveyor 'has no attachment with the EC/IRB to be surveyed' (SIDCER 2005). They are, in Sally's words to

> serve as a resource person, meaning that the local surveyor must be familiar with the local language. The role of the local surveyor is one of great importance to the team, particularly for committees whose documentation is not submitted in English.

Chinese, Taiwanese, Thai and South Korean committees often used their own languages for documentation and while FERCAP regards it as a strength that they do not require committees to translate all of their records into English (a costly and time consuming exercise) the task falls to the local trainees and local surveyor to coordinate and translate the committee's work so that it can be 'seen' by Surveyors.

'It's really difficult being the local surveyor', said Sally 'you are stuck in the middle of the sandwich.' She had taken the role of FERCAP's local surveyor in Taiwan several times, and told me that she had felt a great deal of pressure. The work of translation not only requires a local surveyor to represent the country's national regulations and 'culture', but also has the potential to embroil them in sometimes highly charged representations of the surveyors comments and the IRB's responses. Surveyors from other countries, while "objective" also do not know "enough" about the local context, which some people, such as Sam, think should come first.

Sally had translated protocol documents and books of SOPs for the foreign surveyors, and performed a running translation for IRB members during the closing meeting. The members of the IRB, she told me 'they are very proud of themselves, so they always question, challenge what you say.' As I have suggested, FERCAP's capacity to offer recommendation and critique to committees is both performative and negotiated. The feedback session at the conclusion of the survey is a time of vulnerability for the surveyors, as they make their comments. Some, as we saw, frame critical remarks with reminders of the friendship which is brought in to underpin a

supportive ethos, but Sally also recognised this as a pre-emptive mechanism. 'We come as friends' is stated at the opening of Surveys, she said 'for their safety issue!' 'They make problems with your questions, say you are not an MD, what do you know? Especially if you do not have a PhD, they question more, because maybe they have a high SCI index.' Her comments reveal not only the challenges of asserting authority but also how hierarchies are demonstrated. 'The IRB gets defensive about your comments,' Sally goes on:

> they argue with you, and ask you to explain your reasoning. They want to do it their way, and if you suggest that this could help your IRB become better, they say no, I don't think what you suggest is good.

Sally thought Taiwanese committees, composed of persons of senior standing in institutions, were intimidating, even if individually members are friendly. As she put it, 'people in senior positions are asked to be on EC, and if they think you are criticizing them,' she drew her breath in sharply, 'they don't like it.' Sally generalised her observation for me, saying senior persons were the same 'all across Asia: they all say they are open, but they are not.' She recalled an occasion she had been translating a FERCAP surveyor's feedback on SOPs to a Taiwanese chairperson and the chairperson became agitated. Speaking in Chinese, he had claimed that contrary to the recommendation of a foreign surveyor, the IRB's SOPs were 'perfect.' It had been up to another trainee to translate back to the surveyors the view of the incensed chairperson who was coming close to dismissing the authority of the surveyors to make recommendations to his committee. As Selwyn argues, 'the possibility of rebellion, betrayal, upset and sudden reversals of status, are by definition, always present,' (2000:34) but in standard hospitality set-ups, it is the host whose moral authority must be accepted by the guest. Here it is the guest whose moral authority is being challenged by the host.

These challenges can pose difficulties for the local surveyors, particularly when they are called upon to translate for the lead foreign Surveyors. Walking with Edith, an IRB secretary towards the underground one evening in Taipei, we talked about recent surveys in the country. 'Nobody wanted to do *that* survey,' she said, mentioning a prestigious institution as we waited at a crossing. 'Why not?' I asked her, curious. Shaking her head and waving her hands in front of her she said 'Just avoid! These people are grant decision makers, they are very powerful! So Dr Shang did it.' I asked her why he, over anyone else, was able to do the survey. 'Because he already has enemies, what is a few more?' she told me. The exchange at the time highlighted for me the uncomfortable position that the "local" surveyor has in the survey system, but it also demonstrated the dynamics of ethical review as an inevitably embedded practice. Doctors practice at institutions, serve on

committees, make decisions. All serve on ethics committees *in addition* to another job. Just as ethics committee members worried about turning down the applications of influential colleagues, they worried about taking part in a survey of a grant awarding institution, in case their affiliation with a critical event (whatever its intentions to help) resulted in hurt feelings. 'If there are problems, the chairperson of the surveyed committee will blame you for criticisms made. And people know each other,' Edith said, glancing at me sideways as the lights changed to green. 'Taiwan is very small. If they don't know them directly, if A doesn't know B, they will know someone who knows B.' This was why, she thought, the Taiwanese Department of Health gave very little notice for their own surveys: 'So there is no time to influence anyone.'

For both Sally and Edith, a good survey depended upon the attitudes of both 'sides' — the IRB being surveyed and the surveyors. The IRB had to be 'really openminded and open to all comments' and the surveyors had to 'really understand the IRB and respect their speciality.' Sally was critical of the attitude of those who thought they were already perfect, and saddened by it. She described such people as having 'eyes on top of their heads' (*yǎnjīng cháng zài tóu shàng*), indicating with her hands cupped on top of her own head. 'So you see', she lamented, bending forward at the waist so her 'eyes' pointed at me, 'unless they bow, they cannot see.' Together, the 'local' and 'international' surveyors must find a way of making recommendations not seem like criticisms.

Findings

I began this chapter with the Survey's closing presentation of recommendations to the Committee. This is the point at which Surveyors remind the committee that they have not come 'to *judge*'. 'We're an *approving* survey', they say, 'we come as *friends*!' The emphasis is revealing of existing concerns. One of the local trainee surveyors was filing with me near the end of the survey when the lead Surveyor reminded us that we were not 'fault finding'. 'Sometimes that *is* how it feels,' he confessed,

> it is sometimes thought of that way. Even with good intentions, its hard to appreciate when you're on the other end of it. You're probably doing the best you can, and here comes a group of people trying to find out something wrong.

'Well,' I said, 'the committees do *invite* the survey.' While acknowledging that the Survey was voluntary, he shook his head, gesturing at the lead surveyor who was hunched over his laptop at the head of the table:

> That's why I don't understand why it's an approval or disapproval, if thats the purpose, to be supportive. Why not make recommendations and then return and see if there's been an improvement? Helping, rather than [acting as a] supreme court?

The trainee points to the limits of helping when it is combined with the promise of recognition and the risk of non-recognition. Although improvement is always emphasised, no grade is offered on the committee's work. 'It's not a competition about how is best', said the lead Surveyor to an anxious committee in Manila. The attitudes of both Surveyors and Surveyees changed what the event was, she said:

> It's like if you're a policeman, I'm not going to tell you my weaknesses. I'm going to try and cover everything up! We are not police! If it's a surveyor, they can say, 'I don't know how to do this, what do I do?' and FERCAP suggest. It's a different feeling. Though you want to do better, the person who has come has come to evaluate you. You want to show your best, and sweep the bad stuff under the carpet. But with surveys its about quality improvement. Sometimes they don't tell you, but because we're like family already, I don't feel so bad if you tell me my child is ugly! The surveyors come and say "your baby is ugly", but there's a way to make the baby look nice. Because the surveyor has a plastic surgeon with them!

In this vivid description of transformation, the Surveyor is drawing on the 'family' metaphor explored above to encourage the revelation of 'ugliness' on the part of the hosts, and observation of it on the part of the guests. Relationships between Surveyors and Surveyees have often developed over several years, and the hospitality committees and surveyors show one another serves to 'promote an already established relationship' (Selwyn 2000:19). While sitting with Marisa, who had worked for some time with FERCAP and taken a role in establishing FERCAP surveys and trainings in China, I asked her about what she was missing in order to be taking part. We had been doing a survey for the previous three days, and she was comparing the time she was spending as part of the Survey to her daily occupation. 'It's such a different work environment', she reflected,

> I can give my suggestions, I can be myself. For the first time, I feel free to laugh! In China, the work environment is very hierarchical. You have to hold political relations, even if you think something is right you can't do it, because you're not the one who decides.

Marisa's comment is further confirmation that FERCAP differentiates itself from other models of audit, accreditation and recognition. 'We ask *them* to take charge,' explained Cristina. 'The lead surveyor finds the evidence to support [recommendations]. They take responsibility.' In her published summary of the volunteer program, Cristina writes that

> voluntary participation, relevance and local support are required for sustainability. [...] Trainers and surveyors reduce the cost of conducting FERCAP programs in various

> countries at the same time that it affords the volunteers opportunities to learn from each other and contribute to a common cause (Torres 2010: 50-52).

From a coordinating perspective, this was considered 'grassroots', or 'ownership' of the program, and her role had reduced to become one of 'keeping 'an eye on quality'. Recognising that she could not attend all of the surveys as the demand grew, she told me that it 'increases little by little, and there are the local — national — forums (FERCSL, FERCI, FERCIT etc see p.42). We use these people as surveyors, so they exchange in many different ways.' The language of friendship and family permeates the recognition program: 'You're together for four days, sometimes a week, solving the same problem', said one surveyor. 'Surveys are an *exchange*, of ideas and practice', said another. Cristina writes that FERCAP works:

> to motivate people to volunteer and to contribute their efforts to accomplish the task of developing the capacity of ECs/IRBs [...] FERCAP is about taking responsibility for one another. Our forum is about a friend helping a friend (Torres 2010: 52-53).

Since the end of my fieldwork, the Forum has established a 'Help an IRB' or 'Adopt an IRB' program, calling for volunteer trainers and Surveyors 'to support ethical health research capacity building in Bangladesh, Cambodia, India, Laos, Myanmar, Nepal and Vietnam'. These volunteers (and/or their institutions), write FERCAP, 'are expected to shoulder the cost of their participation' (FERCAP 2012). Let me explore a little more of what they participate in: the technicalities of the SIDCER 'recognition program', the standards upon which the Survey is based, and how these are imagined.

Technical aspects of the Survey

Marisa and I sat at the back of the board room in China, considering the expression on the face of the lead surveyor. She told me the survey were were undertaking wasn't 'as clear as our usual surveys'. Curious about how this compared with her perception of 'usual', I asked 'How so?' 'I think they went for survey too soon', she told me. Tapping the sheaf of documents on her lap, she reminded me: 'They only changed the SOP in February. With their volume, only 10 per year, you don't get the experience, you don't learn how to do a good review'. Learning to conduct a 'good review' came with practice, which in turn came with a committee receiving protocols for review. The committee we were surveying was one of several in a hospital which was the site of limited research, and as such did not see many protocols. If the committee had waited a little, she

thought, it might have better 'evidence' of its capabilities in the form of meeting minutes, archived trials and ongoing files.

If finding means of creating objectivity was the focus of my attention above, here the creation of evidence comes to the fore. The work of Shapin and Schaffer (1985) and Ezrahi (1990) amongst others have shown us a great deal of shared techniques of authority between science and politics, the act of witnessing evidence being central to both. As we saw above, it is in the Lead Surveyor's presentation that a Survey must provide evidence for its recommendations. It is as important for there to be evidence of good practice as it is for there to be evidence of error, to support 'recommendations,' to explain why. During the introductory remarks for a survey in the Philippines, the lead surveyor remarked that the most important thing was to 'find the evidence':

> if we make comments, we need to have some evidence. Otherwise, we prefer not to say it.[...] Everything you find, you write down as evidence. Use your camera to document. It is better to let them see the evidence, otherwise they don't believe it. In the final report, we have to mention everything with the evidence. [We]] cannot make a judgement without evidence.

The day would run on in this way. Photographs were taken of the offending documents - missing signatures on informed consent forms, missing dates on countersignatures. Trainees made diagrams of the committee offices, and leant over the shoulders of secretaries to scrutinize their databases. In the closing meeting, 'evidence' would be gathered together from the teams: 'What protocol number? What page?' Evidence was collected with the final powerpoint in mind,[16] details and references hoarded for each end of day summary meeting, and the ultimate feedback to the committee under scrutiny. Evidence did not simply serve the Surveyor's "safety", however. Take this Surveyor's description of the Survey's approach: 'The approach is going to be evidence based. We survey the EC then we evaluate the ethical practices based on its adherence to and compliance with national and international guidelines.' Borrowing from the corpus of ethical principles that the organisation *teaches*, the organisation is applying to itself and its Survey the same standards for its international operations as it expects for its ethics committees.

Recognition is based on five standards (Figure 13), and the assessment is structured around an evaluation of the quality attained by the committee in relation to each of them. Not only would the Survey be 'evidence based' but its methodology was described as 'just like research

[16] As Miller remarks (2003:61) for the Best Value quality control final meetings he observed, the use of PowerPoint to make final presentations is one of a number of factors that mediate the construction and aesthetics of the final document (Harper 1998; Riles 2001:114-42, see also Tufte 2003).

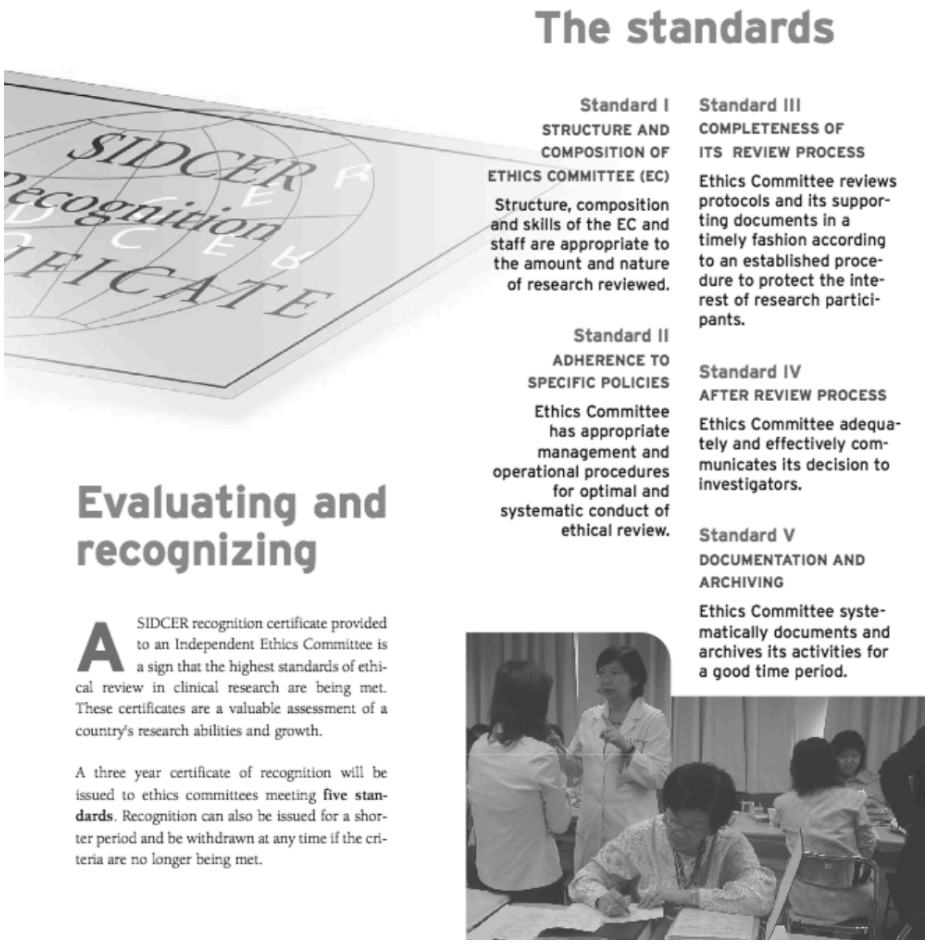


Figure 13: SIDCER Recognition Standards

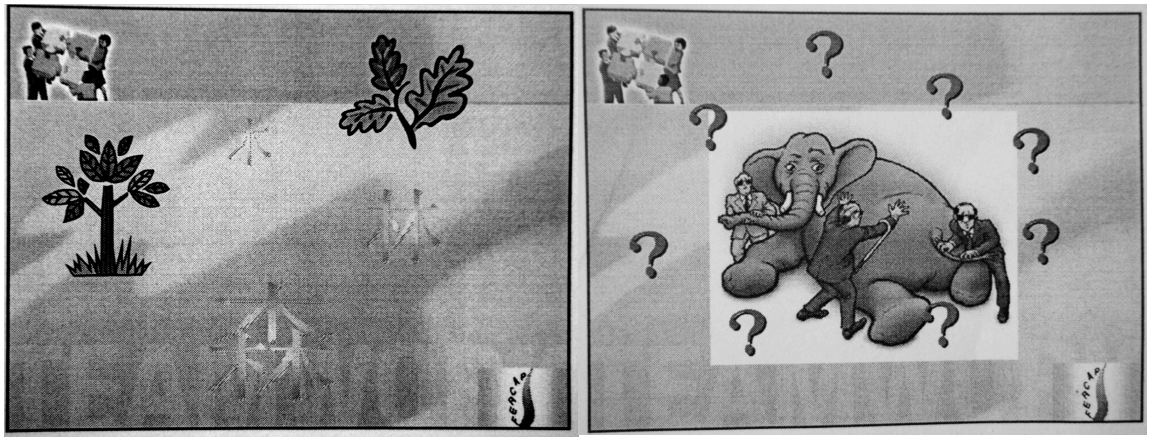
methodology.' At these events, as much as there was evidence based ethics, there was also an ethic of evidence which ran through the survey, and was inculcated into the teams who were auditing.

Evidence was also oriented towards the making of an envisaged committee — positive feedback meant one resembled it, corrections meant deviation. During a break, my co-trainee and I were discussing how much there was to keep in one's mind, even within our own designated area. He pointed at the lead Surveyor. 'She carries it in her head,' he said, meaning (I suggest), not only the knowledge or criteria of the Committee, but an image. What is desired is already known. This is 'not open ended journeying but anticipated destinations' (Strathern 2004: 80). It is 'just like research,' but unlike the testing of a hypothesis, the collection of evidence is oriented towards a model already known. Cristina is attentive to what makes a good Surveyor:

> They need to be observant enough to capture what's important, they should have that sense of what's important. Some people can see very small details but not capture the big picture. [...] Sometimes they are lost in the small details, and don't see what's wrong in the system.

> A social science background helps, seeing the macro-micro relationship, having a systems orientation. If you don't have that background, that perspective, it takes a while.

The ability that Cristina calls a 'macro-micro' view was of most importance in synthesizing findings. End of day meetings brought the teams together, building gradually — in FERCAP's language — towards a full picture of the committee. Late in the afternoon of the first day of the Survey I attended in Beijing, Heijan, an experienced Chinese Surveyor who had served as FERCAP's Research Fellow in Bangkok, described the process of the survey to the trainees. She explained that the team would split, the groups would be given different areas of responsibility to examine in greater depth, and they would report back at the end of the day. One team would look at the protocols, for instance, another at the membership records. The chapters of the committee's Standard Operating Procedures would be divided between the groups for assessment. At the end of each day, the groups would come together and combine their findings in order to make recommendations. Perhaps because the program was newer in China, or because the language barrier was 'thicker', trainers employed two inventive metaphors for this work of synthesis.



Figures 14 and 15: Heijan's Leaf and Elephant slides

The first depicted how the survey would reach its conclusions (Figure 14). Heijan projected a slide with three Chinese characters, 木 [*mù*], in the smallest font, was at the back. 林 [*lín*] was printed medium size in the middle, and 森 [*sēn*], the largest, was positioned at the front. The first, meaning leaf, the second, trees, the third wood, she explained that 'The leaves are the detecting method, the picture of the forest is the analysis - how we draw conclusions and necessary system thinking'.

Her second slide (Figure 15) was an image of a surprised looking cartoon elephant, surrounded by men in suits, all wearing dark glasses. One held a cane over his forearm, and had his arms outstretched over the elephant's rump. Another sat on the elephant's leg, holding the elephants tale with a confused expression. Another gripped its trunk, eyebrows expressing bafflement over his shaded specs. Around the image, eight large yellow question marks.

Heijan warned us that, separated into our teams, none of us could:

> expect to know the whole elephant. Each group is only touching only one part at the end of the day - you [in touching the part you do] don't touch the tail or the head. Try to reconstruct form your observations and reports, what does the EC look like, what are its strengths and weaknesses? How does it do its work?

The image, referenced by Cook, Laidlaw and Mair in the Introduction, is usually used within Buddhist texts and teaching to demonstrate the futility of claims to omniscience. In its use here, blind men we find reinforced the idea of partial perspective. As surveyors, claimed Heijan:

> You will say the elephant looks like this, but you only have a part. But together, you'll be able to describe what the elephant looks like. Different people see different things, they see from different parts. We collect every one's opinion and truth, we put it together, and may get truth of whole thing.

During the coffee break, I took the handout of the slides Heijan, and asked her to tell me more about the stories these slides referenced. The elephant story was about the move 'from seeing all sides to arriving at a balance,' she told me. She framed her explanation by pointing to a clipart image of scales of justice, which adorn many of the circulating powerpoint slides emanating from American literature on risks and benefits. 'You must see risk as well as benefit,' she told me, 'you can't just see risk or will say its all bad, can't just see benefit, and forget the risks.' As I was struggling to process how we had moved from the committee's strengths and weaknesses to risk benefit analysis, Heijan changed tack:

> Teamwork, it's about teamwork for each may not see the whole, so not everyone can be completely right. The teams, bring finally together each part, and you finally get the whole picture. Everyone may not be completely right, but they may not be completely wrong. Based on teamwork, we can get to the truth.

And the leaves? I asked:

> The survey is so detailed! We look for missing signatures, dates, we look for checked boxes. How are we going to gather together everything everyone has learned? We need to make evidence, for system thinking, we won't say, 'The way you review this protocol is not good,' we look at the process, on which *procedure* you need to improve. It's Quality Assurance and Quality Control. The Survey is Quality Assurance, evidence, to give the system for Quality

> Control. The leaves on the tree are the detecting method of the survey, where we get evidence. But the forest is our analysis — how we draw conclusions and use systems thinking.

The story fits with the Lead Surveyor's comment 'you see what you see, I see what I see.' There are two points to notice however, in how Heijan has introduced difference into the combination of perspectives. First, through the concept of balance, she has moved from the *survey's* practices of overview and assessment to those of the *committee:* a risk benefit assessment. The image of perspectives not only comprising the object under study but also holding both it and themselves in balance is one that jumps between the committee's assessment and the assessment of the committee's assessment. Second, she has situated in the person their particular 'difference,' the perspective they hold from their life experience or identity. It is this shift, (or mapping) of the effect of comprehension from a physical to a conceptual difference that I explore in greater depth in Chapter 5. For now, I move to one of the areas the teams are set to look at in detail: Standard Operating Procedures.

Standard Operating Procedures

During a Survey, the teams into which the Surveyors split each take sections of the committees Standard Operating Procedures, SOPs, to examine. Surveyors regularly announce to committees that 'You write what you do and you do what you write. Therefore SOPs should always be an ongoing work rather than a fixed document.'

For an ethics committee to operate without SOPs is considered a 'major' violation of GCP, and has the potential to render research data from sites it overviews invalid. Beat Widler and Allan K Johansen, both of whom have been supportive of FERCAP's work, were employed together for over ten years, working on GCP auditing, training and compliance for Roche. In 2005, they presented joint findings of Roche GCP audits to FERCAP audiences, findings which were later turned into slides to illustrate commonly found 'non-compliance' issues to members (Figure 16).

Cristina's presentation on the role of the IRB/EC in GCP (Figure 17) builds on Wilder and Johansen's findings with the following 'common weaknesses' found during the FERCAP Survey.Common to both is attention to written procedures, although in the time between Widler and Johansen's findings of 'no written procedures' FERCAP had started emphasising to committees the importance of SOPs. SOPs provide a written record of the process, capable of

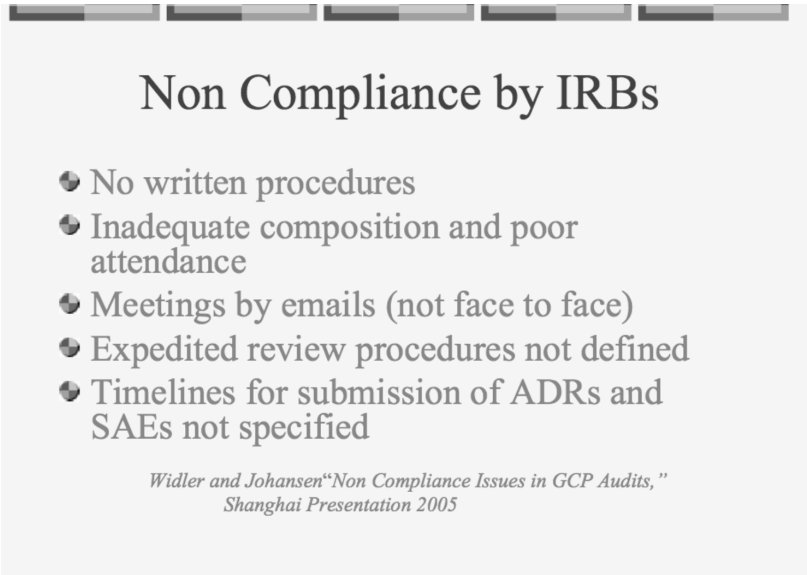


Figure 16

Figure 17

acting both as a *description* of what the committee does and *instruction* for its practice. The SIDCER Survey pays a good deal of attention to how they are written, what they contain, their 'consistency', language and phrasing. Telling me about the attention to SOPs, one surveyor commented that:

> in the old days, a lot of mistakes were made on documentation. But since then, we've had lots of training and SOPs, people are starting to recognise the importance of good documentation. I think we have good models now, people join the survey, and adopt. Modeling is a good method, so it's moving even better.

In 2005, four people[17] created a draft template of SOPs for FERCAP which, surveyors say, has helped improve standards. The template has circulated amongst ethics review committees, been added to, expanded and modified according to national guidelines of the different countries, as well as institutional arrangements. Cristina acknowledges that:

> each ethics committee is unique, even if you copy the SOPs, something different comes out because you have different people, a different hospital. The composition is just like a person — just as each person is different, I have not seen two IRBs the same. I've seen over 50. Every one is different from each other.

Templating and uniqueness exist in tension. In a recent interview with *ClinPower News* — an online website for clinical research the Middle East and North Africa — Widler, whose findings with Roche above informed FERCAP's presentation, comments

> Because I am a strong believer that we should share tools and best practices, in my opinion there's no need that each institution has their own set of SOPs, templates and other elements of a quality management system but should start collaborating and using shared tools. In fact, a clinical trial is a clinical trial, the fundamentals are the same, GCP is the same for everybody and ethics is the same! Then of course you need to have the flexibility to adapt to the local requirements but there are common basics that we should share and pass from one to the other (Widler 2012).

In the 'exchange' of experiences which the network aims to foster, members exchange documents; Widler's vision of shared SOPs is being enacted through FERCAP. After a training session in Bangkok which brought together members of many different committees I spoke with an attendee who had been in conversation with members of a well respected committee. 'They gave us copies of their SOP!' she said. Juntra, SIDCER coordinator, joined in, speaking approvingly of the attendees:

> Circulating their own SOP, that's for me the best thing, they share experiences. I saw your SOP and people think, 'This could help my committee, we don't have that,' and they have to go back and change [their] EC. 'Now that's one we'd never thought of, its a good one.'

In the section below I focus on a meeting in which one of my fellow surveyors in Manila returned to her own committee for the weekend SOP retreat to Balay Indang, an old ginger farm a few hours drive out of the city. She took with her what she had learned on the Survey about what the recognition program requires.

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[17] Francis Crawley, from the European Forum for Good Clinical Practice, Juntra Karbwang of the WHO TDR and SIDCER, Cristina Torres of FERCAP and Sirinart Vasanvathana, Senior Pharmacist in the Office of Food and Drug Administration, Ministry of Public Health, Thailand.

It was four in the afternoon, and the air was cooling down. In a room awash with late afternoon sunlight, we strained to see the projection of the word document on the screen. There were seven women, four men, 5 laptops, and an ethnographer, who sat on a table corner eating the peanuts, taking furious notes. The ethics committee was preparing to 'pull itself up' to the standards that my fellow surveyor and I had seen through our participant observation in a FERCAP survey the previous week. Using her as a reference point ('Do they want this?' 'Yes, they need that'), the committee in Balay Indang revised their SOPs with an almost excruciating attention to detail. Just as we began, I noticed that the woman next to me scrolling through a powerpoint presentation — the 'philosophy of SOP.' 'Is that yours?' I asked her. 'No, no, I got it off the net.' Peering over, I saw that the document was a powerpoint (Figure 18) written by a Dr Bhatt from Mumbai, in 2004. It listed the need for SOPs as a *regulatory* one, tied in to GCP, providing a written record of the process, ensuring compliance with regulations and guidelines, ensuring quality of data, facilitating audit and inspection and (last, though surely not least) assuring global acceptance.

Figure 18: Dr Bhatt's 2004 SOP slide

While FERCAP has provided templates, writing SOPs is still difficult. Half an hour into the meeting, the committee came to a halt in the middle of the projected page, discussion centering around the following sentence:

> A major violation shall results in the ~~suspension~~ possible termination of conduct/approval of research after due process.

The sentence is causing problems because the ethics committee is not sure of what it can do: can it suspend? Should it? The word is struck through, modified to the softer 'possible termination.' Can it actually stop a study? Or can it just withdraw its approval, meaning the study will have to stop anyway? What are the consequences of this action? 'Ethics committee has no power to punish erring researchers. You invalidate the results [of their research] if you withdraw approval,' says someone. 'Suppose it's not fraud, perhaps they made an honest mistake,' says another. The committee's layperson is a lawyer, and he is anxious that 'due process' be written in. The discussion, with different voices differently indented, shows the steps, the possibilities. SOPs are documents of the imagination, and here, in their making, we see that imagination being formed through a theoretical complaint being made about a trial the committee has approved:

We ask them [the investigator] to come in and explain.

But we have to have it [the complaint] in writing

If it's major, then the chair has already suspended [the trial].

No, its not automatic.

This [complaint] can be used agains the PI, [can we really have it that] if anyone just reports, you automatically suspend?

I agree, you do not suspend *just because* - you're assuming guilt before even asking them to explain.

But how can you police that?

Once you've heard their side. If *you* think its major, you'll call an emergency meeting

It's a knee jerk reaction.

It can be used against you [as a researcher].

Which is why I *don't* think it should be written down. We already [did the ethics] review. If higher risk, something going on, you can suspend.

You think the one who calls would want to fill up the form? I don't think we can require it, its like punching them. [...] You make it harder for them to complain.

Can we record the call? Legally, in the future?

You have to think of it that way. We have to have a way even if *we* write it down, he [the complainant] has to sign.

It cannot be just hearsay. It could become a legal case later on. We should protect ourselves also.

You could have the patient review the request and have it witnessed.

Properly documented.

Yes, within a week must sign.

No, a complaint should be valid even if it's a year later.

Yes, but to come within a week once he made the call.

But wouldn't it be unfair to *not* do action because he didn't sign the form, he just called in…

We're not lawyers!

After this exasperated exclamation, there is a pause, during which someone notes that the form they had been planning to use to record complaints has no place for a signature anyway. In describing the process by which they want a complaint to be handled, the committee are forced to think through each stage. 'We've gotta make it simple so we can do it ourselves' they say, 'we can't make it so difficult we ourselves don't understand and [can't explain] when FERCAP interviews you!' As the Balay Indang ethics committee argued into the night, they wrote and edited, wrote and re-edited the document. The clock neared midnight, my note-taking became infrequent. Halfway down a page near the point at which I gave up and went to bed, is recorded the humourous single line: SOP 1.2.1.2.2: If information is deemed insufficient, Chair makes request for additional information.

The slides at the opening of this section show that in the experience of a Pharmaceutical company (Roche) and of FERCAP, committees in the Asian region were struggling with creating SOPs. In its creation of templates and encouragement of sharing, FERCAP has supported committees in the making of their SOPs. On the first day of the Survey in Beijing, for example, the secretary of the committee presented her SOP revision record to the surveyor group:

> Since the Ethics Committee was set up, we have adjusted the SOP four times. The first version was from 2007, October. But when I attended the FERCAP conference in Chiang Mai, I realised some things are not very reasonable, and not very correct. So when I came home, I adjusted the SOP. That was our second version, 2009.10. Then, when I went to Nanjing, I learned a lot, and made a big change to the SOP. That was our third version, 2010.1. Then then I made alterations in preparation for the survey, 2010.03. Each time I edit, it becomes thicker. And now it is very thick, but I say we will do as SOP says, because it will give us more character, and we will be more reasonable as an EC.'

As the Secretary's account and my field-notes from Balay Indang show, the orientation of the committees in their procedure modification is towards the FERCAP Survey. The FERCAP Survey,

in its attention to SOPs, is oriented towards creating committees which are GCP compliant. However, the observer versed in critique of audit practices might observe that at each new point of orientation, the measurements are taken as the goals (Hoskin 1996; Strathern 2003; Macintyre 2000). Standard Operating Procedures are an abstraction of what committees do. As committees are occasionally told, there is no need to re-invent the wheel. I develop the tension between templating and local difference in the next chapter, turning now to the audiences for these achievements.

International Guests and International Hosts

When Leslie spoke to FERCAP about Coast at the 2009 Conference, she noted that the USFDA was committed to checking up on sites conducting trials outside the US territory (see also HHS 2001). She also noted that these check ups would be document based audits. When FERCAP conducts Surveys, Surveyors remind the surveyed committees that while they actually observe a board meeting as part of the SIDCER recognition program, all that an auditor will have to go on is the paperwork. Thus through the promise of the examination of paperwork, concern about documentation grows. Riles (2011:67) reminds us that documents travel across 'cultural boundaries, forms of expertise, institutions, physical distances, by virtue of their material and aesthetic form.' Bhatt's powerpoint and the Thai SOPs are illustrations of the point. For some, FERCAP surveys are a precursor to hosting international research; for some, the hope is that accreditation will attract research to the institution. As Cristina comments:

> [The survey] has an impact on an entire research team. You can put the name on your website. I receive queries from sponsors who ask us if we've visited this EC and if we have recognised them. Sponsors like assurance that EC is doing their job. Thats how we do our work.

What can be said of ethics when it is international guests one hopes to attract? A Bertrand Russell quotation from the concluding slide of a GCP training in Manila gives us a starting point for reflection: 'Ethics is in origin the art of recommending to others the sacrifices required for cooperation with oneself' (Russell (1981 [1917]: 82). A woman a few rows away in the lecture theatre pushed him to comment. 'I was thinking', she said, 'how to interpret it?' The lecturer pushed against the lectern, looking down. 'Um, well the way I see it we are all aware of ethical principles', he began:

> And it really requires a lot of sacrifices. But there is a need for an external body to be able to tell us if what we're doing is ethical or not. Because of the presence of the possibility of
>
> conflicts of interest. That's my thought on that. We know that there are sacrifices that we have to undergo when we are involved in ethics but it has to be recommended by others, or to others. I don' t know if that's what Bertrand Russell meant, but [trails off]

'But why would you consider it a sacrifice to comply?' asked another audience member. 'No' he said, 'its not a sacrifice to comply, its a sacrifice of removing your interests in whatever study you do.' The quote the lecturer chose is, in one reading, a Russell quip. It is a laconic reflection on the selfishness of ethics — of teaching to others the sacrifices they must make so *they* can work with *you* — given your principles, your 'ethics.' In this interpretation, 'ethics' is reduced to self-interest. But in the extract from my field-notes, the lecturer's explanation carries quite another spin. The self is not the requiring self, but the sacrificing self; the sacrifice you make upon the request of an external body. This shift of subject position is revealing, as it neatly reflects the positions of host and sponsor countries in research.

As many researchers are very aware, in order to undertake US sponsored research, the site, investigators and IRB must conform to American specifications. The export of these regulations is exactly — and non-ironically — the requirement of the former interpretation: *you* must do these things so *we* can come to your country. A researcher I interviewed in Sri Lanka had been involved with a research project with Duke University in America. He made some perceptive, and revealing comments on the course he followed in preparation for the project.

> For their IRB, before being researchers we had to follow a course. They sent us the teaching material, [we] read, they asked us questions, we had to mark the correct answers and submit. They sent us all these documents — consent, anonymity, confidentiality, about minors, assent. They covered all areas with documents. We were expected to read through and answer the email questionnaire. What they really want is for us to be educated. They don't want to find out how good I am, they want to educate me on research. I thought that was very good, because before we embarked we knew what is good and wrong. So we would not make the same mistakes. [We] would tarnish whatever institution collaborating with, if we did.

As Cristina's pitch of the SIDCER recognition program to the Cancer Center in China showed (p.26) attracting research is no small part of achieving recognition. The researcher's comments above about 'tarnishing' a collaborating institution added to the sacrificial spin of the lecturer's interpretation of Russell illustrate just the frame in which the desirability of international research mingles with ideas about developing the host through the presence of the guest.

While FERCAP aims towards an equilibrium of a certain standard, tailoring its improvement recommendations towards each committee, some committees are seeking further, 'higher' recognition. In Taiwan FERCAP's success (recognising over 21 committees in six years) left it with a problem. Having been the object of competition between committees, as Edith had explained to me, the question was becoming 'what more can FERCAP provide? Further unique comments?' In interviews, Taiwanese IRB members were concerned that FERCAP might lose its competitive edge to an accrediting organisation called AAHRPP[18], the American Association of Human Research Protection Program, based in the USA. AAHRPP has, in recent years made inroads into the Asian market, accrediting a committee in Singapore, a high-tech post-colony which does not participate in FERCAP's activities, as well as China (1), India (3) and Korea (3).[19] Cristina reported a conversation she had had with Marjorie Speers of AAHRPP in Geneva:

> where she presented her accreditation program. I said our [FERCAP's] approach was developmental and if a group is just starting up we try to help you achieve a level of competence. That is why we call it "recognition " not "accreditation'. Their focus is *institutional* - the human protection program of the institution. So she said we complement each other, we are different. And I suppose we are. But in Asia they think of the US as the gold standard. It's the WHO that's important to us. That is where we derive our… reputation, and some amount of, how to say, some sense of importance.

During my research, AAHRPP had begun to perform accreditation in Taiwan and South Korea. 'In Asia, if one gets [it], others feel pressure to get [it],' commented Desmond, a researcher who served on an IRB in Taiwan. 'Now that almost all the committees in Taiwan have been recognised by FERCAP,' he told me, 'some are trying to shift to AAHRPP. Now *it* has become the gold standard.' From Desmond I got the impression that it wasn't just the fact that one committee in Taiwan had succeeded in getting recognised by AAHRPP, it was the three others, in South Korea. His committee colleague Dana was sure there was an element of competition in the committees seeking accreditation. 'We like competition,' she said:

> It's our culture. Because, if you were independent, and I have AAHRPP or FERCAP and you don't have, people will think your IRB not good enough, so that's the reason why we have to get more and more.

In this quick sentence, Dana has mapped out a logic that I saw repeated again and again in my interviews in Taiwan, which I tried to unpick with the question 'good enough for what?' Dana's reply was 'quality of review.' 'For our thinking, we can say I've got an international recognition, you know I'm an international level.' I pressed her on why she thought this was this important.

[18] Pronounced "A-Harp"

[19] Numbers of accredited institutions per country correct as of September 2012.

'For fame!' she told me. 'If people involved in IRB thing, they all know about FERCAP, if [you] get recognition, they'll think you're so international level quality.' It was not just the opinion of others that mattered, though. Dana explained that when her committee was recognized, she felt a strong sense of pride. 'I know how it feels,' she said,

> If I got FERCAP recognition, it means our IRB is well organized, our procedures are no problem. Just as some institutions proud of AAHRPP put accredit mark on their website — to show themselves they are excellent.

Although she raised them, she felt ambivalent about AAHRPP's 'excellence':

> I think AHRPP is *too* detailed. I don't *know* the details, but because AAHRPP is American, from America, and regulations are not...not really subject to our country. I think FERCAP is OK because they can see the requirements, it's not limited to just some countries, its very basic for procedures and archiving. If you finish FERCAP recognition, you get a whole view of IRB procedures.

Compare Dana's explanation of accreditation with Edith's, as she explains how it is that her committee is 'good.' 'We have two certificates,' Edith tells me 'the international FERCAP on, and one from government. Because we have to follow the local laws and regulations in Taiwan, we need the Taiwan accreditation. And the other we want, the international, so we have got it.' She pauses. 'I know another system', she says. 'It's an accreditation for the US, mostly,' she tells me, 'but they have also done some in Asia: AAHRPP. [Committees] get AAHRPP because they are more strict than FERCAP.' Edith's perception of AAHRPP as 'more strict' lent it status but, like Dana, Edith wasn't entirely sure of how this strictness took form. They had many criteria, like FERCAP; it had to be renewed every three years, like FERCAP; and she knew it followed a similar procedure. Nonetheless, 'getting' it was 'very hard.' Dana expanded on the topic, saying that while hospitals had FERCAP recognition, they were starting to think it 'was not enough.' 'They wanted AAHRPP,' she said. Dana linked AAHRPP's appeal to the existing markers of quality that her committee had attained, and the motivations that had fueled them.

> I think we want to make sure our quality is very good and we want to have a high standard, and reach, and they can teach us more how to improve. It is for continuing improvement. [...] In my way, I think our committee is just the beginning, it is not mature.

Dana's colleague Desmond however, was skeptical of the success that AAHRPP would achieve relative to FERCAP, claiming that despite the appearance that it occupied the same niche, it was a 'different type of thing':

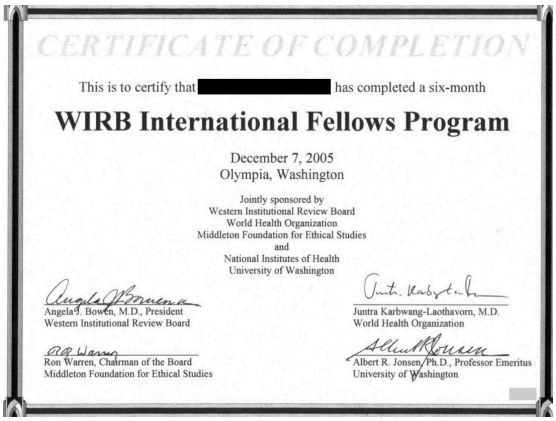
> FERCAP has recognised 50,[20] AAHRPP has recognised 200 in the US territory alone. It wants to jump into the Asian market. You can't apply a US standard though. The money is different, the structure, and the mentality are different. If you want something here you can't use the US standard. FERCAP can operate because it doesn't cost too much. They use rotating volunteers, it's a good strategy. With AAHRPP, it's 'you pay, we send.'

What does Desmond mean when he says the money, the structure and the mentality are different? I listen as he tries to explain. First, the price tag on an AAHRPP evaluation will sway people, he thinks. 'It is more expensive, therefore it must be better,' he tells me. Then its origins in the USA carries cache. Furthermore, it will demand a great deal of work. The survey becomes an audit, in name as well as practice now, encompassing the committee, PIs of projects reviewed, officials of the institution and staff. Desmond thinks interrupting the work of such 'high' people for a foreign audit would be the most difficult task. Then there is the matter of the auditors themselves. 'They don't accept anything no hotel, flight.' His interpretation of such refusals was that — for Americans — it would amount to a conflict of interest. 'They know if come to Asia they will be treat[ed] nice[ly], so they say no hotel, no meal, only cup of coffee. Not a banquet, not a souvenir.' AAHRPP's anticipated refusal to engage socially with the committees appears as the antithesis of the 'mutuality' that FERCAP is trying to foster. Drawing a comparison between FERCAP and AAHRPP, Desmond said that FERCAP was a foundation project, its intention to 'build capacity, help build up from ground zero,' whereas AAHRPP was 'already at the top floor of that skyscraper, and it gives the sign of qualified.' Desmond was critical, arguing that assessment external to the region (not just external to the country or the institution) might raise standards on the surface, but allow practices to suffer: 'Other groups who validate: their mission is to evaluate, and that's it. FERCAP is not about evaluation alone. The intention is to assist and recognise.' The distinction drawn by Desmond between evaluation and recognition here references what Cristina (Torres 2011:50) has called the equity of FERCAP's costings. A shift by more advanced economies to AAHRPP is move that would potentially destabilise FERCAP's financial structure of taking

[20] Correct at the time of Interview, 2012 recognition figures are nearly double that.

(donations) from the rich and giving (help) to the poor, since it was those who could pay who showed interest in migrating.[21]

AAHRPP is not the only means by which American standards, accreditation and systems were spread amongst the people I worked with. Several observed that it was 'American money' that had made them capable of doing the jobs that they do through funding six month trainings at Western IRB (WIRB) in Olympia, Washington (Figures 19 and 20).


CERTIFICATE OF COMPLETION

This is to certify that [redacted] has completed a six-month

WIRB International Fellows Program

December 7, 2005
Olympia, Washington

Jointly sponsored by
Western Institutional Review Board
World Health Organization
Middleton Foundation for Ethical Studies
and
National Institutes of Health
University of Washington

Angela J. Bowen, M.D., President
Western Institutional Review Board

Juntra Karbwang-Laothavorn, M.D.
World Health Organization

Ron Warren, Chairman of the Board
Middleton Foundation for Ethical Studies

Albert R. Jonsen, Ph.D., Professor Emeritus
University of Washington

Figures 19 and 20: A certificate awarded to an International Fellow and a summary of the WIRB program

'American money is here', commented one secretary, pointing to herself. Though the 'centre' is geographically east of most of the countries who look to it, Western is the name it takes for its location on American's West coast. Its name also has the effect of carrying with it the conceptual orientation towards 'the West'. Dana and Edith were not the only secretaries I met who had received training at WIRB (Figure 19). Cassandra, who had been to WIRB for an international fellowship keeps a photograph of her group of international fellows on her desk at work in her

[21] It is also possible that some institutions may 'leapfrog' FERCAP and move straight to AAHRPP. AAHRPP accredited its seventh institution in Asia, Jehangir Clinical Development Center, in Pune, India in September 2012. AAHRPP stated that

> the accreditations are the latest indication that organizations are embracing AAHRPP's goal of one set of standards worldwide — for CROs, independent institutional review boards, research-intensive universities, medical colleges, hospitals, and other entities engaged in research involving human participants. To attain AAHRPP accreditation JCDC had to show compliance with both India's requirements for research protections and U.S. regulations [...] JCDC CEO Pathik Divate [said] "We viewed AAHRPP accreditation as the logical step to take our program to the next level—for research participation, standardization and quality. We've also sent a message to the rest of the research institutes [...] If they're serious about clinical research, they should be thinking about AAHRPP accreditation (AAHRPP 2012).

IRB office. When I asked her about the experience, she explained that WIRB was a 'well established, well organised major company', whose job was to review human subject research. Through the Fellows program she felt it was making a contribution to training Asian ethics committees, helping them 'learn the best knowledge of IRB'. She told me that people sent there can:

> get the knowledge. When they come back, they can modify it, use the base of the knowledge to give suggestions or comments to the policy makers...They don't want to influence our - they will not - they, when we were in Olympia, they encourage us, they say 'This is only for USA,' maybe not subject to your country.

Cristina had also trained at WIRB and knew the US regulations,

> I say I learned these things, but I see it from another perspective...The US regulations are not international regulations. That's why when I make a presentation I give GCP, Helsinki, and also say this is the practice in the US.

Surveys often exposed the limits of adopting American standards. At the close of a Survey in China, surveyors were making recommendations on how the committee determined whether to classify an application as exempt from review. The survey had found a study involving genetic material which had been classified as exempt by the process the ethics committee currently had in place. The surveyors were concerned. 'It is the job of the ethics committee to determine whether there is a [genetic] identifier or not. Exempt means you do not do the review!' When the committee replied that it was something they had adopted as a result of their secretary's time in America, the surveyor became annoyed.

> That's something they exempt in the US, we do not exempt in our setting. They don't get information from China and use it in the US. So don't adopt OHRP,[22] that's for the American population.

The lead surveyor stepped in to explain:

> It's because [Americans] have more regulations, they can control these things. They are automatically controlled by other mechanisms, especially HIPAA[23]. The US have an infrastructure to support and catch other things. They fall into other jurisdictions.

The irate surveyor interjected 'Records are covered by HIPAA law. HIPAA protects you. Do you have HIPAA? No!' The lead surveyor smoothed once again: 'Some of them [USA regulations] don't apply because there is a different infrastructure. So you have to think about *your* ethics committee, in that case.'

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[22] Office for Human Research Protections, Department of Health and Human Services, USA.

[23] Health Insurance Portability and Accountability Act, (United States Congress 1996).

Concluding remarks

Shyrock (2008) points out '[h]ospitality is always partially unseen. As a social performance, many of its most important elements are time delayed or acted out elsewhere' (2008:59). His comment builds upon Pitt Rivers' study, which observes that

> While a host has rights and obligations in regard to his guest, the guest [...] incurs [...] the right and obligation to return hospitality on a future occasion on territory where he can claim authority. The reciprocity between host and guest is thus transposed to a *temporal sequence and a spatial alteration in which the roles are reversed* (2012[1963]: 514-515, emphasis added)

The Survey is not only a form of standardisation that links locations across space: in time, as with Pitt Rivers' observation, the roles are reversed. Surveyors — who themselves come from ethics committees — will be surveyed. Those being surveyed have the chance to learn to be surveyors. 'They're surveyor in one place, surveyee in another. You'll be surveyed yourself. The surveyor will come from somewhere, some other country,' explained Juntra. Unlike the reversal in Pitt Rivers' study above however, hospitality on one's own territory does not come with a claim to authority. Pitt Rivers observes that '[h]ost and guest can at no point *within the context of a single occasion* be allowed to be equal, since equality invites rivalry. Therefore their reciprocity resides, not in an identity, but in an alteration of roles. (1963: 21). This forms a mutual interdependence, described as a 'self-sustaining model' because the groups relied upon one another to 'keep the standard' of the recognition program. The annual Conference was 'like a reunion of family' because, over the year, delegates have been working together, 'visiting one country, visiting another.' To Juntra, since all the surveyors had been 'talking about the same goal that each one contributes to', 'instead of competing or being jealous, because of exchanging, people are accountable to one another.' This 'accountability' led to a common interest in the quality of the recognition program, so that the standards would not fall, and the value of the recognition would be maintained:

> The recognised people say we need to keep up with quality - if one of us jeopardizes it....so they're looking after themselves. They talk to each other and suggest ways to improve. This model is very good.

Juntra's description of her *intended* outcome — that it creates a self sustaining system made up of equally invested partners in a dance of reversing places. In this, the survey program itself is at stake. If mutual investment in the quality of the recognition program leads to a mutual monitoring, there is also the question of what and whose standards are to have the final say. In the making-equal of surveyors and surveyees through the language of friendship, the edge of

authority of Surveyors diminishes. The threat of non-accreditation remains, of course, but the atmosphere meant that the surveyees were very willing to question and engage the surveyors in discussion about their 'findings.' Nonetheless the influence of American priorities is clearly felt:

> It's about power, influence. The NIH you see is funding research. WHO, maybe their presence is not as much. [We] see lots of US projects. WHO is seen as more humanitarian, not affiliated to one country. This one [US] there's pressure for you to comply because you're receiving money. The Americans also feel that their standards are the best.

Interest in becoming hosts to American research means there is also interest in being recognised by American standards. What FERCAP's approach to standard making through mutuality shows up is the difference they perceive between their hospitality based survey and the attempts of other recognition programs to break into the Asian market. As Selwyn writes, 'the rules and principles of hospitality stand at one remove from the principles and procedures of the market place,' reminding us that both Mauss and Malinowski warned against interpreting the meaning of gift exchange in terms of trade (Selwyn 2000:35). I have shown how FERCAP differentiates itself, places itself 'at one remove' from audit models based solely on evaluation and the marketplaces of both committee accreditation and trial attraction. I suggest that the framing their program of mutuality through hospitality helps illustrate this difference more clearly.

Foregrounding the hospitality of the Survey has also allowed me to demonstrate what Candea and da Col (2012: S14) refer to as a scale-shift through reference to Herzfeld's observation of an:

> essential homology between several levels of collective identity - village, ethnic group, district, nation. What goes for the family home also goes, at least by metaphorical extension, for the national territory (Herzfeld 1987:76).

Homology here is more than metaphorical extension: surveyors applying the principle of gender balance as 'ethics', for example, want to see equal numbers of men and women both as Surveyors *and* as committee members. In the material above, like hospitality, objectivity appears to shift scale, applied to the committee meeting and to the Survey. The Survey, aware of its politics, borrows from the familiar scientific language of its participants the tool of objectivity. Through combining the views of each of the Surveyors into the corporate person of Dr Sam, and by amassing the 'evidence' that will be used to support the recommendations, objectivity emerges as a social strategy, to neutralize the dangerous tensions of critique. As Candea points out, 'points of tension in practice coalesce around scale-shifts: when an individual's action is taken to be representative of an entire group, or, conversely, when an entire group is seen to act against a single individual' (2012: S46). Here I have shown how the emphasis on evidence deflects from the

possible insult of judgement. But in its familiar of evidence and through its mimicry of science, perceived as 'good' it leads to surveyors focusing on that which can be evidenced. This in turn encourages committees to regard evidence for decisions as essential. What is interesting about this instance of hospitality is that it is employed in a form of governance. How people handle the potential for critique causing insult is central to the next two chapters.

Chapter 3: The Rooms of Ethics

Shapin and Schaffer claim that in the English 1600s the question,'Where can I find a natural philosopher at work?' would have had no single reply (1985:333). The creation of a 'special professional space', at least to one of their book's protagonists, Hobbes, was a 'threa[t to] the public status of philosophy' (1985: 333). In this chapter, I show how a room assigned to an ethics committee is not just an anonymous office but is given meaning by the staff who work there, the committees who convene there and the Surveyors who visit.[24] For the ethics work of FERCAP, however, the creation of a 'special professional space' is a criterion upon which the enterprise of a systematised ethics rests. To draw out the importance of a room let me first recount an encounter with a committee *without* a room.

The first ethics committee meeting I saw when I arrived in Sri Lanka in early 2009 was being held in the Medical Faculty in Colombo and I saw it entirely by chance. Thirsty, and hoping to fill my water bottle before leaving the faculty, my colleague and I had stepped into the Senior Common Room in search of a water cooler. It was mid-afternoon, and the water of the monsoon rainstorm was pouring down the windows. 'Looks like an ethics committee,' I joked to her quietly, as we crossed the room across from a table piled high with paperwork, around which a dozen or so people were sitting. It *was* a joke, because less than two weeks into fieldwork, I was still very much focused on finding and getting access to these committees. I had no reason to imagine I might literally walk in on a meeting. Yet as I stood, filling the bottle facing away from the table, murmurs of the 'benefits to Sri Lanka', and talk of 'risk' drifted across the room. 'You know, I think it actually is!' whispered my colleague, having turned to face the deliberators at the table: 'Here they all are.' She had started research in the country over a year beforehand, and recognised faces I too would soon come to know. I filled the bottle slowly, wishing I could stay, but unnerved enough to leave, knowing that my own ethics application for research had been reviewed by that same committee in same manner it was now reviewing another just a few meters away.

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[24] Sometimes, as in the example above, offices are connected to the boardrooms where deliberations happen. More often, the office designated for ethics committee work is separate from an institution's boardroom which is used for the committee meeting. I pay attention to both spaces - as the survey does in its observation of both the office, and the ethics committee meeting.

That the committee were meeting in a common room which, while partially restricted by being 'senior' was still open, had little meaning for me at the time. In an interview a few weeks later, during a discussion about capacity building, the first hints of a link between the 'where' of ethics — its physical institutionalisation — and its social robustness began to emerge. The term 'grounding' might be useful in two senses here: both as a physical grounding in a room, and the grounding that an individual conversant in a field of knowledge. My interviewee, Dr Suraj, was the chair of a department at the same medical faculty. He been involved in establishing 'ethics' in the University, and was adamant that unless 'local people have capacity to train others, institutions will not develop.' We were talking about research ethics, and its presence in Sri Lanka. He drew his examples from histories of his own department:

> Psychiatry was not a department in the 1970s. It was one person. Now, there are six. It is a separate subject in the undergraduate curriculum, people can get interested in it. It is like this local knowledge can develop. For example, there were all these dams built. One by the British, the French, the Dutch, all of them said, 'We'll come in and do capacity building, we'll teach you how to do it yourselves, so Sri Lankans can do it.' That never happened.

His examples were a way of talking about how research ethics as a set of knowledges was being introduced:

> Something happens in the UK or the US, someone gives a lecture, comes, goes away. That is useless. It is not of help to Sri Lanka. We need a group of people here, developing knowledge, discussion. Without indigenous institutions as the knowledge base, no subject will live.

Dr Suraj then proceeded to 'ground' a knowledge of ethics, and the potential for ethical thought, in all people. At the same time, he traced the 'grounding,' or institutionalisation of ethics within the physical buildings of the university:

> *Suraj*: People feel ethics is exotic, it has experts. I don't believe in that. If you really look at ethics in the world, it's in every field. In medical schools, it is the case that in almost all of the classes the teacher knows more than the students. But that is not true in ethics - in ethics, both are equal. It is just that the student is not sensitized, they haven't developed an analytical rational expertise.
>
> *RDJ*: How might they do that?
>
> *Suraj*: It is a value system. You must value ethics as important. And then you are interested in it and learn. So it was a 'sensitisation process', people realising that ethics is related to clinical work and to policy. We started talking about equity systems, and public health, organised in different ways. This lasted five or six years. Lots of people were exposed. Ethics became something not alien, exotic, something to do with day to day work. At that time they had no guidelines, institution, workshop. So I got the WHO funding, books computers, training programs. I got that room.

RDJ: Can I ask you why that is important?

Suraj: Otherwise it is person, there is not a system. The ERC, I recruited them, but unless we have commitment to the development of ethics….[shrugs]

Leaving the offices where we had talked, I stopped by the room he had mentioned. The tall wooden door bore a small printed sheet reading 'Ethics Committee Room,' and though the glass was dusty, through it I could see a pair of interconnected rooms. Paint peeled from the walls and wooden furniture was piled up against one of the windows. It was a site of disarray. When I asked around about the room, I was told that progress on its restoration was slow going, funds were difficult to find. The suggestion was that some of the barriers to financing the room were also barriers to the formalisation of ethics, but that with dedication it 'would happen', indeed, had to happen, in order for the committee to be surveyed by FERCAP.

This all happened during my first stay in Sri Lanka. By the time I returned, just over six months later, the room had transformed. The space had been cleared, freshly painted and a new floor laid. It was filled with new furniture and equipment, chosen with the recent Survey in mind. On arrival, I went to find Madhubashini, one of the secretaries I knew, only to discover her in her new office, overhead fans whirring, brand new filing cabinets lined up behind the desks. Another secretary had been recruited to join her, and we talked about their experiences of the FERCAP survey. As I went to peer into the adjoining room, to which Madhubashini had just delivered some 'short eats' from the canteen, she blocked me with her body. 'Confidential meeting,' she said.

For Suraj, the room was a change in the status and permanence of ethics in the institution. Unlike the people who carried the knowledge of ethics, who could leave, the room could be a container for that knowledge; it would remain. Anthropologists have long paid attention to the relationship between the arrangement of persons in space and the conceptual work that those spaces are made to do. We can recall Wagner's diagram of the inversions in a Usen Barok *Kaba* mortuary feast (2001: 34-47), Mitchell's Foucaldian treatment of the disciplined and disciplining spaces of colonial Egyptian schools (1988: 78-79) or Humphrey's analysis of a Mongolian hut with its male and female domains (1974:26). In this chapter, I attempt a related approach to committee rooms, the physical arrangement of space and the conceptual and social relationships therein. In opening with Shapin and Schaffer's work, a study that tracks the 'nascent laboratory' of Boyle (1985: 334), I am making a case that there is something akin to the 'laboratization' of ethical review processes. The room is at once a template *and* a unique space in an institution or hospital, and the Survey assesses both. In the language of capacity building, the space of the room is both a

marker of capacity and a capacity in itself, indicative of a change in the relationship between those who championed it and their institution. But I would like to suggest that there is more to be gained from the analysis of a physical room. As the chapter proceeds, I embark on an analysis of what happens inside the confines of the room, taking first the discussion of its physical boundaries during a Survey. Through this, we become aware of the room's edges — how the discussions of people within it reference the world outside of it — and how what happens within it is translated for that outside. This translation I consider through the art of minute taking, the innovation of 'realtime minutes' and the visibility they offer both during the meeting and for future audits. Visibility is, however, of concern to some committees when it comes to making a decision. I detail decision-making devices, real and ideal, as committee members struggle with voting and consensus. Issues of visibility and concealment which link these three vignettes are brought to the fore in my closing discussion of Conflict of Interest, in which the invisibility of the relations that committee members may have (relations configured as interests) leaves the FERCAP trainers and committee members anxious.

Room: for improvement

> FERCAP is for improvement of IRBs, not pass or fail. If the IRB level is like this [holds hands waist height] we encourage them to improve like this [lifts hands above head]. If the IRB is like this [high hand] we encourage… There is *still* room for improvement. For example, if you do not have a separate room, you cannot be…[trails off]
>
> Trainer at Survey Training 2010

Cannot be what? The trainer left his sentence hanging, communicating into the silence a sense of inadequacy through the absence of words. His comment occurred during a re-survey of a committee in Manila, at which the committee's office became a hotly debated topic. I joined the surveyors on their trips into the office, accompanying not only my own team (we were set to work on reviewing protocols) but also the other teams as they examined the room. We received strict instructions before the tour:

> When you visit the office, everyone will check. Use your eyes. They should separate the active and closed files. That's the purpose of archiving. The flow of the office and the job of the office staff: do they have a job description? Do the staff know what to do? If there's only one office, maybe there is no confidential issue on [the staff]. If there is more than one [staff], who takes care of the lock and the key, who receives documents, who knows the

> password, who communicates with the PI? In the office, you can take a protocol at random and then you check whether it is complete or not.

The visit would be a test by questions, visual examination, expectation: a checklist, distributed to the surveyors as part of their pack, guided questions as the groups entered the room. The ethics committee office in this Philippine institute was along a main corridor, and clearly labelled with a sign that hung out into the hall perpendicular to the wall. 'Institutional Review Board,' it read. We checked off the first box: 'Is the location appropriate'? Was there an organogram on the wall? Yes. We were shown the technology: a fax machine and phone, a shredder, a photocopier and a printer. The surveyors photographed these for use as evidence in the summary powerpoint (Figure 21)

Figure 21: Slide from closing powerpoint, evidencing the presence of the committee's technology.

The biggest problem on this survey in Manila was access to the room, and the things in it. Let us first deal, as the surveyors did, with the things in it. There are two highly sensitive areas in the office, the filing cabinet and the computer. What is sensitive is not these containers, or their value in themselves (nobody seems too worried about the computer being stolen) but what is *within* them, namely research protocols and the EC's database of files. A surveyor asked after the seal of the IRB, the mark of an authentic review which is stamped on approved documents. The secretary explained she keeps it locked up, in a drawer. The security of these items is carefully guarded, and in a similar way, the space is too. I had signed a confidentiality agreement in order to be inside the room, because according to the secretary taking my signature, we would 'see some very

confidential things.' I asked her whether research proposals were 'confidential,' and she replied 'Yes!' in a tone that implied 'of course!': 'You might be working on something very new, or be in competition.' The secretary unlocked the door and let us in. As she did so, a surveyor asked her who else had the keys, and how many people had the password to the computer. She replied that she was the only one, implying that this was good — the room was secure. However, another surveyor was not so sure: 'I'm not happy with just one girl having the keys, what if something happens to her?' The lead surveyor shared his thoughts with me: 'In Taiwan,' he said, 'we're crazy for IRB. You have to sign your name if you visit, that is what they do in the US.' I asked him why. 'Maybe you'll steal,' he said, seriously. I pointed out that in most cases, and on the recommendation of the Survey, files are locked in cabinets. 'But we need to control people going into the office,' he replied, gesturing to the door.

The main door to this Manila office opened onto the corridor. While the room, then, had its own door, which could be locked, it was partitioned off from a larger room with a five foot wall, in which there was another door. This second door, and the partition caused comment:

> There should be a wall there! This is a confidential space, [it should have] only one door, not two. Someone could jump over the dividing wall, or get through the door from the other side!

The wall became a matter for a discussion when the groups came together at the end of day summary meeting. One group of surveyors (I will call them 'A') thought the partition ought to be made higher, 'because you can reach over'. Others ('B') disagreed, arguing that the secretaries of the EC were sharing a photocopier with the office next door, and the door in the partition was convenient for them.

A member of Group A said: 'So she has to go out and round. We say "limit the access to IRB office from other staff'." This was a direction to the person compiling recommendations in a powerpoint. She in turn paused on the bullet beneath, which to follow the layout, needed to be filled in with a reason for the recommendation: 'If you are a mix of other people you cannot keep confidentiality,' the person from Group A continued: 'That's why we want a separate building and independent structure.' Addressing the typist at the powerpoint he instructed her to write: 'Partition should be higher.' At this point the secretary of the committee being surveyed called out, as she was delivering documents to the usually closed end-of-day meeting. 'But we only have one air-con!', she said, 'if you make it higher it won't get through.' The possibility of 'reaching' over the wall then turned into 'jumping,' and the familiar secretaries next door became altogether more sinister: 'In that office before, researchers actually came in at night and looked for their

protocol.' Group B protested. They had been shown by the petite female staff in the neighbouring office that the partition was far too high for them to reach over. With this, the matter was closed for the evening.

On the second night of the Survey, the partition came up again, because of new findings from Group B. One of group B's members had spoken to the secretaries, who felt it would be difficult for them to comply with a raised partition or a wall. Raising the partition might be possible, they said, on the condition that the new, higher section was *transparent*. The secretaries' spokesperson told the teams this was 'because they only have one boss. They need visual access, so the boss can see if they're sleeping!' The following exchange then took place:

> A1: No, it should be closed completely.
>
> B: So there's only one door? You want that?
>
> A1: Depends who will be on the other side.
>
> A2: I say close the door permanently. They can go out the real door. The entrance to the ERC should be separate.
>
> B: How can they close [the door] permanently?
>
> A2: Throw away the key! It's up to them to think how they can implement it. Before recognition, [we'll] ask them to take photos. They should send evidence for us to see they've revised it. Maybe that wall - I will ask for a picture that they made it higher.

When, on the final day, the lead surveyor had finished his presentation, including the recommendation that the partition should be raised by *ten inches*, the ethics committee members were given the opportunity to ask questions about the recommendations. One of the secretaries asked why it was recommended that *ten inches* be added to the partition. 'Please explain the rationale,' she said.

A surveyor replied:

> It is better to have isolated, secluded space where no other irrelevant people can have access. Now you have two doors but the other side office has access. It depends on the composition of people in the other room. The partition is to restrict access, so there should only be one door. We think it is reasonable to keep the confidentiality of the room. In other IRBs if they share office space, they have to have mechanisms to keep the confidentiality of those people.

The chair then spoke on behalf of the committee.

> Our building is overflowing with people and offices. There is no space for an *exclusive* IRB office. If we had a higher partition, someone can just climb back. We thought putting files under lock and key would suffice. The IRB is competing with other offices for desired

> space, we're bursting. It's difficult to say it can be done. There is also a leak which has been unresolved for a year.

The surveyors answered:

> But the recommendation is not asking for *more* space! We know your constraints. The only recommendation is to make it more secure. Make the partition higher and correctly close the door.

The disagreement I have recounted here speaks to the physical and symbolic segregation of ethics, not merely the claiming of space but the achievement of closing it and making it confidential. It was a repeated concern across Surveys I took part in: a separate room was preferable, but where space simply wasn't available other measures were necessary. In one instance, a Survey coordinator announced to a hospital considering seeking recognition that they did need 'something that separates, a door you can enter. You cannot have science and ethics together, there has to be a marked division.' The outward appearance, and visibility of the room was also important: 'This is the EC? But it's called Science Research Admin!'

A common worry was the permanence of rooms acquired by ethics committees, and conversations often circled around a room's limits. Archiving and the anticipation of future audits meant that space for the continually accumulating files and documents would always be in demand. Several offices I visited in Taiwan were described to me as 'temporary'. Sitting with interviewees in the hallway outside one of these, I watched as they staked out what they would do, given sufficient budget: walking along imaginary new walls, encompassing the hallway and bay window into a new imagined archive area, claiming space. They drew up a new area with a table and a chairs for sitting and 'educating' PIs. The existence of room is a marker of having convinced the administration that ethics requires its own space, and the university that a committee needs financial support: the imaginary room that they drew up for me speaks of the expansion of ethics through its physical archives, but also its ambition to draw researchers into it.

The standardisation of procedures and practices is well documented (Brunsson and Jacobsson 2000, Dunn 2005) but this is another access point: standardisation of a space as part of disciplining practice. This version of reproducibility is a carefully worked out standard, inscribed in the Surveyor's checklists and in the weight of its arguments during the course of the four day visit. If knowledge of ethics committees travels through the survey, it finds its resting points in the rooms. What the 'wall' example illustrates is the tension inherent to the objective of the survey: a standardised room which takes in its context. The Surveyors are trying to make a room that can be context independent, while at the same time also trying to take in context dependency.

Minutes

As the Survey demonstrated, in this world evidencing activity is as important as the activity itself. 'If it isn't written down, it didn't happen,' surveyors say.[25] FERCAP Surveyors go inside the Committee Room during a a committee meeting as part of the Survey, usually sitting around the edges of the room looking over the shoulders of the committee members (Figure 22).

Figure 22: Surveyors observing a committee meeting, on tables surrounding the committee .

They warn, however, that this is not standard practice amongst auditors from trial sponsors or the US FDA. If a committee is audited, the minutes will be the only record of meetings, 'So it is important that [the minutes] capture what went on,' committees are told. Under such

[25] An almost identical phrasing was used by the Contract Research Organisation Monitor working on the trial documented by Simpson and Sariola (2012): 'Things that were not normally documented had to be recorded according to the dictum: "not documented = not done." In his view, if test results, examinations, the minutest of adverse reactions and observations were not recorded in writing, dated and signed, it would be the same as if they had never happened.

circumstances, documentation of deliberation is taken as indicative of whether the committee is compliant with GCP. As one Surveyor explained it:

> when they audit, they look at the minutes. Are there missing things there? How did they arrive at decision? So is not just he/she said, its what you should do. Take notes, mark discussion points. Decisions should be based on discussion points. That is the expectation from the ethics committee. An ethics committee that works without minutes is not GCP compliant.

The accuracy of minutes can cause problems during a committee's first Survey. 'Unlike other areas,' said a secretary from the Philippines, 'where you can look at international guidelines, Helsinki, CIOMS, there is not a guideline for minutes.'

During fieldwork, I noticed that some committee meeting minutes were being taken using a laptop, projected onto a screen at the opposite end to the chairperson. This practice was known as 'realtime minutes,' and FERCAP encouraged it on the dual grounds of efficiency and accuracy. 'Everyone will be able to see,' said one committee member. 'Nowadays', said another, 'due to improvements in technology we can do a draft on the spot so members can already see what will be in the minutes. At the end of the discussion, we ask people if we missed anything.'[26] A concession was made for languages where it is difficult to type fast enough to 'capture' the discussion. In such circumstances, minutes would be typed up using a recording and circulated to the committee members by email, the 'old fashioned way'. Accuracy was cast not only in terms of committee members seeing whether their comments had been recorded, but also in terms of

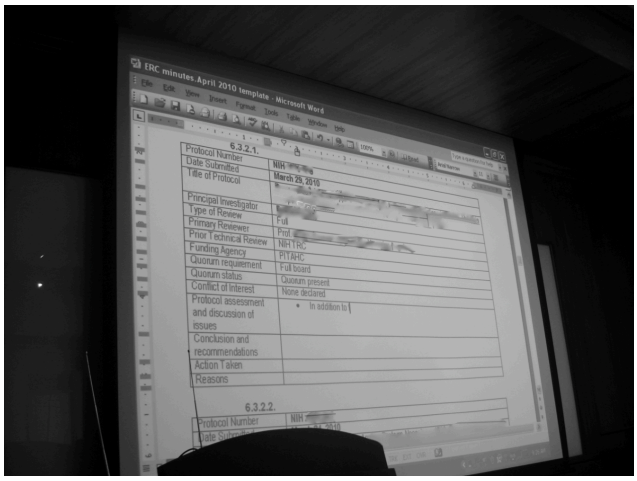

Figure 23: Minutes template

[26] This did not always meet with the intended success. As one Surveyor remarked of a Full Board meeting we observed, '[The layperson] asked, does using these [contraceptive] pills lead to cancer? And instead of cancer, the secretary wrote abortion!' Nobody on the committee noticed, but the Surveyors did.

accuracy in discussion could be ensured by having the themes it would be important to minute already templated. Minutes templates are prepared, waiting to be filled in with discussion: 'then nothing will be forgotten.'

FERCAP facilitated the 'travel' of this method through trainings. In 2009, the pre-Conference workshop in Chiang Mai, Thailand a secretary from the Philippines had created a sample agenda, to guide minute making (Figure 23). She displayed an anonymized sample document which listed categories such as technical issues, elements of design, ethical issues, assessment of issues, further questions, and required modifications. This was considered easy to generate, 'all my staff do it now,' she said. It is a way, she noted 'in the future, even if I'm not a member of the IRB anymore, to check what happened'.

In her work, Stark suggests an 'anticipatory perspective' in the study of documentation, arguing from her study of American IRBs that

> board members' sense of how the minutes of their current discussion would be written served as a social resource that they used to manage relationships - between each other and between themselves and researchers (2011a:252).

She suggests that 'unwritten minutes [...] steered the course of deliberation as it was still underway' (2002:252). My findings here support her argument. It is clear that committees are aware of the possible future uses to which minutes of meetings may be put, even if the 'anticipatory perspective' they exhibit is largely in anticipation of needing to anticipate.[27] But with the creation of realtime minutes, rather than focusing on the deliberations of members and how they put their arguments across, I want to look at those who write the minutes during the meeting.

The creation of minutes is the work of the staff-secretary. The etymology of the word, with its roots in secret keeping, is particularly apt for the way Fiona and Karen, secretaries in the Philippines describe their work.[28] When I joined the survey of their committee, Fiona was just handing over to Karen. During our interview, Karen she was laughing when she told me how difficult she'd found it to write the minutes. 'It was a disaster!' she exclaimed:

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[27] According to the Code of Federal Relations (21 CFR §56.115a(1) and (2), the US FDA require, complete documentation. Deficiencies in record keeping can result in warnings, for example the Warning Letter issued to Teneo IRB (US FDA 2009), but as I have noted, the USFDA do not yet look at committees outside the USA.

[28] Shapin and Schaffer note that the word 'laboratory' arrived in English usage in the seventeenth century, carrying with it apparently hermetical overtones: the space so designated was private, inhabited by secretists (1985:335).

> I did not know what to write! I had to keep copying Fi's notes. I had to write it down, so no notes were missing, but I couldn't listen to them speak. I still get so *mesmerised* at how well they speak. At first, I couldn't follow the thoughts. At the first meeting, the speakers were speaking, one would say something, one would clarify, another would tell another statement which doesn't correspond to the other, you have to input another line [...] I just couldn't delineate as to where to start!

Fiona was sorting paperwork as Karen talked to me, but at this description she looked up.

> I think you need to follow. I was taught by Adelina how to take notes, and only get those relevant to the protocol. Other comments shouldn't be part of the discussion, so you put them out of mind. So, each issue: what are the recommendations? What are the technical and ethical issues regarding the consent form? I categorise them in my mind during the meeting.

Karen explained that though she had a background in science, she found herself ill prepared for her secretarial role.

> At first I don't know anything about ethics. I'm a biology graduate, I didn't know what to expect in a review meeting, especially with doctors, professors, who kept saying things I don't know. So I didn't know what to write either. After that, [Fiona] taught me how to organise my thoughts and take down notes properly. Sometimes, they have very strong comments on one another, 'I do not agree with your point!' What do you do then?

In the 'real time' system, full board discussion is recorded by editing the speech of the committee members. As I have shown, a decision must be evidenced as resting on a discussion. But as Karen points out above, it is difficult to summarise a discussion as it develops. I know the difficulty myself, having tried to record by hand the discussions in ethics committees. Even with the flexibility that pen and paper afford over typed script on a screen; even with the ability to record expressions and gestures, multiply indent and annotate, it is difficult to say (from notes) *how* a decision is made, to track persuasion and rebuttal. Fiona took the opportunity of our interview to explain her thoughts not only to me, but also to Karen her new colleague.

> *Fiona*: [to be a secretary] a person must know how to organize their thoughts well, and be able to multitask and remember. You learn how to divide your mind. Manage your mind and manage your time. Need to have good communication skills, and have confidentiality.
>
> *RDJ*: How do you 'have' confidentiality?
>
> *Fiona*: Like, we put a guard on ourselves - restrain ourselves from commenting, and remain silent, [to prevent] people asking follow up questions. If in this office, we share. If another office, no, because we signed [a] confidentiality agreement.
>
> *Karen*: The other office [staff] do not know what we are doing! They think we prepare for the meeting and we photocopy. They know how to appreciate [our work], that we're always. They say ,'What are you doing, why are you always so home late?' Bosses don't understand when I haven't finished the work. They think its easy, write a letter, print, send protocols to

> investigators. It seems easy. But when you're in my place it isn't work that requires intelligence, it requires time.

Fiona's diversion of the conversation towards confidentiality recalls the attention paid by Surveyors to it in the room. Confidentiality appeared regularly, adhering to persons, times, material objects and spaces. I signed confidentiality agreements on entering committee rooms in Thailand, the Philippines and China; filing cabinets were under lock and key 'for confidentiality'; computer record systems locked with a password 'for confidentiality'. The concept had a curious flexibility, and occasionally, those presenting its use would trip up on quite where they were placing it. Due to its ubiquity as a principle, sometimes it seemed to cross circumstances even in the same example. During a lecture on ethics in publication, the lecturer below slips from the reviewer of an *article* for publication to a reviewer of a *protocol* in an IRB meeting, using an example from an ethics committee to illustrate his point about publication review:

> Reviewers also have rights to confidentiality. In fact the reviewers of protocols, reviewers of articles for journal publication, their identities should be confidential. So I don't know how you do your reviews in your institution, do you give up the name of the reviewer of the pap[er]… of the man[uscript]… of the protocol? When [our committee] was new some years ago, the staff didn't know much about confidentiality. So she gave up the name of the reviewer to the investigator. The reviewer happened to be very, very good reviewer, with many, many comments. Seeming like the protocol will never be approved, of course the investigator wanted to question the reviewer. No! This staff actually gave the name of the reviewer. That's bad, that is not allowed.

The slips in what reviewers review — the paper, manuscript, protocol — show the implementation of the principle of confidentiality slipping between circumstances. The reviewer of a paper does her job at the completion of research, the review of a protocol before it begins.

But let us return to the minutes Fiona and Karen are producing. As well as creating a far-future record for possible auditors, the minutes of a meeting serve another purpose: they are the guide from which secretaries proceed. Fiona and Karen are on the receiving end of inquiries from principal investigators, who are often in a hurry to get approval.

> Sometimes researchers don't know that they will need ethical clearance and they request that their application is treated urgently. They think it'll be easy, someone will review, and they'll get it. I have to explain this is our process.

Reference to 'the process' allows Fiona to deflect the blame for delay that PIs might otherwise place on her shoulders, but she finds herself in a mediating position:

> The one who submitted [the protocol] thinks it can be expedited but the board thinks no. He keeps saying 'Why? Why do I have to go through full board review?' It is a challenge for

> me, how can I say that board doesn't agree this should be expedited? Sometimes I show [them] the standard operating procedures.'These are our criteria for expedited review considering your research. According to your board we cannot expedite because of the following issues.' I just ask investigator to look at it. I give warning it'll undergo full board, that this usually takes two to three months. I also say board may request you to modify your protocol so you have to expect [that]. I refer to chart on the wall to calm them — so we don't have to explain every time they come. 'Read our workflow,' I say.

In both spoken and written communication with PIs, she says:

> It's very hard to be in the middle of everything - we have to satisfy both. Be transparent. There are the requests of both parties — I have to find the compromise so no one gets offended. To the investigator I say 'Follow what the board tells you,' but I break it gently. It's very different comment from reviewer and give to investigator. You soften it. [The committee secretary] helps us rephrase. The *contents* don't change, just the way... You use softer words. In meetings you usually hear harsh words. The members are outright. Not *really*, like last week, [in the meeting] someone said 'This is scientifically unsound,' but we cannot say that [to the investigator].

I'm interested in the changes that Fiona is describing. So what do you put in the letter?' I ask her, 'The recommendations from the minutes?' 'Yes,' she says,

> but we edit them. Just to make statements clearer, to make it....sound better. Sound softer. It's better to give them....Well its the values of the Philippines. You get a negative perspective if you tell them something outright. We present it in a softer way, so they'll be able to accept the criticism."

Fiona reveals that she has learned how to distill points that are important from general discussion, writing only those as 'evidence' of a measured decision. These are recorded as the 'minutes.' She will then re-read the minutes and take the points, rephrasing them as she writes the letter to the Principal Investigator. She includes the comments from the evaluation forms of the reviewers, edited, in the letter. At each point, she tells me, the words are softened, made 'less harsh.'

The few studies on ethics committees' authority and legitimacy (Stark 2011b, O'Reilly et al. 2009) indicate that decision letters are one of the most significant vehicles for a committee's activity, 'understood as a solution to the administrative problem that there is a need for a single authoritative ruling on the ethical standing of any application, but there are competing claims as to how that standing should be assessed' (O'Reilly et al. 2009:258). Karen and Fiona describe tensions between researchers and the committee members in the making of that authoritative ruling. I now turn to the tensions that they must, in the real-time minutes, record: disagreements between committee members as they come towards a decision.

Voting and Consensus: decisions and the visibility of opinions

In the committee meetings I saw with FERCAP I observed a variety of decision making tactics. The WHO 2009 booklet on Capacity Building in Research Ethics states that:

> [m]ost committees make decisions through a process of consensus. This means that, instead of taking a vote and following the decision of the majority, they strive to make decisions that most people in the committee feel comfortable accepting (2009:22).

However, the majority of committees I met with tended not to explicitly aim for consensus, even though it was acknowledged as the ideal. The following discussion from a training session in the Philippines lays out some of the difficulties. A committee member said that while she recognised in meetings 'We have to have consensus, what if the group is not at consensus, but the members all have valid points?' Cristina, who was running the session, responded:

> That's the problem with consensus, if you do not vote [...] Consensus means you cannot vote. In Thailand, they table the protocol![29] Consensus means everybody agrees, or at least there's only one who disagrees, but how do you know?

The question asker persists: 'Isn't it the point of having a diverse composition, to get diverse points of view? What if both points of view are valid?' Cristina nods, but challenges back:

> But how do you make a decision? You *have* to arrive at a decision. That's a problem. When there's a difference in opinion, you arrive by voting. There should be something in the SOP that gives you a way out. You cannot be deadlocked. An EC is about decision making. Sometimes it's like this: the chair sits there, the EC members are fighting and they finish then the chair says "approve"! But what did you approve? It has to be very clear, otherwise we cite that as a weakness. Decision making is very important to us as surveyors. The reviewer has no authority to make a suggestion [to the researcher]. It's the full board. This is my problem in [Country X]: you give feedback and then they quarrel with the investigator. The investigator finds out you're the one.[...]In full board your opinion can change, *the final decision is a board decision, not an individual one.*

The difference revealed in this exchange between a consensus opinion and a board decision is subtle, but important. Consensus, the term used conversationally in my fieldwork, meant both the discussion and the decision: it was a process which contained a result. Discussion and voting, on the other hand, could be separated. In Cristina's example, the board members are 'fighting', and then the Chair says 'approve.' She is using this as illustration of poor behaviour, since no link can be discerned between the discussion and the decision.

[29] Used with the American meaning: to put the protocol aside and return to it in the next meeting.

In Stark's detailed research into how decisions are made on IRBs in the USA, she writes that rather than consensus being the formal requirement and voting being the norm, voting is the formal requirement and consensus making is the habit: 'group members act *as if* they should each agree on a shared judgement that they all can get behind' (Stark 2011a:236). Her observations brilliantly show how people persuade one another and how a committee comes to arrive at recommendations. What I want to look at here is how American models of open discussion and a consensus-vote (see also Guston 2006) are not easily adopted.

A change in staff at a hospital in Taiwan had prompted the decision to send an administrative secretary to Western IRB for training. Edith, the committee's long serving secretary was chosen, and she spent 6 months in Olympia, Washington USA at Western IRB. In our discussion, two years after her return, she focused not on her time in America but on the changes that she had implemented on her return to Taiwan:

> When I came back I just follow[ed] this way [they taught me] and have something to make the IRB more strong. And I did some SOP: now we have 30. In beginning, [we had] just 5-6 SOP. Now, we follow it and we do the things right. Then we got FERCAP recognition to make sense of our quality quite good.

Not all the changes Edith had tried to implement had been successful, however. In hopes of effecting greater efficiency, Edith tried to get her committee to change their manner of making decisions. She had watched and participated in committee meetings at WIRB during her training, and seen 'the rule': '[They] say 'OK, did anyone have different opinion, or don't agree. If [you] agree [with the proposed decision], say aye, and raise [your] hand.' 'When I came back,' she said, 'I tried to use this, but,' she shrugged and shook her head:

> I say OK, I know in some IRB in Taiwan we use voting paper and they just write, agree/ disagree. But I think this spends more time, you have to give the paper, calculate, collect. So after, I say, maybe we can use the raise hand.

'This way,' she paused, 'maybe not good.' 'Why not?' I asked her. 'If board member see every board member raise hand, maybe they just follow. So after,' she said, brightening, "computer voting!' I hardly needed to ask Edith whether this works better. 'We don't know who voted for which one!' she said, with a big smile:

> We just only have the number. 1 for agree, 2 for disagree. So they press, we don't know [which] they press. Then maybe they have their own decision, not affected by other members. Another [good thing] is that its very quick — I just press enter, see how many agree.

Decisions cast in the language of efficiency take in a variety of points and are the moment at which interpretation ceases. I decided to ask Edith why raising a hand might be OK in WIRB, but not in her hospital. Her answer was considered, but she rested it initially on the idea of 'cultural difference'. 'Because I think the culture is different,' she said.

> In the West, people are more... They have their own opinion more stronger. In Asia, especially in my opinion we are more...[she gestures at me] Maybe if I saw Rachel raise her hand, maybe I follow because I don't want to become the different person.

For Edith and her committee, the moment of decision itself was a moment of uncomfortable interpretation which needed a solution. The invisible vote provided it. While all could vote equally under the invisible voting system however, opinions given in discussion could not be dissociated from the speaker. Edith spoke about the discussions her committee had at the same time:

> Now in the Board Meeting they speak, they just say their opinion — I think 'Good.' Doctors, you know, it's something different with them. Doctors in hospital think they are dominant [...] When I joined, they just....Now we have more time to discuss - since I joined the IRB. Doctors, they say 'Oh, our meeting is quite long, why?' Sometimes we discuss just one proposal for ½ an hour, sometimes more. Because every member they have different thinking.

Edith's suggests that the 'different thinking' of every board member is an achievement of a particular sort. Her ingenious voting system creates the space for a difference between points of view that is assumed to exist, and permits the expression of it by removing the social visibility that would otherwise — she claims — hamper its expression. The ability to conceal a single person's vote is also useful when one wants (or needs) to see the outcome of the vote as the decision of a committee: the decision retrospectively creates that which decided as single, rather than multiple. As Cristina emphasised in the training earlier, a final decision is a board decision. Similarly, when the lecturer slipped from the reviewer of an article for publication to a review of a protocol in an IRB meeting, he was at pains to remind his listeners that:

> When your EC reviews, it is your committee that is reviewing, it is not just one or two people reviewing. *The board speaks as one*. So it is only the name of the chair of the IRB, not everyone, in that communication [to the PI]. It is a mistake to inform investigators or authors that, 'Dr so-and-so reviewed and found your article questionable because of the following.' OK?

During an interview with Chandeep, a Sri Lankan committee member, I found he wanted to make the point explicitly: 'an ethics committee is not an *individual* its a *committee.*' Procedure, he thought, would help a committee *be* a committee:

> You realise that there are many factors making committees not work as committees. There is this thing called groupthink. People fall into line, perhaps because of who said something, say I say 'blah blah blah' and because its *me* who said it, or because a certain individual told that, people aren't going to critique. I don't think that's *real* decision mode. Dynamics should be set in such a manner that all get the chance to speak [...] ethics committees should have an operating procedure to make decisions on consensus basis.

Chandeep's description of a committee as a procedure reveals his assumptions about what a 'real' decision should look like. When he described to me the perils[30] of 'consensus' he revealed concern with *who* makes a point and how that affects decision-making:

> With groupthink, if there is a catchy personality, then the rest of the ideas...The role of a chair is to ensure there is good participation so there is proper consultative decision making.

His reference to groupthink reveals his education in an American bioethics tradition. William H. Whyte coined 'Groupthink' at a time when American tensions between individuality and 'the dark forces of conformity and collectivism' (Shapin 2008:120) were at their height. Bureaucracies were regarded as a threat for those like Whyte, who sought 'to protect the creative scientific spirit that resided in the unique, autonomous, and free-acting individual' (Shapin 2008:119). Whyte's anxiety was with 'rationalized conformity — an open, articulate philosophy which holds that group values are not only expedient but right and good as well' (Whyte 2012[1952:114]). As Champney summarises:

> [t]entativeness and humility are needed in group processes, not only because a group can be unanimously wrong but because the unreconstructed individual (however much he may sand up the group bearings) has a vital role to play in the total picture (1952:384).

This 'unreconstructed individual' is Whyte's 'layman, the what-the-hell sort of character who carries his center of gravity on the inside of him' (Champney 1952:383). This particular reading of the layman puts an era-driven positive spin on the individual point of view in a group setting.[31]

Stark uses transcripts of EC meetings to demonstrate how opinions are evaluated; how people persuade others, or fail to. Her concern is to demonstrate how, in the creation of 'the social actor known as "the IRB", documents liberate individual evaluators to make what they consider to be extreme judgements' (2011a:235). She draws on a committee meeting she observed where Kevin, a junior researcher serving on the IRB found fault with the protocol of a more senior researcher he

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[30] Chandeep referenced the Challenger disaster as an iconic case of 'Groupthink'. For an academic account see Vaughan (1996).

[31] A more historically oriented thesis might look at contemporary concerns of IRB censorship raised by Katz (2007), Hamburger (2004) and the 'New Groupthink' (Cain 2012, see also Safire 2004) in relation to the concerns of this era of American history. Unfortunately, such a project is beyond the present work.

knew. Citing his professional experience, he persuaded fellow members that a change really should be requested, but was reluctant to allow the board to act upon it, however, since he would be "dead meat" on campus. The senior researcher, he thought, would know it was he who had recommended the change. It was not calls upon his 'duty' to protect human subjects which swayed him to permit the change, but the fact that he would not be identified in the meeting minutes. To Stark, 'the fact that individual opinions can be presented as the view of "the IRB" erases personal accountability' (2011a:235), creating a situation in which documents enable the 'impression that there is no *one* to hold accountable' (2011b:71).

Where Chandeep wants a board decision to be made through a consensus in which 'all get the chance to speak' sometimes, committee members (particularly laypersons) felt slighted if their thoughts could not shift the tenor of conversation in a consensus oriented discussion:

> Why end up with consensus? Why is my comment more or less valuable than someone else's? Sometimes [my comments are] not taken well, not appreciated. I feel [my comment] is supposed to be out there, otherwise, why [should we] still get a diverse composition? Get doctors and that's it.

Yet discussion is 'part' of what makes a committee a committee, according to the measures FERCAP has set down in the Survey. When I visited a committee meeting in Taipei, my host took pains to translate the conversation, and point out to me the kind of concerns that the various members were raising. A lawyer had asked questions about the validity of the informed consent form, a layperson had queried terminology. 'Our discussion', he said proudly, 'is as good as America.' However, as Edith discovered, applying standards, largely American, did not always go smoothly.

Conflict of Interest: invisible relations

Another challenging standard was 'Conflict of Interest' (COI). During my visit to the Philippines in April 2010, I attended two FERCAP surveys and several trainings. On the opening day of one survey, Cecilia a chair of various national boards, explained to the surveyors and trainees some of the challenges of conducting ethical review in her country. Classing conflict of interests as an 'obstacle' to quality ethical review, she lamented that in the Philippines:

> [w]e do not understand or easily recognize conflicts of interest. One time, we had a member in the National Ethics Committee, a very respected researcher who was also a head of a

> health institution. He said, 'I think our health institution should be exempted from ethics review because we've been doing research for so long.' I said 'OK byee!' So its not very clear yet what this is all about. Since we do not recognise conflicts of interest, we do not manage [them].

In not permitting experience to stand over submission to ethics, Cecilia illustrated how both researchers and institutions had to adapt to the changes brought about by GCP and research ethics: neither experience nor seniority provided exemption from external evaluation. As the amount of internationally sponsored research increased in the Philippines, so did attendance at trainings on international standards. I joined a lecture in theatre 222 of the College of Medicine, where some forty or fifty course attendees had gathered for a presentation on Conflict of Interest by Dr Rodriguez, Professor of Legal Medicine and Ethics at the School of Law. His lecture echoed the concern that it was something 'difficult to see'. The *potential* in Conflict of Interest which makes people anxious. It can — as Emory University found out — put you on the front page of the New York Times.[32] In the same way as 'confidentiality' flipped from being a concept committees *sought to ensure for participants in the trials that they reviewed* to being *something the committee itself must demonstrate*, conflict of interest is a topic committees examine in the protocols review, *and* one which affects them directly. Although committees are tasked to consider the former concern, Canadian commentator Lemmens (2006:32) points out that COI has a vast reach. The assessment would include the clinical trial agreement between researchers and sponsors, the budgets of trials (particularly the incentives for the recruitment of subjects and any payments to them) publication agreements, the scientific validity of the trial, access to data and the publications that result. 'Should RECs be expected to do all of this work', Lemmens asks, 'indeed, are they capable?' (2006:32). In his view, they 'cannot take sole responsibility for unraveling the complex relationship between scientists and the companies that sponsor them[33]' (ibid). The knowledge that brought committee members to their 'expert' role on the IRB was also the knowledge that made the exercise of this role problematic: if they knew the field of cancer, say, it was also likely that they knew who worked on cancer in their institute. Even

[32] Despite 20 different COI policies in the University. (U.S. Department of Energy 2011).

[33] The relationship can be even more complex, when, writing about India, Gulhati considers hospitals owned by drug companies, and their institutional ethics committees, since there is 'no legal requirement for investigators or members of the Ethics Committee to declare a conflict of interest [in India]' (Chatterjee 2008: 577).

anonymized protocols, reviewers would probably be able to deduce whose protocol was under review[34]. Rodriguez described this social proximity as 'bias':

> There is always this tendency of bias, when you talk about a committee who are all *barkadas*[35] of the one conducting the research. You know our culture, Philippinos. Our *barkadas*, as medical students we are a close group, close friends there who went through thick and thin all throughout. 'Hey, this is a proposal from Dr so and so. And I'm the one reviewing it?' So there is always this potential.

Rodriguez reminded his trainees that they will often know the applicants: '[w]e are faculty, same institute. It is a problem as much as you *like* them, as if you *dislike* them. You still feel something towards them.' He also reminded investigators who sat on committees that they may know how to do clinical trials,

> but when you sit in the EC you wear a different hat because you are supposed to institute that check and balance. You're supposed to present an alternative perspective, not the perspective of an investigator.

Those with experience of the clinical research environment were often considered useful people to have on ethics committees, so the appointment did not prevent them from conducting research. However, Rodriguez pointed out that 'practically everything you do now you see a sponsor, a multinational corporation funding the researchers.' He warned committee members to be careful:

> In the US, all members make a declaration about their investment. They think anything over $10,000, in WIRB[36], if they do Pfeizer protocols. Those with stocks in Pfeizer have to leave the room. That's how they look at COI [...]. In the US, it was said that the $10,000 is a minuscule, a negligible amount. But here in the Philippines $10,000 US dollars is really something.

Translating from dollars to Philippine pesos was an attempt to evaluate the amount of money that would cause an 'undue influence'. Things got more complicated however, as money, he told us, was the 'only tangible thing in the array of secondary interests. It's always easy to address it because money is there, you see it.' Other things were less visible, and required different forms and degrees of self awareness.

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[34] I should point out that I am not arguing that this problem of finding relations in a committee is exclusive to the countries where FERCAP works. A recent anonymous posting to IRB Forum, an ethics discussion group, made public a recommendation by Penn's legal department to dissolve its internal IRB and use an external commercial IRB due to concerns about internal conflicts of interest (Corman 2009: 10). However, the existence of companies conducting ethical review in the USA does mean that the landscape is less personal: one could send a protocol away to another more 'independent' committee.

[35] Filipino slang for a group of friends or peers. With thanks to Atoy Navarro for translation assistance.

[36] Western IRB, based in Olympia WA has had significant interaction with FERCAP and ethics committees in the Asian region through its WHO funded developing countries training program. See Introduction.

Secondary Interests

'We think of COI in terms of your perception' counselled Rodriguez:

> You are an ethical individual and therefore you can not do anything wrong. But that's not the definition of COI. COI means that you are ethical [and] at the same time you recognise you have a different role and a different interest.

Recognising these different roles and interests meant being aware of 'secondary' interests — and with this, we entered the realm of the intangible. 'We cannot come up with a researcher without conflict of interest,' Rodriguez told us, 'Life desires to have fame. How do we measure that desire?' Secondary interests applied as much to ethics review committee members as to those who conducted research, but as I observed above, often these persons were one and the same. While those who sat on ethics committees tended to have an interest in research, *interests* were something different:

> Problems occur when secondary interests dominate, unduly influence, distort, or corrupt the integrity of a physician's judgement in relation to patient health (Thompson 1993) Fortune, fame, and family threaten the integrity of the professional judgement.[37]

So how are these 'interests' to coincide, to come into 'conflict'? The extension of 'interest' reveals for anthropologists the starting assumptions on which COI disclosures are based. Anthropologist Chris Gregory, in revisiting anthropological readings of economist Adam Smith, finds them selective, focusing only on greed and rational self interest: the *Theory of Moral Sentiment*, he argues, is more subtle (Gregory 2011). Smith scholars such as Griswold (2006) and Bhanu Mehta (2006) would agree. Consider the passages of Smith selected by Griswold, writing on the imagination and its relation to self interest:

> The "natural misrepresentations of self-love can be corrected only by the eye of this impartial spectator" (III.3.4 cf III5.5) Moral self-consciousness requires that I "divide myself, as it were, in two persons" (III.I.6). The idealized judge is still a spectator - the stand-in for "the public" (Griswold 2006:38).

Based on these excerpts, Griswold argues that 'the theatrical relation is thus internalized; we become our own public,' concluding that '[o]ur understanding and moral assessment not just of others, but of ourselves as well, depend on an exercise of the imagination' (2006:38). Through contrast with other ways of thinking about persons that we can see the contrivance of imagination at work in the concept of Conflict of Interest. As Strathern remarks,

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[37] See Thompson (1993) for the counter argument that conflicts are usually not illegitimate, indeed they are frequently necessary and desirable.

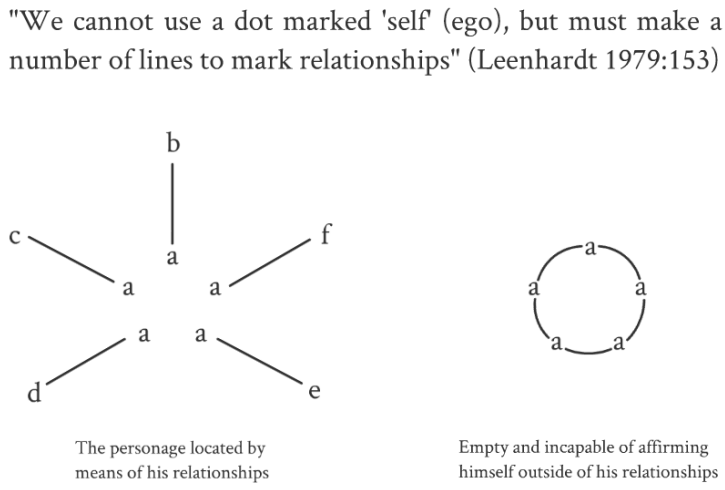

Figure 24: Replication of the diagram produced in Gender of the Gift (1988) in which Strathern's critique appears.

> [t]he center is where the twentieth century Western imagination puts the self, the personality, the ego. For the 'person' in this latter day Western view is an agent, a subject, the author of thought and action, and thus 'at the center' of relationships (1988:269).

Strathern is reflecting on a diagram (Figure 24) drawn by Maurice Leenhardt (1979 [1947]) which depicted his understanding of New Caledonian 'personage.'

While this diagram works well for the way Conflict of Interest is imagined — locating a person by means of her relationships — for Strathern it revealed in visual form a limitation in Leenhardt's depiction of Caledonian sociality. In her critique, Strathern observes that even in attention to the way in which peoples relationships make them up, the individual subject is foregrounded. She remarks that 'Leenhardt's star shaped configuration carries the one and same presumption: living within, guided by, driving, functioning as, or knowing through these structures of relationships must be the individual subject' (1988:269-270). What COI makes explicit is the tension inherent in this model of the individual subject. While COI models do not re-imagine dividuality, they exist because of the recognition that people belong 'to a matrix of radiating relations' (2004 [1991]: 68). The attention to relationships provoked by Conflict of Interest suddenly appears as a way of seeing people that looks a lot like certain proposals for theorising 'social reality':

> If we are to produce adequate theories of social reality, then the first step is to apprehend persons as simultaneously containing the potential for relationships and always embedded in a matrix of relations with others (Strathern 1990a: 10).

What is the difference between seeing people as always embedded in a matrix of relations and seeing these as 'interests,' contained within?

Discipline

Rodriguez continued: A conflict exists whether or not decisions are affected. Conflict implies only the potential for bias or wrong doing. And the basic step that you must consider is *failure to disclose is wrong*.' Participants in the training were encouraged to 'think about' what conflicts of interest they might have, with the lecturer assuring them that 'half the problem is solved if the presence [of interests and their possible conflicts] is recognised'. Having listed various potential conflicts of interest — with conflict itself understood as 'potential for bias or wrongdoing' — disclosure was introduced as the next step. 'Disclosure is the cornerstone of the Conflict of Interest guidelines and regulations,' Rodriguez announced

> You can keep it to yourself, but you will be taking a risk because once its discovered or if a third party disclose it, then you are in deep trouble. In the US it is a very big thing because I think the regulation carries a penal clause, meaning they can give a penalty. It's not only a concept of 'Hey, what you did was wrong.' [...] It's imperative that all clinical researchers would have this openness when it comes to Conflict of Interest. You simply cannot hide one or two and disclose the rest because eventually it will be discovered. That is a requirement that you alone can perform [...] So you might as well start by disclosing it.

According to Rodriguez, the revelation of conflicts of interest required 'discipline', as there was 'no other way for others to know' if one was harbouring a conflict of interest around the table at the committee meeting. It would also, he implied, be difficult for those who knew to point to someone. 'It's a cultural thing, if we say "You have a conflict of interest, get out", there will be hurt feelings.' This sort of discipline, the revelation of internally held knowledge of relationships external to the committee, meant committee members were told they could not 'be silent', but had to 'manage' their conflicts 'preemptively.' We see here legacies of Durkheimian thought, with its public and private dimensions, both visible and invisible, external and internal (Durkheim 1992, Ezrahi 1990). The 'perceived relationship between inner and outer worlds' (Strathern 1992a:184) provides a model of human thought and action lends itself well to a consideration of 'interest' in the phrase 'conflict of interest'. Interests are not visible attributes, they must be declared, moved from internal to external. The focus for conflict of interest has moved, replacing an examination of relationships between committee members with an examination of one's relationship to oneself (thought of as containing or composed of relations), by finding a position from which this can be viewed. I return to the work of Griswold (2006) above, as he traces Smith's comparison, or conflation, of moral and visual judgement:

> Smith [...] compares the process by which we learn to exercise balanced *moral* judgment to that by which we learn to make correct *visual* judgments. He has Berkeley's New Theory of Vision in mind, a book of which he thought very highly. The basic idea is that just as I cannot gauge the correct proportions of objects of different sizes and at varying distances, except by "transporting myself, at least in fancy, to a different station, from whence I can survey both at nearly equal distances," so too I cannot accurately evaluate the magnitude of my passions in comparison with another's except by viewing them "neither from our own place nor yet from his, neither with our own eyes nor yet with his, but from the place and with the eyes of a third person, who has no particular connexion with either and who judges with impartiality between us" (Griswold 2006: 38)

On this point I wish to pause: there is more potential in the study of this point of Conflict of Interest than I can draw out here. The material resonates with the creation of objectivity in the Survey through the 'distance' of foreign surveyors, it parallels the moralisation of objectivity in the work of Daston and Galison (1992: 81) and draws 'truth' and representation together under the banner of moral obligation. For now, what I wish to draw attention to is how members are problematising concealment and revelation, for the duration of the meeting, as a moral act that only the individual member is capable of performing. For a committee, this requires thinking of people as already related: as individual committee members or researchers they have their relationships, and thus their potential conflicts, 'built in.'

In the Philippine ethnography above, COI may not only jeopardize the 'objectivity' of a researcher, but also cast doubt upon the research enterprise itself. Members' relationships outside the committee come to be constitutive of the trustworthiness of the committee as a unit. When a person discloses a COI, s/he will usually stand and leave the room. The recognition and management of COI can be evidenced by minuting that bodily action. Cecilia and Dr Rodriguez both indicate that for conflict of interest has the potential to inhere in any of the relations of which a person is made up. It can reside in their internal attributes (their ambition) and their relationships (through kin or money) which, during the committee meeting, are seen to be carried in the body of the (in)dividual committee member.[38] As Rodriguez says, it is not that some of the *people* to whom one might be connected might be bad. Rather, it is that the *connections themselves*, *unrevealed* might cause difficulties. The distinction, as drawn by the lecturer, was that it is not a crime to have conflicts of interest, but to not declare them. Thus it becomes the responsibility of each member to scan their relations. This is the nature of their 'disciplining.'

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[38] I suggest they are thought of perhaps more as 'dividual' (Marriot 1976; Strathern 1988) at these moments than individual, since their 'internal composition depends on external relations' (Fowler 2004:26), an observation which perhaps, given my revisitation of Smith (re)complicates the individuality of the models from which notions of COI are drawn (see also Hess 2006).

Munro observes that '[w]here the consciousness of individuals is regarded as primary, [...] the tendency is always to re-locate relations inside these 'wholes' — to the domain Kant called the 'universe within' (2005: 256, references omitted). The 'interests' of which Rodriguez speaks are thought of to be both 'out there' in society and 'in' the individual. They are seen to be forces that move without people: financial interests, company interests, pharmaceutical interests. But it is also easy to imagine these interests 'into' persons, in their financial motivations, their ambition. Furthermore, if those interests are 'in' persons, then those persons can then come to stand for those things. 'Conflict of Interest,' I suggest requires a 'holistic model of society in which specific interests would be located in relation to one another' (Strathern 1988a:26), one where Ethics Committees are called to to 'play a role mediating the interest of particular groups' (Tupara 2011:369). In Chapter 2, I showed how during the survey it is the company of others that makes objectivity possible. The views of Surveyors are de-personalised in their combination, making the Survey's recommendations seem objective. Here, the possibility of concealed interior relations prevents objectivity. Relations — configured as interest — *constitute* rather than *dilute* bias.[39]

Concluding remarks

I initially paid attention to space in this chapter because I wanted to highlight the way the ethics committee — in its physical, enacted form — constitutes a knowledge space. Drawing on David Turnbull (2002), we could think of the requirements of the space, oft repeated in surveys - a computer with a database, a fax machine, a printer, a photocopier — as 'templates' for the cathedrals of ethics, assembling standardizing, transmitting and utilizing knowledge. The closing reports of Survey project images of these pieces of technology as achievements of the space, the space the achievement of the will of the committee. The organisation has been convinced.[40]

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[39] Or, in Haraway's terms, 'embedded relationality is the prophylaxis for both relativism and transcendence' (Haraway 1996:440).

[40] I am not suggesting that the 'achievement' of space is unique to Asian contexts, rather that as we saw above, hospitals and universities may need convincing. A parallel of the significance of 'taking' space for Ethics is found in the language of Auerbach's report on an Amherst alumnus, Ezekiel Emmanuel, a bioethicist who took up a role at the US National Institutes of Health:

> Emanuel [...] took one look at the government-issue green-hued rooms where NIH scientists did their work and [said] "That's not the right environment for bioethicists." Emanuel created a central common space. Under a giant conference table, he placed an Oriental rug, and on the walls, he hung "real art", he says, including African masks from his many travels to that continent. Emanuel tore down walls to expand the bioethics department's territory, and he has colonized other NIH institutes to add faculty to his department. (Auerbach 2009)

However, I do not want to over-emphasise technology. It is evidently embraced as an 'ally' of both ethics and audit in its facilitation of reports and minutes (see Strathern 2002b:308). Its mere presence in the photographed contents of offices is also used as a measure in the Survey. But Juntra, the SIDCER coordinator once told me that good ethical review is *not a technology*, and that any country can 'have' it, developed or not. I found the phrase repeated on powerpoint slides. What does this assertion mean? She tries to explain:

> What I want is [a situation where] everywhere they can analyse ethics issues in their country for public good.[...] If you don't have electricity you can still run an EC. If [we're] discussing efficiency, if you have lots of protocols, those technologies can help you work faster. But you can still can do it with everything manual. The way how you review [is] still the same, it's based on same principles. You can't follow up as completely as those with technology. It's different from other types of Lab. If you don't have technology, you can still function with paper and do it the old fashioned way. But the Ethics Committee is not a lab, that's why if [they] don't have technology, [they can use] paper, conservative way. They just have to organise the system differently [...]. Some EC could be recognised without a computer, as long as they review properly and follow up properly.

First it is 'different from other *types* of Lab', and then 'it is *not* a lab.' Juntra slips easily between the descriptions, since to her, I suggest, the Ethics Committee is a way of thinking,[41] supported by a certain arrangement of space. Standard Operating Procedures detail who (what kinds of persons) it must contain. These people are defined largely by their knowledges: a powerpoint listing composition of the Ethics Committee in Taiwan read 'profession: layperson'. But despite strong appeals to templating, (even in the form of discussion) there cannot be a template for the social life of those who form the committees. I have argued in this chapter that the ethics committee, as a group of people sitting around a table in a room, both relies on and denies the relations those persons bring to that room. Dealing with the personal that attaches to the official is problematic. A PI is one's boss, a reviewer is also a colleague, those sitting around the table with you, deciding, are your superiors. By routing these concerns through the room, we arrive at its permeabilities. Indeed, the mechanisms of 'Conflict of Interest,' recognise the embodiment of those relations, as one must take one's connections to those people out of the conversation by removing oneself from the room. Edith's solution to the problem that connections cause when one is visible to another, is to make the voting invisible.

If we are usefully to regard the ethics committee as a laboratory then, it is not in the sense that it is experimental, rather in the sense that the enclosed space lends it a robustness, particularly in comparison with spaces where questions are not disciplined (e.g. Callon et al. 2009, and Callon

[41] I explore this further in Chapter 5.

and Rabeharisoa 2008). Through the Survey FERCAP desire a system in a room that will produce replicable results: in the documents they look for consistency, they look for completeness, they look for discussion in the meeting. A room can be made and peopled with those who will produce replicable results, within the measures set. The 'objectivity' of ethics committee members is sought, demonstrating the 'political action in the sphere of attestive visual perception' (Ezrahi 1990: 170) transferring from the physical to social world. Lamont's work (2009) on the 'mechanics' of deliberations shows that 'technolog[ies] of evaluation around which evaluative cultures are intertwined [...] define and constrain possibilities' (2009:23). This chapter is evidence both of the material and verbal aspects of her assertion.

I opened the chapter with Hobbes' concern over the designated space for natural philosophy to point to his concern with its public status. I want to suggest that in the 'attestive visual perception' of the Surveyors lie links with the dispute about the witnessing of which Shapin and Schaffer document (2011[1985]). As the Surveyors bear (mutual) witness to the standards of one another's ethics committees, the ethics committees bear witness to the science in the protocols on their table. This has not gone unnoticed by scholars (Hamburger 2004, Stark 2011b). What is sought is the 'objectivity' so desired by Hobbes and Boyle, witnesses to the making of a ethically sound science, but now — in the absence of 'gentlemen' (Shapin 1994), their society and assumed attributes (Handler and Segal 1990, cited in Strathern 2005a:44) in a way that is perceived as democratic. I develop this point in Chapter 5.

In summary, the 'ethics' of this chapter has taken the form of walls, locked cupboards, well phrased letters, examinations of the self, standard operating procedures and organograms. But it is also the concerns *in* the room, the acting out of the concept of conflict of interest, and what it betrays about the sociality of a committee meeting. An editorial in the *Indian Journal of Medical Ethics* entitled 'Ethics in Ethics committees' (Jesani 2009) criticized the 'silence' on the operation of ethics committees. 'Why is it', he asked:

> that even 30 years after ECs were first established in India, we do not have even experiential accounts (let alone systematic studies) on ECs in the public domain? Why have EC members not narrated the challenges and dilemmas they have faced, and discussed how to make regulations effective. Would doing so compromise the confidentiality of research and the ethics review process? Unless committed individuals find ways of speaking out on EC functioning, ECs will continue to function as secret societies unaccountable to the public and with poor public credibility. While specific information related to projects and individuals may be confidential, this is not true of the ethics review process itself' (2009:2).

I suggest that perhaps some of the issues raised above might begin to answer Jesani's question. For example, we see his concern with confidentiality emerge as more than it might first appear. It is a bodily attitude on the part of the secretaries, it is my signature on a form at the door of the committee. It is the shredding of documents before sale of scrap paper, it is the height of a wall. The physical boundaries to the room combine with the attitudes of those who use it to form a combined assemblage: 'They don't know what we do', remarks Fiona, speaking of friends in the office next door to her. Jesani's complaint reveals the tension anew: confidentiality must be kept from becoming secrecy, a term not imbued with the virtue of the former (e.g. Easter et al. 2004). Here lies one of the tensions Jesani identifies: its bureaucratic secrecy and its public service, its every-man ethics and its scientific expertise. Although '[b]ureaucratic administration always tends to be an administration of "secret sessions": in so far as it can, it hides its knowledge and action from criticism' (Weber 1946:233). This is precisely what Jesani queries. Returning to the text with which I open, Jesani's comments also resonate with Hobbes' claim that 'the privacy of experimental space did its own political work' (Shapin and Schaffer 2011[1985]:320). Jesani is asking whether "secret" work on behalf of the public is acceptable, particularly when, Stark reminds us, IRBs 'change what is knowable?' While I take up this theme again in Chapter 5, the next chapter rests with the difficulties encountered by Edith, Fiona, and Karen. I suggest that these stories relate to the modes available to people to make criticisms. Indeed, not simply the modes, the force that certain modes can take. This I develop through the comparisons of the next chapter.

Chapter 4: The Jury, the Ethics Committee and the Law.

I arrived at FERCAP's Bangkok offices in March 2010 on a pink motorbike. It was not my intended method of transport, but the bus at Thammasat University had taken an unexpected detour and I had found myself on the wrong side of campus, lost. A secretary took pity, fired up her motorbike and dropped me off at FERCAP's office. It was a modern glass building called 'Academic Affairs' on the edge of Rangsit Campus and it also housed the WHO TDR Clinical Coordination and Training Center. When I walked into its air-conditioned atrium it was the lunch break of a training workshop. I sat amongst familiar faces who offered me tea and fruit. Their discussion was focused on how FERCAP was effecting change. Juntra was speaking:

> In the old days, people tended not to *say* that they couldn't do something, there was a problem of losing face. Now the culture has changed. If they don't know, they should take responsibility: "I should be trained on x." That's what GCP is about. I think FERCAP has done a good job in bringing this to a certain level. Before it felt like it was like a jury - to give a sentence. We have to change that perception. Your job is to get the investigator to feel they need your advice on that. *They'll* come to *you* because everyone wants to do their research better. To change that attitude, which has been there for years. Many are better now.

Juntra's reference to a jury resonated with something I had heard before. Six months earlier, I had been interviewing Harsha, a layperson on a Sri Lankan ethics committee. We had been sitting in plush executive chairs at the long, black boardroom table of her employer's office, waiting for her secretary to bring us tea. As it arrived, I asked about her experiences on the ethics committee: 'So, what's it like?' I said. 'Well, Rachel,' she began,

> It's like a jury. Sometimes, the common man's view is taken up, and the questions that are asked by us three [laypeople] they are *so* non-medical. Sometimes, they give them ideas, they discuss while we're completely clueless, they go into detail for us. Sometimes, our responses give them an idea of how the common man might react. For example, if there was organ donation or something, the questions we ask - for example, how explicit is it, is it usefully explained? What is its history? Has there been testing on normal patients? The cross section of members is useful, as in a jury. I wonder, sometimes, whether we're just there to add acceptability to the Ethics committee.

Though the emphasis is different, the common comparison both women make is that an ethics committee is 'like a jury.' Juntra's concern is with judgement and the relationship between the committee and its applicants; Harsha's with the relationships within it, how different people deal differently with information, weighing it, making decisions, knowing why those decisions were made. My concern in this chapter takes off from both of these, forming a commentary on the

difficulties people experience sitting on ethics committees, and how they find ways around the negative connotations of judgement. The counter of a jury allows me to bounce comparisons back, illuminating in the process ways in which an ethics committee is both 'like' and 'not like' a jury. As the comparison progresses we see points that, approached directly, might slip away. I speak particularly of the model-like features of the Ethics Committee, how that model contains within it certain assumptions of what 'society' is and what it requires that concept of 'society' to do or be in order to operate. In negative comparison, I draw out the differing role of publics, expertise, laypersonhood and locality as a way of highlighting the ethics committee's ideals.

My interviewees were not the only ones to observe (or experience) a similarity between a jury and an ethics committee. To begin, I introduce a version of the jury-ethics committee comparison made by Carl Coleman. Coleman is an American lawyer who has worked closely with the WHO, and attended the FERCAP Conference in Shanghai. I draw on his conference discussion on the revisions of the WHO *Silver Book* (2000, 2011) below. At the outset however his academic voice, in conversation with fellow lawyer Lars Noah, offers us some points to think through what anthropologists will recognise as an old problem: social control (Ross 2009 [1901], Colson 1953, Gluckman 1955, 1972; Gulliver 1963, Strathern 1985). Their debate begins to reveal a division between governance through external sanctions, such as the law, and others considered internal, such as education and persuasion. I suggest that it is no coincidence that the discussion about governance through ethics recalls British mid-20th century public and academic debates on law and morality, given the replication of that era's basic antinomies in the language now used to speak about ethics. In the second half of this chapter, I address the relationship between ethics and the law, as perceived by my interviewees.

The debate

Coleman's article, '*Rationalizing Risk Assessment in Human Subject Research*' (2004a) found a response in Noah, whose reply '*Deputizing Institutional Review Boards to Police (Audit?) Biomedical Research*' (2004) forcefully counters the jury comparison. '*Why have IRBs at all?*' (Coleman 2004b) concludes the exchange. Racing across the pages of law journals, this academic disagreement splits open a dichotomy central to FERCAP's concern with governance. In brief, Coleman (2004a) draws strong parallels between IRBs and juries, and suggests training committee members in legal reasoning and the use of written opinions. Objecting, Noah likens the IRB to a peer review system, arguing that IRBs should instead focus their efforts on 'inculcat[ing] a commitment to

ethical behaviour' (2004: 291). Coleman considers this wholly 'inadequate', stating that 'this sort of vague directive to "do good and avoid evil" is so devoid of content that it provides no useful guidance for those genuinely concerned with protecting human subjects from unjustifiable risks' (Coleman 2004b: 301). What is of interest to me in the disagreement — and the reason I spend time summarising it below — is their differing approaches to the committee as a tool of governance and how these approaches illuminate Juntra and Harsha's experiences.

Coleman's article starts with a sense of suspicion, the kind that in powerpoint presentations on ethics usually takes the iconic image used on the 'Human Guinea Pigs' cover of Time magazine in 2002 (Figure 25): a blonde woman in a green hospital gown, caged, with a drip feed hanging from the bars (Lemonick and Goldstein 2002).[42]

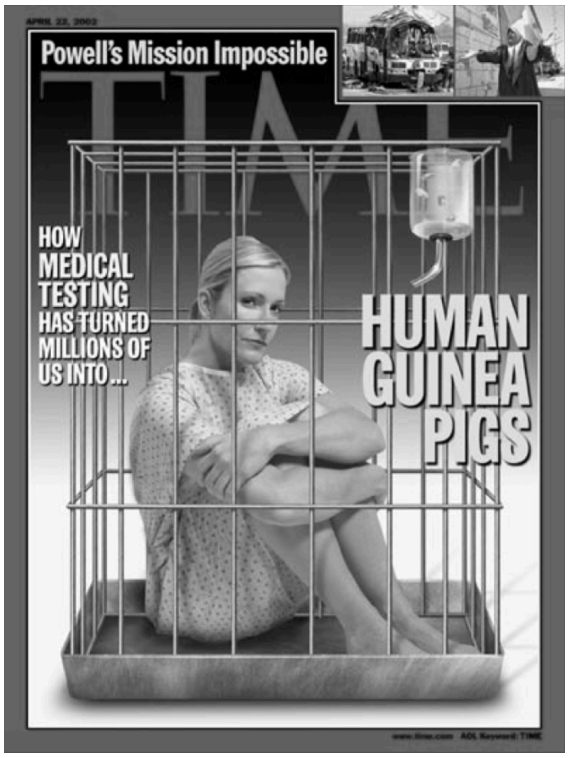

Figure 25: Time Magazine front cover, April 22, 2002.

'Americans', he writes, are 'deeply suspicious of medical research' (2004a:2). Fear of being experimented upon, the deaths of healthy research participants and the revelations of 'deep and pervasive problems' in 'systems' (2004a:2) lead Coleman to ask how public trust in biomedical research can possibly be restored. His article suggests the reform of IRBs. His premise is that in the USA, 'IRBs are engaged in a process of *legal* decision-making, insofar as they interpret specific

[42] April 22, 2002, 'At your own risk' was Time Magazine's cover story. More recent attention include a New Yorker article (Elliott 2008).

regulatory requirements pursuant to authority that has been delegated to them by administrative agencies' (2004a:4). Hence his comparison with the deliberation of juries. Ethics committees, he says, share with juries:

> a reliance on general, impressionistic judgments unsupported by specific reasons; the absence of any obligation to explain or justify decisions; a focus on individual cases rather than general principles or rules; and the potential for inconsistent determinations in similar situations. Juries are also justified by the same values of localism and community input that underlie the current system of IRB review (2004a:16- 17).

The thrust of his argument is towards the reform of how decisions by ethics committees are made, with a particular focus on risk assessments. Using the similarities of form that he detects, Coleman outlines decision-making methods used in law, such as the use of written opinions and reasoning by analogy (Sunstein 1993, Brewer 1996). He considers how IRBs could take up some of these 'strategies,' and in doing so, makes explicit the parallels he sees between healthcare and legal-judicial systems (e.g. Hadorn 1992).

In the Introduction to this thesis, I pointed to the localism that the idea of ethics review capacity building held implicit. Recall that calls came for local capacity building (Bosch 2003) when it was felt that a review that was otherwise competent in Geneva would be inadequate or inappropriate in some way if it were done for research that would be conducted elsewhere. 'Juries', writes Coleman,

> are justified by the same appeal to local values and attitudes that underlies the IRB system. The most common justification for jury decision-making is the jury's ability to 'bring[] the common wisdom of the community to bear on the resolution of the private dispute' and 'to legitimize that solution in the eyes of that community' (Brodin 1990:15). These justifications mirror the emphasis on localism in the system of IRB review (2004a:18-19).

He points out that familiarity with 'the actual conditions surrounding the conduct of research', is thought to give local committees an advantage over regional or national review. Drawing on the National Bioethics Advisory Commission's 2001 report, he cites the former director of the Office for Protection from Research Risks (OPRR) who writes that

> [i]t is local review by individuals who are in the best position to know the research at the site, the resources at the institution, the capabilities and the reputations of the investigators and staff, the prevailing attitudes and ethics of the community and most importantly, the likely subject population (Ellis 1994:31-32 cited in NBAC 2001:119).

With the development of multi-centered trials, however, 'local' review often leads to many committees reviewing the same protocol, and changes demanded by one can have knock-on effects for others. I explore the implications of both the multi-centeredness and localism below.

Noah's response to Coleman's original article makes evident that they share a common concern in the operation of IRBs: 'consistency and transparency' (Noah 2004: 269). What they disagree on is how to go about ensuring these principles are adhered to. Where Coleman has advanced an argument that plays to the strengths of his legal background, Noah insists that the parallel to juries is problematic, and that improvement can come from methods that 'do not necessitate mimicking the judiciary' (2004:269). In an earlier article, Noah expresses the concern that:

> IRBs may become preoccupied with reviewing the niceties of the consent form and perhaps less concerned about their separate obligation to make independent risk-benefit assessments about the research protocol, confident that potential subjects can "vote with their feet" so long as the consent form contains all of the necessary information (2002:384).

In his view, the comparison with juries is unsustainable, as he does not think IRBs 'resemble juries except in the most superficial of ways' (2004:271). He re-arranges the 'pieces of a puzzle' (2004:273) and offers an alternative comparison, suggesting that what IRBs 'much more closely (and appropriately) resemble' is 'peer review mechanisms utilized by the scientific community' (2004:268). He sets himself wholly against the 'recasting' of IRBs as 'adjudicatory bodies' (2004:267), a move which he says 'may appeal to those with training in the law, but the scientists and physicians who staff IRBs will predictably — and I think appropriately — recoil at any such suggestion' (2004:274). He suggests instead that 'IRBs may do the most good by helping to educate researchers at an institution about the basics of federal law, as well as working to *inculcate a commitment to ethical behaviour,*' with a

> flawless protocol crafted with extensive collegial input by an IRB following guidance from institutions around the country and accompanied by a thorough written opinion mean[ing] nothing *if the researcher has not "bought into" the process* (2004:292, emphases added).

Coleman and Noah are talking specifically about American IRBs, claiming the common goal of 'human subject protection' and asking how they can best work towards that aim. They sketch their answers between the poles of law-like enforcement and the encouragement of responsibility, each having sought to pull ethical review in their own direction. In the debate we have at least four versions of the comparison laid out already: that a committee is like a jury because it judges; a committee is like a jury because it deliberates and evaluates information; the committee is like a jury because of its localism; and a committee is like a jury because it performs a delegated legal role. What, then, are the problems of ethics committees that can be illuminated ethnographically through the jury comparison? I arrange the following sections around the implication of these four versions of the jury-committee comparison. Let us return to my opening observation at lunch, on campus in Thailand. Juntra tells us that '[b]efore, it felt like it was a jury — to give a

sentence. We have to change that perception'. Perhaps the jury comparison will help us find out why.

Judging

In 2006, the American press reported that Japan was embarking on 'an experiment with democracy,' with a plan to re-establish juries within three years. From 1928 to 1943, Japan had operated an 'American style' legal system, but a wartime lack of men (and it was only men who could serve as jurors) made the system impossible to sustain. 2009's new *saiban-in* ("lay judge") system promised consequences for the citizenry of neighbouring countries such as China, Taiwan and Thailand, all of whom were said to be 'calling for greater involvement of citizens in their legal systems' (Precht 2006). The international attention attracted by Japan's 'experiment' included a seminar held by Cornell Law School,[43] where the pros and cons of the new system were aired. 'Japanese people pay more respect to authority than to the individual and are afraid of being isolated by the majority,' Kiichi Nishino, a former judge now at Niigata University was reported to have claimed; '[u]nless a juror is bold enough to disagree with the legal professionals, then this system is meaningless' (*The Times* February 28, 2009).[44] Professor of Law and Public Health Jeffery A. Fagan said he thought it was 'a difficulty of human nature to argue with someone of a higher status'. These concerns seemed to be borne out in the comments of the first jurors on their experience: 'I don't like the idea of judging other people,' said Mr Number Two, his and his co-jurors code names designed to allay fears of retribution.

What the introduction of juries in Japan makes us aware of is that at no point in the IRB/Jury comparison in the American legal debate does status, hierarchy or even discomfort in making an ethics assessment arise. Yet these are issues of high concern for both Japanese and American commentators on the Japanese take-up of *juries*. From the material already presented in this thesis, we know that these problems have the potential to become serious, since in fulfilling the requirement for scientific expertise, reviewing members of institutional ethics committees will often know the applicants personally, as colleagues. In Chapter 3 we saw how Edith strove to find

[43] Citizen Participation in East Asian Legal Systems, September 22-23 2006. Cornell Law School, Ithaca NY.

[44] More recently, Professor Nishino has commented that 'The greater the burden people feel, the more reluctant they are to express their opinions. We should assume that fundamental problems with this system are hidden in voiceless opinions' *Japan Times Online* May 30 2012.

a way to comply with her American WIRB training, eventually introducing an electronic voting scheme which ensured each person's act of judgement was concealed. We have seen some of the tactics used by Surveyors to soften the impacts of criticisms, with people creating a distance so that the Surveyor could be considered 'objective', avoiding the potential referencing or inflection of personal relationships through the fiction of a corporate person.[45]All these tactics also neutralize potentially hostile or fractious tensions associated with the problem of judgement. In the stories that follow, I focus on the *education* of the Principal Investigator as a strategy, a committee's external means of dealing with the problem that (their) judgement causes.

The PI of my research notes is a multifaceted character, cast sometimes as an enemy, sometimes as a friend. PIs can be criminal, such as those at Tuskegee (Rothman 1991, Reverby 2009), or more recently, the Hwang scandal in South Korea (Hwang 2010). More often, they are thoughtless, 'cold', trained to think scientifically. At times they are objects of suspicion, such as overseas collaborators; they can be 'important persons' capable of swaying the 'objective' judgement of the committee if permitted to put their case in person, not in writing.

During a Survey in China a disagreement arose between Surveyors and committee members on a 'new practice' that the committee had introduced, ostensibly to smooth relations between the PI and the committee. It arose during Criteria 3 of the Survey, 'Completeness of Review Process.' The committee being surveyed had introduced something they considered a 'major innovation': they invited the PI to present their protocol to the committee during the meeting. 'We have an interaction with them and we've received a positive reaction to that,' one of the committee members commented. Questions that arose for the committee could be resolved there and then. Having seen a Quality Management-inspired emphasis in FERCAP, we might expect the Surveyors to approve of the apparently efficient innovation.[46] But they do not.

International Surveyor: That's good… It's a good idea.

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[45] Concern with judgement applies to both the ethics committee and to the survey. At times during analysis, the two would become confused in my mind, the styles, traits appearing to blur. This was as a result of how each was spoken about in the field: 'We are not police!' — a phrase uttered by Surveyors who have not come to investigate potential (past) crimes of the ethics committee but to help, in the hope that this spirit of cooperative support will encourage committees to be open about their difficulties (p. 53). 'We are not police!' — a phrase uttered by ethics committees who cannot, through lack of time and resources pursue the investigators, check up on them as they proceed with their research. Occasionally, commentators would begin by addressing their comments to the Surveyors, but end by speaking about the working of the ethics review committee. In the study of an audit of an audit, attention to how the two were conceptually kept apart and where they collapsed into one another was a constant challenge. I return to the implications of this observation in the Conclusion.

[46] Indeed, efficiency was one of the key drivers in a recent study into the presence of PIs during IRB meetings in the USA (Taylor, Currie and Cass 2008).

FERCAP: No, I think you should discuss first, and then invite the principal investigator. Documents should speak for themselves. It's not speaking for itself, then it should be revised.

SIDCER: Yes, the protocol should speak for itself. Decisions are based not on what you hear but what you read. Sometimes, you're affected by the person presenting. In China, we always hear 'famous famous'. You're not looking at how famous he is, it's the document he made. It affects your objectivity. He is famous, I'm not famous…Prepare questions first, don't rely on what you hear. The only reason to do all this [have the PI present] would be that the documents not clear enough for people to make decision. We should encourage people to do more documentation, 'cos thats what it *is* - that'll be there forever. Sometimes you don't capture what the person says, but it's in the documents. You may say many things, just to convince me. You listen to Obama and he convince[s] you. Doesn't mean its going to happen.

FERCAP: Sometimes their way of speaking influences you.

Local surveyor: You can document what the PI says at the meeting though?

SIDCER: But *you're* documenting. It's second hand. You ask [on] paper to say "we don't understand," it's all documented. That'll teach them. [It'll be] a learning experience for investigator to do next time. Make it very clear. I've seen conflicts arise when not very professional - it becomes personal. That's why you need objectivity - clarify what going to do. Lots of people who have skill to speak - politicians…

Local Surveyor: Politicians don't need a protocol!

In the discussion about the jury in Japan, what was at stake was the possibility of a juror disagreeing with legal professionals. Here, the Surveyors are concerned that committee members will be swayed by the presentation styles of the researchers, persuaded to allow research to go ahead. As Stark (2011a:239) writes in her overview of the crystallization of the current American human-subjects review system, 'researchers were increasingly removed from ethics deliberations because they came to be seen as contaminants, rather than aids, to sound moral evaluation.'[47] The other side of this concern is FERCAP's focus on documentation as a technique of

[47] Although see Stark (2008:784), which states that a more 'radical' move is to invite investigators to meetings, 'an unwitting return to an internal NIH strategy [...] phased out 40 years ago.' While the persuasive influence of PIs may have been removed, her recent work clearly delineates strategies by which committee members persuade one another through reference to different types of authority: professional, personal and publicly available information. This comment hints at another arena of research which stands to be opened, although it is beyond the scope of this present thesis: the way in which speech is moralised (Kipnis 1997:115) both by committee members and researchers. Kipnis terms this the 'nonrepresentational ethics' of speech. 'In the West', he writes, 'an ethic of accurate representation entails both emotional "sincerity" (accurately representing inner feelings in outward expression) and "honest" speech (accurate verbal representation) (Kipnis 1997:104). In his discussion of *laoshi* (translated as "honest") in China he discovers that '[b]eing "honest" or "dishonest" was more than a matter of representation; it involved the *purpose* for which one used language. False representations were only "dishonest" if they were done for selfish purposes (1997:104). Further research could examine parrhesia (Foucault 1985b) on ethics committees.

'objectivity'[48] The PI's absence is an opportunity for education, turning the distrust in the PI's tactics of persuasion into a (solve-able) matter of ignorance, in which good intentions could be preserved. As a Taiwanese doctor who had been working on an ethics committee for several years put it:

> I think all PIs have to be educated and because they…Everyone *wants* to do the right thing, they don't intend to do harm to patients. The problem is they don't know *how* to do that, so we have to educate. That's why I teach young investigators [...]They have to know patient rights and IRB and genetic study how to inform patient how to get informed consent, what is this, how to do the grant application. Older men — my age, nearly retired, 60 — you think that is not necessary, sometimes we take it for granted.

Education, then, is seen as part of the pre-emptive apparatus of the committee. The role of a jury, as the new Japanese jurors learned, is that of assessing the evidence presented and reaching a verdict. But in an ethics committee, the assessment is pre-emptive; no crime, except possibly that of omission, has yet been committed. It is thus *possibility* that motivates both the review, and 'education' in the committee's forward-looking temporality. The comparison highlights how an ethics committee regulates behaviour, and attempts to ensure ethical, moral action through intervention before the events that are assumed to hold potential for harm have occurred. Ethics, as a set of actions, a process, is in this view preventative. Its own potential lies in its scrutiny of the detail, its knowledge of the relevant size of samples or the necessary frequency of blood draws, its knowledge of the intended participants. Its potential as an activity both anticipates and is generated by the potential in research.

For IRBs, it can seem that oversight duties grow, but their ability to enforce change is limited. As one surveyor put it, 'an IRB doesn't have police power, but it has to ensure things are right.' As we have seen, 'continuing review' is a means by which this 'ensuring' takes place. While I have emphasised the necessity of decision-making, I would now like to foreground the erosion of the *finality* of decisions. Where trainers initially emphasised the history of bioethics, processes of deliberation and principles to follow, much more weight falls now on SIDCER Survey Criteria Four, 'Continuing Review'. An ethics committee must still make a decision, but committees are increasingly being advised to limit the duration of their approval. The protocol may change in the interim year, and so may the researchers. They may become less committed, and the requirement for renewal is a means of keeping them not only under surveillance but also remind them of their 'duties'. This shift does not, I suggest, lie in the discomfort of judgement nor in finding ways to

[48] e.g. Mahidol University, Thailand has a Change History document, which reports changes prior to the Survey included "9. Section 7.5 has been revised: (1) clinical investigator and ancillary staff may be called to EC meeting but are not allowed to stay during EC discussion' (Mahidol FTM ECS-004-05, December 2011).

neutralize it through reducing its finality, for at the point of judgement, a permanent positive decision would be favourable to the investigator. What the committee gains through limiting the validity of its approval is a maintained connection to that investigator.

The difficulty of performing continuing review arises during a workshop in Bangkok, when I discuss the day's sessions with an older man from a committee in the north of Thailand. What has he learned that was new to him, I ask? 'Many breaches!' he says, speaking of the cases we have heard. 'I can't tell whether it is just because they don't know, or if they intended [the breach].' 'How might you tell,' I ask?

> Well, if they get angry, defensive. We [IRB] have our reason, they have their reason. People we work with, we know them. Usually they come to see we're right. If in working, they come across an issue they can come to the committee. Well, they can but not many do. We are trying to help them. If there are no problems after the process we just guess its OK, smooth, but it is not necessarily OK. Every week we see lots of projects come. But we don't have the time to go and check up on them. We will not shock them [hitting motion] We'll try to help! Well, very carefully. Go see them, 'Hi , how is research going?' Little by little, approach the point, 'I heard someone went to IRB...'

The hope is that through education, PIs will come to 'see' ethics for what those who take part in committees see it as, a necessary protection of research participants: 'human subjects.' A member of an ethics committee in Taiwan spent an afternoon telling me about disputes between his committee and PIs. If staff and PIs 'don't have the same understanding and knowledge, then there is fight between the IRB and investigator,' he told me. 'We want them to *know*, to think it is very important.' His approach was to cast the problem as one of an imbalance of knowledge, ameliorated through education: *reason* will prevail. Asked for his opinion on a dispute that had arisen in a local committee, he had informed his colleague that:

> Ethical review by IRB is kind of business based on "reasonable" judgment. Therefore, I will not say which side of decision is right or wrong. But I think all can be discussed based on this reasonable person standard. I guess the IRB's decision is always of good intention, and sometimes might be a little bit exaggerated. The only effective solution for such dispute is continuing mutual learning between PI and IRB.

The education agenda therefore is directed towards a future in which judgement is hardly necessary, both the IRB and the PI have the same attitude and objectives, and the situation is marked not by tensions or disagreements about delayed research, but a by mutual understanding. We know, however, that this is not the case at present.

Deliberating: A continuous committee

Harsha, the Sri Lankan whose comments opened this chapter, had been a member of her committee for over a year. Coleman and Noah both acknowledge as a significant point of difference between a jury and an IRB that the latter is a 'continuous body,' 'whose members decide multiple issues over an extended period' (Coleman 2004a:19). Its comparative permanence contributes to the particularity of committee meetings as a social space, something I have begun to explore through attention to the room in the chapter above. Here, I examine that social space more carefully, arguing that during meetings, certain ideals of democratic decision making and notions of equality are acted out; ideals and notions which can cause difficulty for the committees I studied. I use the comparison with the transience of the jury to highlight some of the challenges of the ethics committee's continuity. From Harsha's initial comments on her very 'non-medical' questions, I present four interrelated conversations from fieldwork which detail how the issues of seniority alluded to above are hard to forget inside the committee room. First, my conversations with Peter and Camilla in Taiwan show the way the committee as a 'continuous body' in amongst a continuous body of colleagues requires careful management, and how ethics is regarded as a site of tension in professional affairs. I then offer the experiences of Vinaya and Malika in Sri Lanka. Vinaya uses her experiences in America to compare institutional cultures, which I then use to consider relationships on the committee. Malika's approach as a reviewer allows me to compare the relationships committees build with PIs and applicants to the ethics committee. Together, their stories demonstrate another stage to what Edith is trying to ameliorate with the blind vote in Taiwan in Chapter 3: the effects of questioning one's seniors and voicing opinions during decision-making.

Peter and Camilla

Peter, a Taiwanese researcher with whom I had spent time in China and Thailand, explained to me the dynamics of his ethics review committee meeting and the strains on its members. He had been involved with ethics committees for over ten years, and felt it was important for each member to air their 'different thinking' despite the tendency for this to lead both to lengthy conversations and 'conflict' in the boardroom where his committee held their meetings. He told me that the struggle in Taiwan was always in the boardroom, finding ways to reduce conflict between physicians and IRB members. 'Conflict' to him was not just conflict of interests but a

careful management of existing and future relationships. 'You must have good relations with colleagues,' he told me. 'In clinical service, it is teamwork, you need other people's help.' But this reliance on teamwork, he suggested, permeated the boardroom, and caused problems. Committee members needed to be aware of the decisions the board took not only for the sake of patients, but also for themselves: 'One day, if you disapprove something, maybe next time, "OK no time for you!" Some day they get promotion, they say "OK IRB, you have too much budget," and maybe they will cut you down.' The 'they' of Peter's sentence is the researcher, who stands to lose time and possibly funds if his or her research is delayed or 'disapproved.' Peter did not think these problems were contained to Taiwan. 'In Asia,' he generalized,

> People's relationships last from position to position, especially in older life. If there is someone you disapprove, if you kill the approval with your opinion, maybe they'll say "I'll revenge you." Your operation can affect the project of the IRB.

He had, in discussions with other FERCAP members, found that they too struggled with these 'same problems.' Citing the Dr Hwang scandal in South Korea, he speculated that if committee members were under social pressures to succeed, 'they might not check everything, approve something, and disgrace themselves.' However, he said the committees had recently developed ways to 'protect' the committee members. 'If there are 21 people on a committee, who disapproves, nobody knows.' This provides another insight into why electric voting was so important in Taiwan: 'you can show your different opinion and disapprove and nobody knows,' he said:

> Even in records of meeting, it doesn't show who speaks. Before we had names in the minutes, now we use member A, B, C. So we try to use that. So, with the subject protected, [we] also try to protect our members.

Peter's protection of committee members through anonymizing the minutes echoes the concerns reported for jurors in Japan, and Edith's invention of the blind vote so that hands would not have to be visibly raised. But some committee members feel that their opinion, and their assertion of it, is a virtue. I met Camilla, a Taiwanese former IRB member, in a hospital corridor, during lunch. I sat with my notebook on my knee, she rummaged in a backpack for some lunch and Peter, who was looking after me in the hospital that day, went to call his wife leaving us to talk. Camilla told me that she had just returned from a nearby hospital, where she gave a talk on Genetic Ethics. 'I went to threaten them!' she said, laughing.

> Because now, before you initiate genetic studies there are more regulations to be aware of. You need to focus more on privacy and confidentiality, more sensitive issues. So our government tries to educate people.

Her focus on education was largely as a remedial practice, a slow change that she believed would manifest its success in better research. 'I can't tell how much they change,' she told me 'but gradually they change their thinking of ethics:

> Medical doctors, they think of research; [the] patient, who cares? A lot of MDs, their mind is set on research but not really ethics, but may have an idea how to do this ethics thing. They might not think of it at all, before someone convinces them. [The] medical doctor way - "I treat you," their thinking is different.[...] Sometimes it is hard to change their attitude or thinking. Sometimes they still argue. It's a long time process to educate these people. Even in a committee you find doctors still doing things very unethically - after all the education, I am always shocked that you still see these kinds of people around, still.

I asked her to elaborate on 'these kinds of people.' She shrugged, and told me she had been one of them: 'When initiating a research we'd do unethical things, for consent - ignore things we were supposed to do. Just say "Hey, give me my proof - my IRB approval letter." [They] forget everything about ethical things.' Her criticism is aimed at researchers but she extends it to the committee — suggesting that under pressure, committees bend to the expectations and demands of their colleagues:

> In our committee, the Chair is high. It's very common here because of structures of hospitals or government or school. The hierarchy system is very strong and people are afraid to lose their job. Committee is a nice way to do this, 'cos we have backup from each other. We can speak out. [We are] not afraid to have a "big mouth."

I said nothing, writing furiously. She reflected on what she said for a moment, then seemed to change her mind. Her account of the committee as a form of challenging authority through group discussion dissipated as she went on to reveal that it was her enactment of this ideal of speaking out that led to her becoming an *ex*-IRB member. 'Well, I was kicked out!' she exclaimed, with a wry smile.

> They want smoothly run, obedient ones. [For me] it's about whether, at the right time are you willing, to speak up for something. Especially for ethics. You're *supposed* to speak up. That's our principle. It's the right thing to do, for myself and participants. You set your mind on the ethical thing and you do it. Not different to becom[ing] a martyr. I'm martyr of the IRB! Honesty, integrity, things you believe in. That's our problem [in Taiwan]. IRB independence.

There are details of a case that she does not reveal, but the point is made. Not everyone is equal, nor able to speak in the same way.

Vinaya and Malika

Asking questions was presented as problematic for some committee members in a similar way to showing one's opinion. While most interviewees told me they felt confident to voice their views,

and comfortable speaking their concerns in committee meetings, Vinaya — a Sri Lankan ethics committee member — openly told me that she thought people were afraid to criticize their superiors. 'They're afraid for their careers,' she said, 'even if they think something, it is better for them to stay quiet.' She served on a committee that had recently been reconstituted, 'new faces' brought in because the older group had been 'dysfunctional.' Comprising many 'senior persons,' the committee meetings had been poorly attended, with a minority doing the majority of the work. 'It takes time to think about the proposal and check it,' she said, speaking of protocol review. 'Very few senior people have that much time.' Having worked in the USA, she explained to me how her perception of authority and questioning had changed as a result. At home, she said, 'asking questions may hurt the person, and the person being questioned regards it as something not good because you're questioning your teacher or your elder.' In America, she had found that people did not find question asking derogatory, and they don't think it will 'hurt'. Vinaya found this to be 'a good way,' but at the same time, she felt there was no respect for older people. A solution to the problem of question-asking, she thought, was blinding the review, so that the reviewers did not know the name of the person whose research was being reviewed. 'I may be more free, then, to give my view,' she said. What that view meant, however, she was not entirely clear about. In the end, she told me, it was the chairperson and the Dean who took the overall decision, 'because everyone can't take the decision, we can give our views, but in the end, they take the decision.' She expressed doubt about whether the decisions being taken were 'correct':

> We look at whose research it is, so-and-so has been doing it for so long, influence, done so much for the country, they're faculty, and at the same time someone is trying to start, they may be harsher on the evaluation of that research. That has big reputation behind it, this doesn't. Animosities, maybe, or at the same time, friendship. There are large bloated egos in research.

In these two examples, the way ethics is conducted is affected by existing social relations, with an implicit critique being made by interviewees of this effect. But I often found that this equation was turned around, with ethics being used to *manage* existing social relations. A de-personalised approach — to employ standards that must be complied with — was considered an advantage, particularly when ethics review was being newly introduced to faculties. In Colombo, Sri Lanka, the Regional Collaborative Workshop held by our hosts and the ISBC project attracted attendees from several other universities and disciplines. One of the attendees was Malika, a social scientist at the Open University, who went back to her faculty to encourage the establishment of a committee in the humanities. When I interviewed her and her advisor, who had founded the committee, he explained that they had run a:

> step by step introduction of it, we made it known to everyone. In a sense, no proposal can deviate from the established mechanisms, it has to abide by the mechanism. There won't be any different treatment because you're my friend, or you're my enemy.

Relations — friends, enemies — find themselves circumvented through an appeal to 'established mechanisms' and the manipulation of the externality of rules. This is something we have encountered before, in Chapter 3 when Philippine secretaries Fiona and Karen used the organogram posted on the wall to mediate emotion. If an irate investigator visited the office and demanded to know why her/his application for approval had not yet been processed, they would be referred to the chart on the wall, in Karen's words 'to calm them.' Rather than having to deal with the relationship one might have to the applicant, both must turn instead to a third party, an 'outsider': the process.[49] In these moves, the appeal to externality recalls the critical early role of the air pump, the 'neutral instrument [which] factored out human agency from the product. The experimental philosopher could say, "It is not I who say this; it is the machine" (Haraway 1996:431, Shapin and Schaffer 1985[2011]:77). During research I became sensitive, then, to the way in which contact between the reviewers of protocols, committees, and PIs was framed. Malika told me that she often contacted the researcher applicant in order to answer questions she had.

> I contact the person if the application form is not well written, I get some things clear. Some people process the application in a hurry if they want to make the deadline. Some don't understand certain aspects of the ethical approval form. So in that sense, giving a call and getting[50] is very effective.

She did find, however, that PIs could be 'defensive', concerned about being penalized or delayed, and most were 'afraid of being rejected by the committee.'

What Camilla and Vinaya's comment about committees with 'high up' or 'senior' figures in the chairperson's role indicates is that s/he may well play an important role in sustaining existing hierarchies within a committee setting. Discussions over who is chosen for the chairperson are revealing. As one Thai FERCAP conference delegate commented:

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[49] Mann, in her study of jobseekers in contemporary Sudan, writes about '*wasta*', an Arabic word 'meaning both the possession of ties (a person can have *wasta*) and the person who intermediates on behalf of someone (a person can be 'one's *wasta*')' (n.d: 3). She vividly describes a professor at one of Khartoum's top universities who, having been repeatedly asked for job referrals and financial assistance, had developed an 'extra difficult' test as 'an excuse to reject *wasta*'. 'When the person failed the test, the professor would simply have to show her the numerical score and say '*Malish*!' [oh well!] It seemed that it was more difficult to argue when there was a number on the table' (n.d.15). Mann notes that in such cases, numbers have a moral function: 'they projected a form of professionalism impervious to sociality, the assignment of numbers allowed managers to resist social and moral appeals to 'help' and promised junior members of staff the opportunity to escape personal or political disagreements with their superiors' (n.d. 14). I suggest the repeated examples of appeals to — and the employment of — external lists, mechanisms, standards or flowcharts do much the same thing in these situations.

[50] Sri Lankan English in which 'getting' includes reference to the thing which is acquired, in this case, the information missing from the application.

> I'm impressed when I go surveying in China, and I see that the president is the chair of an ethics committee. They get a lot of support! I go back home and I ask my director to be chair. But you have to balance that. What are the risk and what are the benefit?[51]

The 'risk' was articulated clearly in attempts to revise standards for committee composition during a FERCAP conference session (see also Chapter 5). The standard detailing the chairperson had specified 'high level official,' which raised the concern of a Chinese delegate: 'Let's say, what about middle level official? If you don't perform very well, the president can remove you from the position the next day.' A South Korean delegate, who had previously been keen to promote the profile of research ethics in his country, said 'Actually the other idea was to get the head of the institution,' but, he pointed out, 'if the head of the institution is the chair of the committee and somebody wants to have a complaint against them, who do they go to? There's nobody else to bring a complaint to.' Cristina then intervened, noting that that the motivating concern was to 'ensure that the members of their committee felt free to express their opinions' and *weren't* concerned about saying something that might 'risk their jobs'.

This overt concern with the consequences and intricacies of seniority is part of a wider trend seen in Chapters 2 and 3. Where in the West committees may struggle to achieve the authority necessary to issue ethics judgements (O'Reilly et al. 2009) it is often the case here that those who are appointed to the ethics committee are chosen *precisely* for their seniority, and hence, authority.

Localism Revisited

In my overview of Coleman's comparison of Juries and Ethics committees, I noted his attention to how local review arises as a particular issue in multi-center trials. By far the most complex of trial templates, the multi-sited clinical trial involves the same trial protocol conducted over a number of sites. These sites may be all within the same city or the same state; they may be nationally spread, or, as Cristina noted when pitching FERCAP's program to the Cancer Center in China, they may be very widely distributed across different countries. In what follows, I draw attention to the use of 'local', watching as it shifts from meaning 'in country' to 'in institution,' with attention to the implications. While this section develops the concerns of those above, it can

[51] Another example of the way in which language shapes and shifts arenas: is this management speak? Or is it ethics? More importantly, the speaker's concern with 'risk and benefit' of the social dynamics of having a director as a chairperson illustrates how the balancing of research risks and benefits that ethics committees are required to do is suddenly made to apply to how committees are themselves arranged.

be seen as a prelude to the third section of Chapter 5, where I discuss in greater detail the make-up of ethics review committees.

Coleman's emphasis on localism comes from the contemporary USA, where as he writes:

> [t]he IRB system's radical localism reflects an intentional policy decision by the system's designers, who believed that the protocol review process must be entrusted to individuals familiar with local conditions and the attitudes of the population from which subjects are drawn (2004a:43).

In his view, these priorities 'mirror' (2004a:19) the way localism of juries, cited as the 'voice of the community' (Friedman 2002:89) The 'systemic' emphasis on localism in ethical review, he says, is:

> difficult to reconcile with contemporary sociological reality. While different parts of the United States clearly have distinct local or regional characteristics, developments in communications and transportation have made these differences far less pronounced today than they were when the IRB system was first developed (2004a:44).

He notes, therefore that (2004: 44) 'the system's emphasis on localism is already beginning to give way, due largely to practical considerations raised by increasing use of multi-site studies.' Multi-sited studies have caused discussion about the limits of an IRB's duties: 'do local IRBs have a general duty to prevent harm to research subjects outside their own institution' if they discover problems with a multi-sited study asks Jansen (2005:10). They may not approve it, but how can they communicate with other IRBs that are reviewing it, to alert them to the problems they have detected? (Jansen 2005, Freedman 1994). In an article discussing 'cooperative research ethics review boards', Koski et al. write that the success or failure of any of the models the review 'ultimately depends on institutions' willingness to relinquish some measure of autonomy and to trust Research ERBs that operate outside each institution's primary community' (2005:5). Similarly, Beat Wilder who has worked as the head of Clinical Quality Assurance with Roche commented at the FERCAP Shanghai Summit on multi-center trials in 2010:

> When we do audits of ECs what they notice is that one of the root causes [of multiple review] is a lack of trust. What is done by one committee is not necessarily accepted by another. This is very common. Even in a very small country like Switzerland until recently every hospital, almost every hospital had its own EC and they repeated the whole review and they were *extremely* proud if they could find an error that this other EC hadn't detected .. [this] was used as a justification that they need to repeat the review again and again across hospital and hospital.

This problem is replicated when multi-center studies become *international* multi-center studies. At the 2010 Conference in Shanghai, FERCAP hosted a pre-conference summit on '*Achieving a*

Harmonized Approach to the Ethical Review of Multi-center Studies', which took the local review of trials as its concern. In the words of Robert Ridley, then director of WHO-TDR:

> the responsibility of [multi-center] studies, by definition, rests with multiple organisations and multiple institutions. If you're talking about multiple countries, you're talking about different cultural and social aspects within the communities where those studies are carried out. So as the emphasis on ethical review practices increases globally, it becomes important to consider how we can cooperate to have a common or coherent approach to undertaking ethical review and determine what the responses to different issues are.

The local review of trials is largely the *raison d'être* of FERCAP's capacity building program and the SIDCER recognition program. As Juntra put it, a review elsewhere may be competent but the local issues can only be *imagined*. When one begins with this view, centralised IRBs appear at best a challenge, at worst a problem. Equally, the variable decisions of IRBs (Silverman et al. 2001) is regarded as a problem for multi-center trials, seen as a problem of inefficiency and wasted resources. Three solutions present themselves. The first is for countries to form what have become known as "Joint" IRBs: committees comprising members from several hospitals. These committees can review trials which wish to use several of those sites.[52] An article describing the concept of the Joint IRB in Taiwan, Chern et al. (1998) describe JIRB as providing sponsors with 'a predictable approval time schedule. They have a "one stop for all" JIRB in Taiwan' (1998:1277S). As the Taiwanese Joint IRB states (Figure 26), the joint review 'can enhance human subject protection in Taiwan and also increase Taiwan's competitiveness in attracting multi-center trials, even United States pre-New Drug Application (NDA) trials.' Interestingly, for my argument, the authors describe the status of the JIRB as 'the same as that of local IRBs from the perspective of Taiwan's Department of Health' (1998:1276S), the JIRB itself requiring recognition from local IRBs.

The more recent Thailand Joint REC (Figure 27) also highlights the importance of a JREC for processing multi-center clinical trials which were

> previously submitted for consideration by the ethics committees of individual institute. Each institute has different process, procedure and standard that needs more resources with more time consuming. The joint research ethics committees will be able to strengthen efficiency and economically approved process that draws increasing research fund to the country.

The second solution is to return to that outside viewer, the third man: instead of trusting one another, committees can trust an accreditation program (e.g. Scott 2001, and for critique see

[52] Existing similar models include Central IRBs in the USA (often commercial) and the Multi-center Research Ethics Committee (MRECS) of the UK (UK Department of Health 1997).

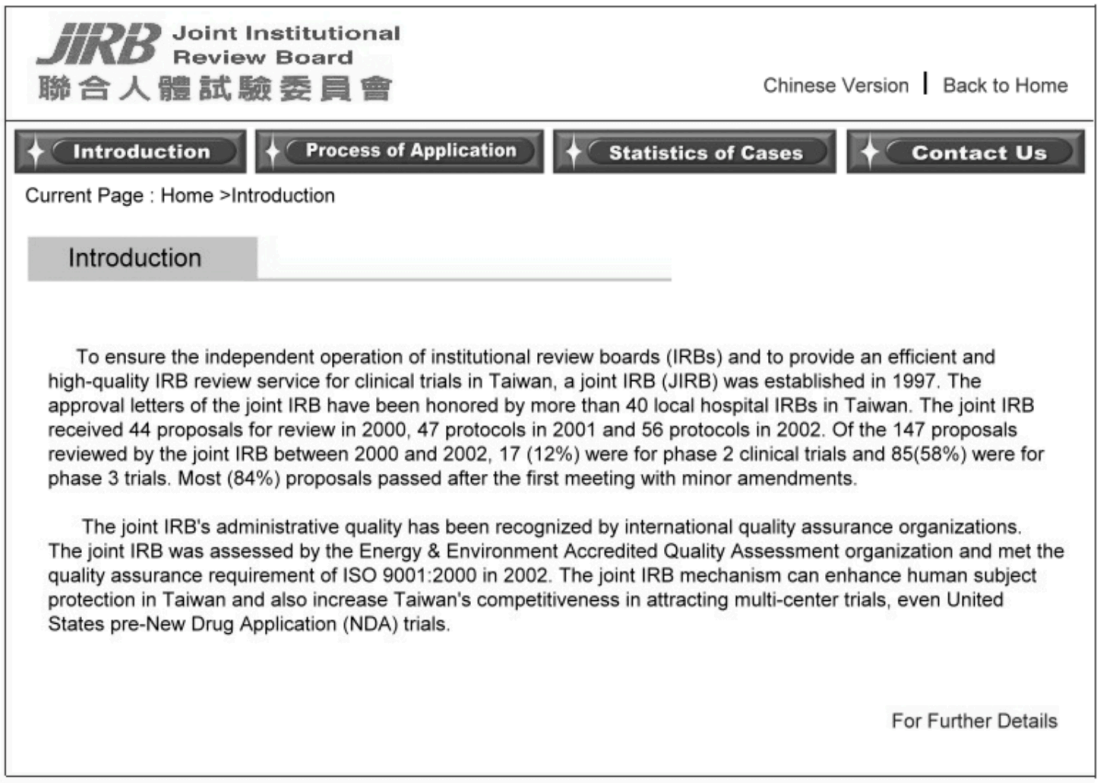

Figure 26: English language summary of Taiwan's JIRB

Figure 27: English language homepage of Thailand's Joint REC

Busch 2011: 220). This is where the continuity of the committee shapes it into quite a different entity from the momentary formation of a jury. Again, this is precisely the point at which FERCAP works. A third solution is to network. Coleman argues that in fact, 'many issues surrounding research are not location-specific, and that attention to local considerations is not inconsistent with more centralized review' (2004a: 44). He takes as an example WIRB, who address the problem of localism through the use of consultants and local IRB liaisons. As their website states '[t]he use of [...] consultants, as well as WIRB liaison with local IRBs where possible, allows WIRB to accurately gauge local attitudes and customs that could affect research.[53]

Figure 28: Western IRB's FAQ, displaying answers about International Clinical Trials

Coleman's example of WIRB's program shows another side to the International Fellows program: in training Edith, Cassandra and many others, WIRB also acquires 'a large network of regional representatives and local advisors' (Coleman 2004a:44). WIRB (Figure 28) is an example of review:

[53] Coleman visited the site March 9, 2003. The image included here was taken August 9, 2012.

> conducted by centralized IRBs, including "non-institutional IRBs" that are managed by private companies. These IRBs attempt to balance consideration of issues common to all research sites, with attention to special considerations likely to confront researchers in particular locations. (Coleman 2004a:44).

For Coleman,

> [t]hese developments appropriately recognise that many issues surrounding research are not location-specific, and that attention to local considerations is not inconsistent with more centralized review (Coleman 2004a: 44).

But there is more to this localism than knowledge of local facilities or staff. Coleman draws on Goldner (1993:95), noting that 'IRBs were originally designed to "serve as a surrogate for the community at large"' in a similar way to jury being 'the voice of the community' (Friedman 2002: 89) as opposed to the voice of 'formal law.' Turning to that 'voice of the community', American author Abramson (2000[1994]) has argued that localism in justice can be problematic. He recounts riots in Miami which followed the death of an African American man during a motorcycle chase. He was shot by an Hispanic officer:

> A local jury convicted the officer of manslaughter, but a state appeals court threw out the verdict because of prejudicial pretrial publicity. Florida authorities then went searching for a fair venue for a new trial. Tallahassee did not have enough Hispanics in its jury pool; Orlando lacked sufficient African Americans. After five shifts in the trial venue, the public had reason to wonder whether guilt in Tallahassee might turn into innocence in Orlando or vice versa: was jury justice so capricious? (Abramson [1994]2000: ix)

In contrast to Coleman's focus on the familiarity of individuals with local conditions and attitudes — in other words, a member's *knowledge* — Abramson's question ties the location of jury justice to *who* is present. His argument that it is 'precisely because we all inevitably view the evidence at trial from perspectives shaped by the lives we live in America, diversity is important to the accuracy of jury verdicts' (2000[1994]:xi). The implicit assumption here is that the lives lived are shaped by whether we are, for example, 'Hispanics', 'African Americans.' In addition, Fukurai (1996) notes that the U.S. Supreme Court 'has recognised the racial background of prospective jurors as an important dimension for evaluating jury participation', but points out that 'the court has yet to give social class "cognizable" status' (1996: 71). He consequently argues for the inclusion of 'social class factors' in the assessment of systematic discrimination in jury.

In the emphasis of local knowledge of ethics committees and the creation of centralised committees for a country, I suggest there are two things going on at once, an intermingling of what could be called logics of localism. The first is that the model which, in its concern with efficiency looks towards combined committees, particularly for multi-sited trials. Coleman writes

that changes in America since the introduction of the locally based system mean that few issues are really in need of local (institutional) attention. When the model of having a single committee upon which several sites rely is transported, however, what can result in a committee for a 'country.' This is evident in Taiwan's JIRB and Thailand's Joint REC. Furthermore, such committees retain their 'local' characteristic *when viewed from a distance:* Committees and their members are from the country, to an incoming international clinical trial they count as 'local' review. What Vinaya and Malika's revelations highlight however, is though people on committees may be equally local, they may not be locally equal. In attention to the former issue, the latter receives comparatively little attention.

The comparison of an ethics committee with a jury highlights this second point. I do not want to suggest that this is a problem particular to the committees I worked with: Abramson's dramatic example, as well as Fukurai's observations, open the question for the USA. Fukurai's efforts to highlight "social class" as a "factor" in jury selection and decision indicates that peoples' capacities for persuasion, their bodies ('revealing skill, charisma and pathology' (Law 1994:183) and the 'networks' they can draw upon matter (Latour 1988, 1993, Strathern 1996b).[54] What I suggest my analysis shows is that professionals represent their expertise and by extension, medicine. The laypersons represent 'society', but *not* their profession (whatever it may be). In this, the ethics review committee contributes to and sustains the asymmetrical relationships experienced by Vinaya and Malika.

Coleman's comparison of the jury and the ethics committee allows a productive analysis not only of the challenges presented by multi-sited clinical trials but also of the issues raised by them. It is perhaps not surprising that the IRB system struggles with Central IRBs given the assumptions about locality it borrows from the legal system. I explore these conundrums further in Chapter 5, through attention to 'roles' on the committee.

A legal role?: Ethics and the Fixity of Law

A close comparison of the ethics committee and the jury has allowed me to talk about problems of composition of committees and the importance of location in contentions of the rightness of

[54] Stark also arrives at the importance of persuasion in her analyses, terming the means by which committee members invoke public, professional and personal knowledge 'warrants' (2011b:22).

how much is known (and by whom). I now move away from that direct contrast, turning to the wider issues in the apparent poles of Coleman's and Noah's debate: the tension in the concept of ethics between compliance and aspiration, between external regulation and an exhortation to 'do good.' Their debate frames ethics review committees and juries as comparable on the basis that they are both instruments of the law. Indeed, as Stark (2011b) reminds us, in America, the ethics committee *is* empowered to make legally binding recommendations. This is not the case for many of FERCAP's committees. In this section, I explore the aspiration for countries to implement a legal framework, as this was expressed during the annual conference, and contrast it with the view of many of those I spoke to during research who did not feel that 'law' would be a suitable vehicle for change. In the final section, I explore some of the reasons why.

At the FERCAP conference in Shanghai 2010, I listened to the discussion during a session on alterations to the World Health Organisation's '*Silver Book*' (2000) which was undergoing the first revisions of its content since its initial publication. Subjecting the drafting of documents to ethnographic analysis has in recent years produced insight into knowledge practices. Riles' work in 'bringing together *responses* to documents' (2006:27 emphasis added) foregrounds them as 'artifacts of modern knowledge', central to contemporary organisations, position taking and fact making. By no means as deliberative as Riles' conference — 'it was not unusual to spend several hours on a single paragraph as delegates agreed to add a clause, to delete another' she remarks (1998:389) — the conversations here took place in a single conference session.[55] Carl Coleman was the lawyer who brought the draft to Shanghai for consultation, describing the long process of 'standard making' as one of the WHO's six core functions. 'The advantage of working through WHO,' said Carl,

> is that WHO has the power to convene, to gather experts from around the world and is recognised as a leader, so countries often adopt WHO standards as their own, or as a basis for their national laws and goals.

Carl emphasised that the draft was not intended as a replacement for national standards, rather as an encouragement for countries to develop their own. They were:

> to look at this as a guideline for how standards could be adopted taking into account that there could be some variations on implementation but that the minimum floor of ethical principles should be the same everywhere.

In the segment of conversation I reproduce below, we see standards in the making, not fixed as they will come to appear in the final document. Discussion brings out opinion and positions,

[55] One of many such sessions for the draft.

while actors attempt to modify policies that they hope to both achieve and use. The first standard, Carl says, is

> the broadest one, its speaking to the system itself and the standard is saying:
>
> *Relevant national authorities ensure that ethics review of health related research is supported by an adequate legislative and regulatory framework, that RECs are adequate to provide a review of all health related research exist at national, subnational and/or institutional levels. An appropriate or sustainable system is in place to monitor the quality and effectiveness of RE review.*

Out of the official language Carl draws three basic elements of the system: a legislative and regulatory framework, committees 'that exist and are adequate to doing the review' and 'a monitoring and oversight system'. He then invites comments on the standard, and those which ensue demonstrate delegates thinking through the implications of the standard in their own countries. A delegate from the Philippines stands. 'At present,' he says,

> we actually don't have the legislative, the laws, although we have Philippines FDA, we don't have an *FDA*, [our] FDA is more of ... although they're all regulatory they don't really function in a regulatory manner. I was just thinking how does one go about getting our lawmakers to pass laws that will create Ethics Committees for the conduction of ethical standards in each country? We have to lobby perhaps? Or if the lobby is strong, then I suppose the lawmakers will listen, but it's a long and tedious process to make our lawmakers to make laws about regulatory frameworks such as this one.

Carl replies:

> In fact that's one of the goals of this document is to have something that in a lobbying effort you can say, 'Well the international standard is that there must be a legal framework.' So the hope is that this will aid that effort.

Cristina comments:

> In many countries, the developing countries, like where I come from [the Philippines], many do not have legislation but they have guidelines, no? So, Philippines have guidelines, so that's the thing thats being followed. It's not as if there's nothing. India has guidelines. Sri Lanka has guidelines. Nepal has guidelines. So my question is would that refer to the system that you are talking about here: that the guidelines are accepted in the country and that's the one thats being followed by the different RECs?

Carl shakes his head.

> My understanding is that the idea is that there should be a legal framework. That guidelines are good and guidelines should exist but that guidelines in themselves wouldn't meet the standard of a legal framework.

Cristina persists, since she is concerned that a number of countries that take part in FERCAP will not be able to reach this standard:

> But in these [developing] countries, the guidelines are issued by somebody who has authority, like India, it's ICMR that issues the guidelines; in Philippines, it's the Philippine Health Research Ethics Board. In other words, these people have some authority but it's not a law.

The question of understanding the different legislative and regulatory systems in which these standards aim to operate causes confusion. As the delegates try to fix the 'levels' on which things can be done it is clear that part of the problem is that countries do not organise their governments in the same ways. Are those who issue regulation authorised through legislation? If regulatory is less than legislative, is it sufficient? What counts as regulatory? If legislators speak of the 'duty of medical colleges to regulate,' does that make them into regulators? The Sri Lankan delegate points out that in his country, legislation can only be made by government, which affects who the 'relevant national authority' being addressed is.

> So if we are to use this document as part of lobbying, to get governments to get laws enacted, then you must say 'national governments should ensure'. It needs to addresses the government as the responsible authority in enacting the law. And I think that's what is going to strengthen our hand if we are to go to government and say 'Look, WHO is saying that you must do this.' So I think we mustn't undermine that because yes, the Forum of Ethics Committees in Sri Lanka (FERCSL) [...] have guidelines, but those have no *legal* authority and that is the reason why we have a lot of problems of enactment.

Indian delegates agree, arguing for regulations over guidelines, feeling the latter are 'not mandatory so if people do not follow them you cannot take [give] punishment'. The delegate from the Philippines puts it best: 'I feel the standards are supposed to be aspired for, not the standards conforming to what is reality but reality being improved to conform with standards.'

During FERCAP conferences, then, legislation is usually formulated as an absence, where countries *with* legislation list it amongst their achievements, marking routes of progress on powerpoints. From the perspective of the American commentator whose question to Cristina opened this thesis, it was considered remarkable that FERCAP is able to conduct its activities in the absence of legislation. From Leslie's Sting story in Chapter 1 and the recent work of Stark (2011a, 2011b) it is evident that the law has a significant role in managing the social relations perceived in science in the American domain. But one could also argue it is a form of collateral (see Riles 2011), sought by science and ethics committees alike against negative possibilities. Depending on the amount of legislation on biomedical research in a country, committees wanted lawyers as their laypersons either to preemptively anticipate problems, or review those which might go against existing legislation. This varies a great deal across the FERCAP countries: where

Sri Lanka has a very light history of litigation against medical practitioners (Fernando 2002, Goonaratna 2005, Ruwanpura 2009), in China scholars report fear amongst doctors of performing complex surgeries because of possibility of a lawsuit (Zhang and Sleeboom-Faulkner 2011:460).

During an interview with Lakmini, a Colombo University lawyer who also served on an ethics review committee, the topic of having ethics set in law arose. Lakmini accepted that from the point of view of committees, it would be 'useful' to have a legal means of ensuring that ethics was 'kept' but she reminded me that the law was something static. 'Here, it is archaic,' she said, 'not amended in years. What happens is society outstrips the law, and the law becomes redundant.' This, she said, would cause problems were ethical principles to be enshrined in national law. The courts, she said, were slow and weighted.[56] 'Law,' she said, 'strives to divorce itself from ethics and morality,' citing the debate in the UK over the limits of criminal law between Lord Patrick Devlin and Professor Hart during the 1950s following the controversial proposal of the Wolfenden Committee to decriminalize homosexuality.[57]

> This raised huge issues for us, the divorce from religion — [the idea that the] secular should regulate morality and ethics with it. That's the fear: when you fix law with morality, there's the danger of having it be stagnant.

An interview with a neuroscientist in Colombo repeated the sentiment that ethics ought not be set into law, but his reasoning was that *ethics,* not 'society' changes. 'As far as the law is concerned,' he said,

> it is written there in black and white. Ethics is not, OK? It comes from within. And it changes over time, we see it in the world. What is ethical now was not ethical then, and we should keep up with that. We should be open to understanding the basis of what changes. And if we don't keep up, we'll get crowded out by other jurisdictions that permit something. We shouldn't just say that shouldn't be permitted and leave it at that and have Victorian attitudes.

'What do you mean Victorian?' I asked.

> Well, you can't be Victorian about it. At the last meeting, someone said, 'We will create a Frankenstein.' Those are antiquated views — as long as it is not unlawful, it can be done. If it meets criteria, and is properly monitored, and the parameters are set then OK.

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[56] When we spoke in May 2010 Sri Lanka's 35 year long civil war had recently ended, and the priorities of the legal system were weighted towards its aftermath.

[57] The committee (1954-57) made proposals that prompted the now famous mid-20th century debate between Professor Hart and Lord Devlin, see Cane 2006 for details. The debate was also the origin of much of the 'harm' based discourse, see e.g. Feinberg 1984, 1985, 1986, 1990.

But the 'lawfulness' of something in Sri Lanka is largely unknown. He tells me so himself:

> Our regulation is very weak and I dare say very grey. [...] The way I see it, there is no probability or possibility of that type of legislation ever coming out for several years, there is not sufficient awareness or focus. So it is important for ethics committees to try and work out modalities which might serve the needs of the research as a stop-gap. We can't wait until Parliament or the Ministry of Health or whatever makes these regulations to start research, because it'll never happen. That seems to be the primary problem the ethics committee has....do you permit people to engage in research and be competitive, or am I worried that the Buddhist clergy will come and protest against me? There is no public debate at the moment but all it takes is a tiny thing, just a little cinder and it becomes huge.

I played the devil's advocate: would not something 'huge' help his case, bring attention, awareness, focus and prompt legislation? His answer was revealing:

> Well you see, a public debate would not be rational debate. People will want to score points and gain votes. It's the same with other things, they say tourism is destroying the culture in the villages or something. And let's be frank, these issues are very complex and there are very few politicians with the brains to sit down and understand it: maybe one or two. As for legislation, I don't think it will come about for a long time. That is why ethics committees play an important role, because they set down certain guidelines which will be used and drafted if the government comes to make laws. They'll look at what is existing and use that. That is the heaviest burden the ethics committee caries with them. I can't see any bureaucrat sitting down to draft guidelines. The committee is the best possibility at the moment. The composition has doctors who are highly regarded, modern in their thinking, it is a diverse group and composed of people of all religions, communities and ages.

The neuroscientist's comments echo Cristina's wish to see FERCAP lead not through agitation of the masses[58] but through the education and support of professionals. They also reveal a further 'burden' on committees operating in the absence of governmental support.

Both the lawyer and the neuroscientist held that rather than law producing change, it was too fixed to adapt to changes in 'society' over time. The temporality of ethics — 'when' ethics was from (not just where) — was a point raised several times in discussions. When one of my Sri Lankan interviewees told me that the Ethics Review Committee was 'quite an old concept,' I thought she was referring to the relatively early establishment of committees in Sri Lanka during the 1980s (Dissanayake et al. 2006). However, what she meant was quite different. An inclination towards thinking in ethical terms was, she argued, already present in Sri Lanka: 'the thought is

[58] They also echo the debate between Lippmann and Dewey (recounted by Marres 2005:217) in which we are reminded that 'issues call a public into being'. Jasanoff (2005) makes this point symmetrically, arguing that political cultures shape how science is conducted at the same time as changes in science and technology create styles and modes of political culture.

there already,' she told me, '[but] without realizing the values are there, we copy and follow whatever comes from developed countries, thinking it is good. I think we must find our own values.' The interviewee had trained as a lawyer, and explained what she meant by referencing an International Court of Justice (ICJ) case on the contestation between Hungary and the Czechoslovak People's republic over the resources and control of the Danube. The judge in the case, a Sri Lankan, had used the following story as a way of explaining the long heritage of the concept 'sustainable development' in Asia:

> Long ago, I don't remember the period, monks were sent from India to Sri Lanka, to do preaching here. When the monks came, the king had gone hunting. They told him, "Don't kill animals. You must be the guardian of the people, the animals, the land water and air. You must not destroy or spoil them." The ruler agreed, and undertook to protect [them]. Now, the judge cited that incident. He said "We don't have to look to the Stockholm declaration, we have the conventions already in our system. It is you who must search for them." We have that, already, in Asian culture.[59]

The sense that ethics was already somehow located in 'culture' (cf Sariola and Simpson 2011: 518) led some interviewees to opine that it could not be codified. A Sri Lankan doctor told me that

> a code to implement ethical principles is absurd. It would be sad if it goes to that level. While you can have regulations and guidelines, sanction based [law] should not be there. Professional bodies and ourselves should enforce it. Of course it is a subjective thing. It'll depend on cultures, it is not something that a rigid legal system can say what is right. In a group among ourselves, the group will know.

He laid his understanding of ethics out for me:

> At the highest level, is the criminal. State is the other side. For example, if A kills B the state makes a case against A. It's beyond the individual, it is a crime against society, society persecutes the perpetrator. Then there is the civil level. Say A and B have a land dispute. The damages are paid from A to B or vice versa. There is a code of law that mediates the whole thing. But ethics is at a lower level, where there should not have a third partner to enforce. What is the right thing? Humans should have the judgement in themselves to do this.

The doctor's idea of 'levels' at which law and ethics intersect reveals his conviction that while law should mediate large scale disputes, ethics, at its 'lower level' pertains to and should come from 'human' judgement. Legislation on ethics, in this view, would be out of place.

While the focus in these examples has been Sri Lanka, as we saw with the comments to the revision of the *Silver Book*, the idea of legislating for ethics carries force elsewhere. During an

[59] In 1997 Justice Weeramantry, a Sri Lankan, was serving as vice-president of the ICJ, and the contribution is recorded in ICJ Gabčíkovo-Nagymaros Project (Hungary/Slovakia) (Summary of the Judgement of 25 September 1997)

interview with the chair of a committee in Taiwan, he explained that he believed research there had 'progressed fast' because they had 'used law regulations to do regulation'. The advantage, as the chair saw it, was that this had ensured that ethics was 'not only for moral problem'. Again using the language of levels invoked by the Sri Lankan doctor above, he said that using legislation as a 'level of regulation' above that of 'moral issues' and turning ethics into 'law issues', meant ethics could 'live on the level of these issues,' and the government could 'use this power to push ethics'. By elevating ethics to the 'level' of law, the chairman said, investigators were made to take it seriously: 'We believe research and ethics here will develop fast and live on a very high level.'

The take up of ethics has been described by these interviewees in a language of 'levels', from the governmental as the 'high' and the personal as 'low'. But the high and the low do not simply represent opposite valuations of ethics: while the Taiwanese interviewee made ethics 'high' and commensurable with law, many of my Sri Lankan interviewees placed a value on ethics as being more of a personal, 'low level' quality that could not, and should not need to be codified.

While Coleman and the Taiwanese interviewee above have sought and framed ethics as a matter of law, Noah and the Sri Lankan doctor above both associate the law with an objectionable de-personalisation, inadequate to the 'aspirational' qualities they attribute to ethics. According to this line of critique, by setting 'the minimum standards of conduct' (Aubert 1979:34), the law instills 'a morality of obligation, not one of aspiration' (Fuller 1964 in Aubert 1979:34). Similarly, the USFDA summons an idea of ethics which goes beyond mere compliance with the law: 'responsible research is ethical, not just compliant…Because the regulations are the ethical floor, not the ceiling' (New Research Challenges Newsletter 2011, see also Goodyear et al. 2008; 2009 Declaration of Helsinki (WMA)).[60] Ethics, it seems, is expected to be something more than just compliance, or just law.

Concluding remarks

'It's hard to imagine how Americans could fulfill their role as democracy advocates any better than helping the Japanese become jurors,' wrote Robert E. Precht in his 2006 *IHT* Opinion piece,

[60] In 2008, the USFDA declared that clinical trials performed outside of the US no longer had to conform to the declaration of Helsinki (DHHS 21 CFR part 312). Goodyear et al. (2009: 1559, emphasis added) argued that 'despite assurances by the FDA, GCP is not an ethical code, but a procedural regulatory manual based on the regulatory frameworks of the US, Japan and Europe. Thus it is a description of existing procedures, not an *aspirational* document.'

where he recommended an exchange program in which 'Americans can visit Japan and share their jury experiences and Japanese can also visit American courthouses and talk with American jurors.' Just as the jury was seen as a turn towards democracy in Japan (a politics encapsulated in a form[61]) ,I have in this chapter begun to give voice to the assumptions that travel with the committee's bureaucratic form. While ethics committees are not seen as cornerstones of democratic participation in the law, they do contain principles of representation, equality of view and voice.

This proximity between law and ethics as modes of governing gave rise to Coleman and Noah's debate. Coleman reports that 'a 1996 General Accounting Office study found that IRBs are are overburdened, underfunded, insufficiently prepared, and often too willing to rely on investigators' *good intentions* as the primary method for protecting subjects,' (2004:11, emphasis added) a situation he finds untenable. Despite Coleman's and Noah's disagreement on how it is that subjects should be protected, I suggest that the anthropological insight here can be to the way in which the debate is cast. The poles of Coleman and Noah's debate re-emerge in the ethnography: governance through external legal mechanisms or through inculcating and encouraging ethical behaviour? These are the issues of legal anthropology, being replayed out of debates on social control, in debates on the nature and use of IRBs. In her essay *Discovering Social Control,* Strathern observes that anthropologists were drawn to the study of social control because 'they appear to validate the act of describing behaviour as an endeavour separate from the behaviour itself' (1985:112). The resulting studies, which find social control 'in institutionalised form' allowed anthropologists to find the law 'set apart as a realm of interaction which deals with, modifies and above all comments on other realms', a move which was a 'hierarchical analogue to the activity of describing society as such' (Strathern 1985:112).

I suggest that the ethics committee — in design and implementation — is a replication of the Western idea that law and regulation is about external structures of governance; one realm (ethics) which comments on another (biomedical research). Ethics, in Chapters 2 and 3, is presented as a set of behaviours brought in by FERCAP, codified in Standard Operating Procedures, rooms and discussions. But the material in this chapter has explored the limits of this view. What the Sri Lankan material in particular presents is an idea of ethics not as compliance with the law, but as a personal orientation, a point which is echoed for example in the USFDA's concern with a turn towards conscience, not compliance (Kahn and Mastroianni 2001, Taylor 2007). These are themes

[61] Although for critique of the form the jury has since taken in Japan see Rozenshtein (2011).

I develop in Chapter 7. For now, in the light of the data provided in this chapter, I want to ask again how is it that committees set up in Asia are composed and run? What is this space, in which all must be equal, but some are afraid to speak? As Shapin (2008: xvii) asks, 'What relations obtain between the authority of knowledge and the character of knowers?' I explore this question in the next chapter.

Chapter 5: On Roles and Perspectives

At the 2010 FERCAP conference, Dr Dipika, a member of an Indian Ethics Committee, described a new monitoring procedures she had helped to implement. A death in a study, coupled with a new SOP for the monitoring of studies approved by the committee, had led to the innovation of EC members visiting sites, speaking to staff and patients. By doing this, they hoped the monitoring would keep better track of studies, and help ensure good conduct. But the monitors had found a startling number of problems, and Dr Dipika listed them for her audience: the protocol being used was not the same as the one approved by the committee. The informed consent sheet in use had not incorporated the requested amendments of the committee, patient signatures were missing. 'How can we rely on this data if the signature is missing?' Dr Dipika asked her audience. Worse, English speaking patients had been given Hindi informed consent documents, a translation that had not been approved by the ethics committee. All this led Dr Dipika to cast doubt on the data being produced by the clinical trial: 'I don't know what the integrity of the data is,' she said.

Rather than expressing concern for the findings of the monitoring study, the discussion following her presentation took issue with the right and capacity of the ethics committee to do 'monitoring'. A WHO representative said:

> I congratulate you that your EC is really committed in terms of monitoring, it is very competent in terms of monitoring, and if it's an ICMR requirement, OK, but I don't think it is a WHO-TDR requirement, and it's not going to be easy for other ECs to do this because it's very intensive and requires expertise.

Others agreed: 'I don't think even 1% of the people in this room can do that. It is intensive and expensive'. Speakers worried about adding more tasks to those carried out by what are, in Asia, largely volunteer based positions. This delegate tried to make her concern felt as gently as possible:

> I'm just, in my opinion, because I *do* monitoring, I train the monitors, I train EC members. I know how hard and difficult it is, to already just sit there as a member of EC to do the job they're supposed to be doing well. So if you add *another* task to members of EC, say do what you do, details of being audited, that is another expertise. For me.

A colleague of Dr Dipika's spoke up in support of the initiative. In her view, Ethics Committees could, and should, also do 'monitoring': 'A clinical monitor does it different[ly], this is EC monitoring, from the *ethics perspective*,' she concluded.

The argument that ethics requires — and can enact — a different viewpoint, premise or way of seeing, as Dr Dipika's colleague suggests above, is one that has been made by research ethics committee members and trainers elsewhere in this research (see Chapter 2). My central question in this chapter concerns 'perspectives,' and what they reveal about conceptualisations of 'society'. The chapter is split into four parts. The first deals in detail with the committee as a group of people sitting around a table. I extend the discussion that emerged around the validity of Dr Dipika's monitoring exercises, the problem posed by a view from 'an ethics perspective', and examine how committees are formed by, arranged around, act upon and make statements which all, in varying ways, rely upon the concept of perspective for their validity. If a monitor from an ethics committee can enact a different perspective from a clinical monitor, what happens when we examine the constitution of that 'committee' perspective? I begin with members of the committee, and the way in which the work of committees is constituted thorough the language of perspectives. The method is discussed by Mol (2002) whose book, she says, 'does not speak of different perspectives on the body and its diseases. Instead it tells how they are done' (2002:vii). What does it mean to 'do' or practice a perspective? For Mol and athlerosclerosis, the practices are slicing, colouring, probing, talking, measuring, counting, cutting, preventing. She pushes away from epistemology, 'concerned with references, [...] whether representations of reality are accurate' and towards 'the way objects are enacted in practices...[and] the way in which problems are framed' (Mol 2002:vii). From the chapters so far, we have seen that the ethics committee explicitly brings together 'different perspectives' as an exercise in representation, and thus appears to be very much about, in Mol's terms, "the epistemological". Using a conversation with Cristina and Juntra about a water bottle, I show how the ethics committee is a device which frames problems, and ask what it might mean to 'do' perspective in a committee.

In the second part of the chapter, I look at the committee as a form for managing the problem that 'no matter how many perspectives are assembled, they all create perspective' (Strathern 2004a [1991]:108). I consider the techniques that the committee uses to contain the potentially infinite expansion of perspective and still retain a claim to legitimacy. In section three, *Reflect, Represent, Have Knowledge Of,* I again take up the conference discussion on the modification of the WHO *Silver Book* discussed briefly in Chapter 4, this time focusing on Standard Two, which deals with committee composition. In turning to the ideal make up of a committee, this conference discussion summons three relations between 'society' and the committee: reflection, representation and 'knowledge of.' An ethics committee is considered to already be in a relationship of obligation or duty to the 'society', *as well as containing it*. Participants in research,

taken as individual through their single bodies, or multiple as communities, societies, nations, reach endpoints both in a *general* 'humanity', and the *specific* 'human' subject of research. How does the ethics committee position itself relative to these conceptualisations?

In section four, I develop the consultation material to show how various *perspectives*, which come to be understood as emanating from society, transform into *roles* in the course of the consultation discussion on that draft. The role given to those who hold the perspective of a 'layperson' provides an example of this process. The example of the layperson, in conversation with section three, also helps me develop themes raised in the previous chapter: reconciling the idea of an equal conversation about ethics with the need for an expertise-laden scientific assessment.

A table and a plastic bottle

Let us start with the committee in its most simple description: a group of people sitting around a table. A conversation from another instance of people sitting around a table, a lunch table this time, provides a story through which we can understand what this 'simple' image carries with it. At a GCP training at Thammasat University, Juntra, Cristina and I were discussing decisions in ethics review committee meetings. It was a theme I had been interested in exploring since the outset of research, curious about how decisions were described as being made and how they were negotiated in practice. As trainers, Juntra and Cristina thought it was important for committee members to not only draw on their expertise, but to bear in mind the patient, protocol and contribution of the research to society. From this breadth, Juntra's first concern was to avoid discussions which led to position taking:

> In a debate, if you adopt a position, you take that and see if you win or lose at the end. You won't compromise your position. But it's not about winning or losing, that's not a good attitude for an Ethics Committee.

Cristina agreed:

> It's not who you are, [if you take a position] you won't be moved, so it's not what you really think. Real life is about decisions, not hypothetical unreal stories. In an ethics committee, everyone should think: 'How could we come up with a decision appropriate for that study that will be the best for people taking part?' The minute you take positions, you try to protect them. All you have is that position. If, instead, all of you have one position, how to contribute to the protocol — if you have *that* position, you can have your eyes open for another's view.

Juntra, who was sitting opposite me pointed to the water bottle between us. 'I can't see the other side of your bottle,' she said. 'Our job, is to ask "how can we describe the whole bottle?"' Cristina nodded, saying:

> Heijan[62] has a nice picture of this. There are three blind men and they are all holding different parts of the elephant. There's this elephant and you touch different things, one has the tail one has the foot. And you say the elephant looks like this, but you only have a part. But together, they'll be able to describe what the elephant looks like.

Ethics committee meetings invariably take place around a table. Indeed, a regulator at the 2009 FERCAP conference fixed them there with the remark that committees 'can't be two people in a corridor, but a meeting around a table'. The table is therefore part of making the committee meeting recognisably a committee meeting. Juntra intends the bottle between us as the applicant's protocol, forcing the bottle into view not only from the literal perspectives of those around a table at an ethics committee meeting, but also their figurative perspectives. That she and I can literally see different sides of the bottle is equated with the different (figurative) 'perspectives' that the members on the committee will bring to the discussion: they may have clinical experience, they may have knowledge of the law. When Juntra uses the bottle she is calling on a literal example of perspectives to illuminate a figurative perspective. In an ideal discussion, we describe the whole bottle — the whole protocol — and what it looks like seen from all sides. The imagined objective of Cristina and Juntra's committee view on the protocol is one which finds resonance with 'a kind of cubist presentation in which every side of the object is presented simultaneously to us in a single — though 'general' — perspective' (Holbraad and Willerslev 2007:334): the decision of the ethics review committee.

It is when figurative *perspectives* become *positions* that Cristina becomes critical: 'the minute you take positions, you try to protect them'. When, during a mock review at a training in the Philippines the trainer announced that 'in ethics committee, you can change your mind as you discuss,' the statement was greeted with applause. 'It is not like a debate, where you stand by what you believe, no matter what,' she said. In thinking through her response to the idea that tolerance might be an obstacle to the open discussion of controversial issues (Trosset 1999), Strathern (2006: 192) observes that

> while you can hold a viewpoint and relay it, you cannot argue from one. In order to argue, you need to have detached yourself from - divided yourself off from - competing positions that you might otherwise (in some other life) have occupied.

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[62] See Chapter 2, p.84.

Cristina's comment on 'positions' echoes this observation, and is critical of such detachment. What Cristina is recommending instead is the holding of a common perspective ('one position'): that of improving the protocol. Using the water bottle as she does, Juntra is using figurative language to get around what Holbraad and Willerslev see as the stumbling block to a 'view from everywhere': that 'we can never actually see things in their totality, simply because seeing in its nature is embodied and therefore perspectival' (2007:334). But what is the embodied nature of ethics committee decision-making?

Bodies and decisions

In Chapter 3 I recounted a moment during a Survey in the Philippines when Cristina was asked by a trainee, 'Isn't it the point of having a diverse composition, to get diverse points of view?' She responded with the importance of decision making: 'When there's a difference in opinion, you arrive [at a decision] by voting [...] You cannot be deadlocked. The Ethics Committee is about decision making.'

We have seen why it is socially advantageous for the anonymity of the reviewer — their point of view — to be concealed within the 'full board,' but here we see another reason: 'In full board discussion your opinion can change, the final decision is a board decision, not an individual one'.

In Chapter 3, I showed how opinions voiced in committee rooms become notes, become letters that change protocols. We have also seen how the arrangement (and disciplining) of bodies in physical space betrays ideas at work (cf. Mitchell 1988: 78-79). Even though Juntra is locating the perspective in the body, her figurative location of perspective is in the minds of the attendees, differently trained, with different knowledges. In an ethics committee, perspectives are thought to be brought in and made present by the bodies of the room. They are, like the table, the materiality of ethics. What it makes visible with regard to those sitting around the table is how perspective becomes tethered to identity. An ethics committee is not, for example, arranged with a circle around the chairperson, nor could it take the form of stage and seats: the idea is not that the chairperson is superior in wisdom or knowledge to those who accompany him/her. This in turn demonstrates the concern of the form with democratic reasoning. Yet as we have seen above, members of ethics committees are persons often chosen for their seniority. How to reconcile these things?

Mol observes that,

> perspectivalism puts doctors and patients on a par, with a great divide between them, because they cast their views from different angles. The traffic across the doctor patient divide attracts much public attention [...] A perspective from one point of view differs from that of the other (2002:20-21).

Commenting on Mol's work in *The Body Multiple*, Strathern observes that Mol

> deliberately takes this conceptual stance against the widespread language of fragmentation that perspectivalism generates, for perspectivalism (I would add) rests on a mathematics that seeks to resolve the world into discrete entities: a unit that does not seem to hold its parts together seems thereby to fragment (Strathern 2011a:92).

The sense that the discrete unit 'global clinical trial system' may not hold all its parts together — that it may fragment — has been a concern voiced at the FERCAP Conference, inspiring Koski's image of the finely woven silk cloth we saw in Chapter 1. When attendees are prompted to imagine how this global system works, and their place within it, capacity is being built. Imagining is the skill. The same can be said to to occur here, on the ethics committee itself. The parts of the committee, chair, secretary, laypersons, reviewers and experts learn how reviewing works. This observation allows me to return my attention to what that 'form' of the ethics committee allows. As Strathern puts it,

> the idea of there being numerous perspectives and viewpoints 'on' phenomena implies that one could ideally formulate some kind of summation of all possible views, or at least a framework or perhaps a generative model for the production of the perspectives themselves (2004:108).

Perhaps such a generative model might rest in the constitution of the committee, as a theory linking identity, representation and perspective, with the objective of producing a balanced view. But such a balance is itself fragile because of the potential for the proliferation of perspectives arising from 'a constant sense that any one approach is only ever partial, that phenomena could be infinitely multiplied" (Strathern 2004a[1991]: xiv). Too many perspectives, or too much representation, could lead to an infinity of impossibilities: research could be impermissible for any number of different reasons. Cristina's recommendation of a common position acts as a limit to re-description, a way of bringing to rest expandable narratives (Strathern 1996b:522). When she responds to a question about diverse composition and diverse viewpoints by emphasising the

importance of making decisions she is pointing to is one method of delimitation. The limit of time is another and the mapping of the figurative 'perspective' onto the body is a third.[63]

The one and the many

In assembling many views and combining them in decision-making, the committee is a device of Euro-American pluralism, 'ontologically grounded in one world and many viewpoints' (Strathern 2011a:92), what Latour terms mononaturalism (2004). Differences in viewpoint are no longer visible in the 'one voice' of the committee,[64] and yet they remain necessary for its 'legitimacy'. To do the work it needs to, the committee must be both a composite of many perspectives (representative), and a single voice (authoritative).

The group of people assembled in an 'ethics committee', are charged, then, with making a decision. More information can be collected, but the aim is a final decision. The combination into single-ness allows it to speak 'as though' it were 'one.' Corsín Jiménez explores this phenomenon in his study of baroque forms of thought (2010b) where he takes up Hobbes' theory of representational personification as a political innovation that 'brought about a political transubstantiation: the Many became the One, which contained, but also transcended, the Many' (2010b: 38-39). Citing the historian Noel Malcolm (2002), he observes that this 'transubstantiation' resulted in 'a curious structure of argument that requires two different ways of seeing the relation between the individual and the state to be entertained at one and the same time' (2002: 228, see also Shapin 2005). This fits with Stark's descriptions of her IRBs as declarative bodies, voices of the state (2011a: 250) speaking as "The IRB." While I am not speaking of the state here, there is nonetheless a version of representational politics at work, and I suggest a version of this 'structure of argument' is repeated when an ethics committee must be both one who stands outside to assess ethics, and made up of many points of view. For the committee to work, it must be seen twice: as Schaffer writes of representation in politics and pictures, '[y]ou have to see each member of the group in its own right. At the same time, you have to see the group itself as a singular thing (2005:196). Juntra's water bottle story suggested that the ideal view taken by the committee is one from everywhere. Holbraad and Willerslev write that if

[63] Stark uses her transcript material on IRB meetings in the USA to arrive at a similar finding, arguing that 'IRB members use latitude each time they apply a regulation, which might make the range of possible decisions seem nearly limitless. Yet the ways in which IRB members go about making decisions is systematic because of the constraints of their social configuration' (2011b:66).

[64] As Rodriguez put it, in Chapter 3; see also Stark 2011a.

the view from everywhere is 'constituted as an ideal from which all perspectives are felt to be deviating in some degree', the ideal 'tends to be experienced as a motivational invitation to change one's position, so as to get a better, fuller, or more optimal view of the perceived object' (2007: 340). They conclude that 'not all perspectives are of equal value' (ibid). We have seen suggestions of this in the chapters above. I now explore the creation of positions from which to view protocols, attentive to the values placed on 'perspectives.'

In Chapter 3 I showed how Conflict of Interest can expand from 'interests' — construed in a purely financial manner — to cover such things as curiosities, ambitions, beliefs and knowledges. Conflict of Interest declarations are described as 'within' oneself: the committee member is the only person who can reveal their relationships, ambitions or beliefs. They are, for the purpose of COI, 'part' of oneself. Colin, a lawyer I interviewed in Sri Lanka, illustrates how this composition of the person informs and intersects with the form of the ethics committee. Discussing his fellow committee members, Colin said:

> They're from different backgrounds, it's a good composition of people, diverse backgrounds and those who have done well for themselves. They're not reliant on others for work, they're not worried about what other people think, so it makes for healthy discussion. At the moment, the committee is looking at guidelines for stem cell research. It's an old argument, what should be prohibited and what restricted and at our last meeting, there was a lot of give and take, looking at the moral and religious issues to have a fairly objective discussion.

'Objective'? I asked.

> Well, people left their beliefs at the door. I don't think people's personal beliefs should have anything to do with what is being discussed at the table. [We are] not there to pass religious judgements. It is a question of what is lawful, and what can be done. The point is that members of ethics committees are not of any particular faith, unless they need to be for the purpose of representation.

What is Colin saying here? How can one leave 'personal beliefs' at the door, and yet be present for the 'purpose of representation'? He is placing a positive valuation on the diverse 'backgrounds' of the members, but finding one *part* of that 'background' problematic. This is worth exploring carefully.

Wedika, a committee member from Galle, in southern Sri Lanka, commented that his committee was 'more confident' if it comprised several different disciplines. His committee had just added a statistician to its ranks, and he said that they found she was able to comment on the mathematical appropriateness of the sample size of a protocol, relative to its scientific aims. Using this as an example, he argued that a variety of perspectives would eventually be good for trial participants.

There were, however, limits to Wedika's desire for variety. While a statistician was a fairly unambiguous positive, and a lawyer was also considered to be important, clergy posed a problem, causing me to recall my conversation with Colin. 'They are important too,' Wedika said, struggling:

> but it's difficult to have lots of people coming — you lose control. Which religion are we going to choose? Then we have to give equal [weight] to all: Buddhists, Christians, Islam. They have their own areas they are very concerned about. If all three are there, I find, I feel some research projects might not go through which should not be the case.

As Wedika saw it, *these* additional perspectives would clog research possibilities. Were the ideal of equal representation actually enacted in the Sri Lankan town where he worked, he thought a great deal of research would stop:

> They may go on minor details, say, 'In our culture, our religion, this should not be asked or questioned or investigated.' Research will all end at that point [...] If monk would sit in our committee, none of the animal research would be possible. They bring in teaching of Buddha, nothing will proceed — though we have thought of having [them on the committee].

He did foresee some possibilities for including such perspectives, albeit in a rather contradictory fashion:

> If we have such people, they need to be educated enough in ethics, so the religious thing doesn't apply to the proposal itself.... Until we can have a panel of educated clergy, better not to have [them].

Embarrassment was another difficulty in including non-medics: 'Even with the lawyer, it's difficult. It is not possible to invite them and then not accept that person's opinion, because it's embarrassing to then disregard it.' At the same time, he worried about 'losing the social part' of research: by concentrating on one issue, 'we medics have blinded ourselves to other things'.

These two interviews give a sketch of what a non-medical person who sits on an ethics committee in Sri Lanka is thought to be. The comments depart from the expert/layperson dichotomy of Euro-American studies of science, in which the literature on democratic of participatory decision-making shows roundtables, open fora and consensus events are 'intended to involve the lay public in decisions' (Weingart 2008:141, see also Maranta et al. 2003, Joss and Durant 1995 although see Flear 2009). In Chapter 3 we saw how certain 'parts' of an abstract 'society', imagined as external to the committee, are seen to inhere in the person and the 'interests' they hold. Here, as a layperson in Sri Lanka, if I leave *my own* Buddhism at the door, I must recognise that I am there to 'represent' wider society too, since that is what the ethics committee as a device demands of me.

Shedding my *personal* religion, I come to stand in for a generic social concept of religion, one that is put 'outside' the committee (which has concerns for 'all' of society), and is re-channeled into the committee through me. Am I then an individual as 'an internal constellation of plural elements,' as conceptualised for example with Conflict of Interest, or a 'life' 'merographically conceived as belonging to many external systems' (Strathern 1992a:167)? The Sri Lankan material I have discussed here shows both versions in use. People are brought in to ethics committees on the basis of a 'merographic image of the individual person as a part of diverse systems of domains beyond him or her' (Strathern 1992a:167) — but some of these domains are cut off. What the committee as a form effectively creates, I argue, is a space in which all perspectives are *notionally* present, but the relative value of these perspectives is predefined, pre-weighted. Some matter more than others. I now want to look more closely at the creation of the ideal in the first place, through the new WHO Standards.

Represent, Reflect and Have Knowledge Of

Riles (2006) observes that a document is a means; it points to an end beyond itself. Under discussion in the grand hall in the Hotel Equatorial, Shanghai, the draft of the new WHO Standards (2011) certainly hoped for an end beyond itself. Carl Coleman, the lawyer whose articles framed the previous chapter, was presenting the draft to FERCAP for consultation. 'Let me preface this,' he began:

> by saying the standards are all phrased in the same way: phrased as describing a state of affairs that would be a *good* state of affairs, the way things *should* be. There's no verb in there, such as 'should' or 'must' or 'encouraged'. It's simply saying that in an ideal world, this is what happens.[...] They're describing the situation as it should be. The question in evaluating any given system is whether in fact this description is being satisfied.

A document that intends to bring the system into being by describing it is, I would suggest, a powerful mode of description. In this examination of the production of 'authoritative knowledge' (Jasanoff 2005:19), the story I compose from the meeting takes up the question of what an ethics committee should look like, and how that description — one we already know as 'ideal' — is reached. Carl tells us that this description of the world as it should be is also a world that can be measured. A discussion of standards forces a description of the ideal, and of the gap between the ideal and what people consider practicable. The first problem the FERCAP attendees

raise is medical expertise. The second, developing out of the first, we might initially gloss as 'social expertise.' Let us look at the discussion surrounding the second Standard. Carl introduces it as:

> moving from the system to the entity that is establishing the REC, which could be a national or subnational entity; it could be an institutional entity. The REC is [he reads from the screen]
>
> "*appointed according to a charter or other document which establishes the manner in which members will be appointed. The appointing official ensures that the REC has a multidisciplinary and multisectorial membership, that its composition includes both genders, that it reflects the social and cultural diversities of the communities from which research participants are most likely to be drawn, and that it includes individuals with backgrounds relevant to the areas of research that the committee is likely to review. Committee members recognise the limits of their knowledge and seek external input where necessary, particularly in relation to research that involves participants whose life experiences may differ significantly from those of the committee members.*"

Carl summarises the Standard as being about 'a diverse representation on the committee and it goes into a little bit of detail about what diversity means.' He asks for questions and Vasantha, the Senior Deputy Director General of the Indian Council of Medical Research[65] raises a hand. 'Of course' she begins,

> [the standard] only talks about backgrounds relevant to areas of research the committee is likely to review. It's not always possible. That's why you need consultants, experts who are attendant to the committee to do the expert views.

The session chair points out that this is addressed in the next sentence, that committee members 'recognise their limitations,' but the chair thinks it's important that the standard notes that 'individuals have backgrounds relevant to the areas of research', even if this is not always going to be possible. Carl agrees, and takes up the point:

> I think part of the question is what the purpose of the standard is, the way this was discussed it was a standard to describe the ideal. *Ideally* you would have representation from all the areas of expertise. In reality, that may be a standard that is going to be difficult to meet in a lot of cases because the committee just doesn't have a lot of options to draw from. That's where the next sentence about limits of knowledge would come in.

Vasantha worries that by making 'representation from all areas of expertise' mandatory, it becomes impossible for committees, particularly those in developing world settings, to achieve the standard.[66] At this point we are about to shift from the limits on available scientific expertise to the limits on a committee's social knowledge. To solve the problem, the chair proposes a link between sentences. If 'committee members recognise the limits of their knowledge and seek

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[65] Whom we met first at the Regional Collaborative Workshop, in Chapter 1.

[66] Finding ways to ensure 'appropriate expertise', from all areas is indeed a challenge in developing world settings, and is acknowledged by documents such as the 2005 Nuffield Discussion paper. I develop this important point below.

external input where necessary', perhaps this will help? But for Carl this linkage produces a new kind of problem : '[t]he sentence wasn't intended to apply just to expertise, it was also intended to apply to community representatives.' There is a pause. Cristina speaks first: 'I think I'd still emphasize that an EC should have the expertise to review the types of research it reviews,' she says:

> If it has no expertise it should not review it, no? I like this guideline because it emphasises that this EC should have expertise, otherwise what's your business accepting that protocol? And you seek external input where necessary. That's the consultant.

Vasantha notes that she expects the protocol to have already undergone an expert scientific review,[67] to which Cristina rapidly responds, 'We don't assume that, that's just India!' which raises a laugh. At this point, an invited speaker from the USA raises a hand. The chair motions for him to speak. 'This is only a suggestion', he begins. 'Not imposing?' jokes the chair. 'Just a suggestion', he repeats:

> When it says that the appointing official will ensure that [the committee] reflects the social and cultural diversity of the committees, you imply that you must have representation from that participating population you are doing research in. Perhaps it should say that they ensure that they have *knowledge* about social and cultural diversity. Not every REC has an HIV infected person on their board, nor do they have poor people, or others from these vulnerable populations that we'll do work with. So it may want to say that rather than ensuring the committee *reflect* the diversity, that the committee have the *knowledge* of that diverse population.

'I see your point,' replies Carl, tentatively:

> I think that's probably something we should discuss a little more, because I think there were some people who felt very strongly in previous versions that the committee should include, or strive to include those people, though it may not always be possible.

In enlarging on a problem which started in the possible limitations of medical expertise in developing countries, the discussion has suddenly shifted to what *kinds* of knowledge are sufficient, who might possess them, and how both people and knowledge should be made present on a committee. 'How can we get those people from that community?' asks one audience member. 'I think it's about having the relevant knowledge,' continues another, 'I think it should say that, "The committee should have the relevant knowledge, rather than the committee itself *reflecting* those..."' We reach a point where this change is being contemplated, when Carl speaks again:

> I'm not sure everyone would agree with that. I see your point, but I'm thinking of the comments we received on earlier versions of this. There were a lot of people saying that

[67] See above.

> there wasn't enough in the existing *Silver Book* to emphasise that this isn't a committee that is looking at the community and making decisions for it but that it is a committee *of* the community. At first it said something like '*represents*' and then there was some concern that that was a little ambiguous and what does it mean to represent a community? So *reflects* was seen as a little bit… But *knowledge of* is almost expressly saying that its people who are not [of that community], it's someone from the outside who *knows of*.

Li Ling, one of the Chinese delegates suggests 'emphasis on the cultural or community consideration of the committee composition,' worried that unless this is specified, it will be ignored. Cristina replies to her, returning discussion to the layperson:

> It's about the layperson not a community representative. [The standard] says that members whose primary background is not in science or research should be appointed in sufficient numbers to ensure that they feel comfortable voicing their views. And that was intended to emphasise that you shouldn't just have a token member that is the community or a lay member, but there really should be a critical enough group.

The shift from sufficient breadth of scientific expertise to 'social and cultural' issues provokes the invocation of three distinct terms: reflects, represents and 'has knowledge of', each carrying its own connotations. Why do these words and terms matter?

As I suggested initially, the creation of the standard is a powerful mode of description. While Vasantha's concern with the scientific whole can be fairly readily supplied with 'experts' and 'external consultants,' the breadth of 'the social' is less easily satisfied. From the discussion above, we have (at least) two types of person for this category: the layperson and the community representative. The deliberation over which of these to use reveals questions about who these 'others' are to be, and how this 'social' field is to be 'brought in.' How are their qualities described? American literature on the topic is clear:

> While no committee can represent all elements of the community where research will be conducted, the REC must be capable of assessing the impact of the research on the community and determining whether the research is relevant in the local setting. This often leads to the inclusion of REC members who do not have a scientific background but are professionally grounded in the community, such as a member of the clergy, social worker, teacher or nurse. […] They should exhibit commitment, knowledge and concern for their communities. The nonscientific and community representative members must be given the same level of respect as their scientific counterparts (River and Borasky 2009:50).

Li Ling's intervention allows Cristina to reframe the problem of representation as one of the committee's expertise. This in turn becomes a question of quantity: 'you shouldn't just have a token member that is the 'community' or 'lay member', but there really should be a *critical enough group*,' Cristina says.

Quantity is the reason given for a recent innovation, community advisory boards (CABs), which provide another approach to involving non-scientific persons in committee decisions (Diallo et al. 2005, Quinn 2004, Weijer and Emanuel 2000, Thaitawat and Chinaworapong 2008). A researcher who worked with a CAB in India said during the 2009 FERCAP Conference that:

> CABs can be conceptualised as an intermediary between the community and researcher. It gives them strength of argument, because on a REB/ERB/ERC, a community member might not have the strength to make their presence felt, they might be intimidated.

Researchers try to ameliorate such intimidation when conducting research. Consider these notes from a discussion at a workshop in Canada in 2005, following presentations on community consent in the 'Promotion of Equitable Research Practices':

> One way to achieve informed community consent is through community REBs. Then it will not simply be a traditional band or tribal leader consent — one person who decided for the group — but a more balanced consent. It is an epistemological question: are we individuals first or members of groups? The answer seems to be neither, and this is the problem (Lemmens and Archibald 2006: 63).

When confronted with community consent, the certainty of the researchers (and of their 'ethics') in the primacy of the individual evaporates. Anthropologists are likely to recognise this 'epistemological question.' Strathern writes that the concept of 'society' construed the individuality of its members as primary; individuals first, their relationships second (Strathern 1996a:62). What the apparent problem of "applying" principles of individual informed consent to others reveals (again) is that — as anthropologists have long known — *the individual is a particular way of thinking about the person* (see also Corrigan 2003). In the closing of her contribution to the 1989 Manchester debate, Strathern puts the consequences strongly: 'The unfortunate outcome of conceiving of society itself as an entity has actually been to make relationships seem secondary and not primary to human existence' (Strathern 1996a: 55). Informed consent is the ground upon which this tension becomes most evident, and has garnered a large share of academic attention (Sankar 2004, Reubi 2012, Molyneux et al. 2005). But effects of this mode of thought are far reaching and, I suggest, sustained and promoted through the way in which research ethics is framed. When the individual whose consent must be sought is not found, indeed the concept not found to hold, researchers look for groups. Groups then require representatives, and the problem recurs.[68] If representation is the outcome of a Euro-Americanism that splits one reification

[68] Sometimes they find themselves caught up in loops, where in order to research problems of informed consent, their own research regulations require them to obtain informed consent from participants, in order to talk with them about why informed consent may not be suitable.

(individual) from another (society) in order to recombine anew and this fails the committee, what then of 'reflect'?

In an interview with Carl nine months after the consultation in Shanghai, he clarified that the draft at the time (September 2010) read 'reflects,'[69] for 'practical' reasons:

> Will you be able to find people who truly represent? 'Having knowledge of' might mean anyone who has read a book. The reflect is more in-between. 'Represent' - you'd need to find someone who could speak on behalf of the entire group. 'Reflect', you could be a part of the group, or it means you're somehow part of it, it's not necessary for you to stand for everyone, you're not necessarily typical. But 'reflect' also goes some way to preventing a total stranger... So we had to try and find a word... Everyone will interpret [it] in a different way, not everyone will read it this way for people who wanted the word represent it helps them, and so in a way it serves both sides. It doesn't say that they do... [it] comes on a little weaker.

Carl's later analysis reveals assessments about the adequacy and type of 'knowledge' desired from persons on an ethics committee. It also makes a careful distinction between types of learning. Book learning seems too little — the person could be a 'total stranger'. Representing seems too much of a demand, indeed, perhaps impossible. Sometimes, for Euro-Americans, 'simply 'knowing' about other perspectives may [...] be regarded as a respectable end in itself' writes Strathern (1999:252). But the discussion around the revisions of the Silver Book suggests that this is not one of those cases. In discovering the inadequacy of "having knowledge", we are led to ask for what purpose it is inadequate, and what is instead required. What is desired is no longer the characteristic of *knowing* something, but of *being* something: being 'of' or 'from' that community, being a patient with a disease that is under discussion. The 'ideal' standards describe not only a broad range of persons in whom scientific expertise resides, but also types of people. Though the standard was ultimately published using the term 'reflect' (WHO 2011), the first 'guidance' point for Standard Two states that:

> Members include individuals with scientific expertise [...] and lay people whose primary role is to share their insights about the communities from which participants are likely to be drawn (WHO 2011:8).

[69] It has since been published with that phrasing (WHO 2011).

Laypersons

> In ethics, the process by which a decision is made is as important as the outcome. For a decision to be ethically legitimate, it must be made in an open and inclusive process that takes into account the views of all stakeholders. (WHO REC Basic Concepts 2009: 22)

An ethically legitimate decision, the Basic Concepts guide implies, might be a difficult thing to achieve. What is it, and how can it arise? The guide demands 'openness' and 'inclusiveness'; focusing on the decision as process. Here, building on Colin and Wedika's comments (p.168), I explore further the kinds of things that laypersons are supposed to do and be. The layperson is a well-established figure in Euro-American discourses of public engagement with science. Maranta et al. argue that this figure is

> not a sociologically comprehensive representation of lay persons but rather an action in the knowledge production which ascribes epistemic and functional competences to lay persons (2003:154).

Recognisable renditions of laypersons are distinguished by their medical ignorance, and in standing in contrast to the medical members of the committee, they assist in creating the latter as experts (Strathern 2004b, Michael 1996). In the sections below, I explore both the theory and lived experiences of laypersons.

i) In Theory

'Doctors are all trained the same, so they think the same', said Wedika, the Sri Lankan ethics committee member who argued above how a (particular) variety of perspectives would improve a committee. In interviews, I often found laypersons were deemed a necessary check on the 'single' view of medicine. In the publication resulting from the consultation above, further guidance accompanying Standard Two reads 'Committees are large enough to ensure that multiple perspectives are brought into the discussion' (WHO 2011:8) and elsewhere, WHO publications assert that a diversity of backgrounds on a committee 'can help ensure that [...] judgements are not inappropriately dominated by a single perspective' (WHO 2009:13).

One of the ways documents attempt to ensure a multiplicity of perspectives on committees is to make decisions made in the absence of a layperson invalid. This is achieved through specifying quorum, the minimum number and type of persons required to be present for a decision (WHO 2000). But laypersons cannot *just* be present. We know from FERCAP's Survey's expectations (Chapter 2) that they need to speak. In addition, according to an American Research Ethics

Training Curriculum, '[t]he nonscientific and community representative members must be given the same *level of respect* as their scientific counterparts' (River and Borasky 2009:50; emphasis added). But how can this 'same level of respect' be ensured? That it needs to be specified already implies that it may not always be given. At a training in the Thailand, Cristina reported a conversation she'd overheard in Taiwan, between a layperson and a doctor, both of whom sat on an ethics committee. 'How can a housewife debate with a philosopher?' asked one trainer:

> She was just a housewife, and someone asked her, 'Why are you bothering yourself to come? There's not much money in it.' She said, 'When I'm at home, nobody listens to me. Here, what I say makes a difference.' That's the nature of the people. Once they get that pleasure, it's hard to explain what it is.

The difference between a housewife and a philosopher was, to the trainer, obvious. But these definitions (and sense of hierarchy, it seems) need to shift. Juntra tells me that in FERCAP trainings:

> We always tell the layperson, 'You're equal.' Yes. In Thailand it was really strict before. Now I say, 'The only place you're equal is that table.' Lots of professors don't like me for saying it, but they can't say anything against me, I am one [a professor]! They can't say anything to me! Professors feel they know lots and feel others know less. That's a problem. It's not *about* your profession... People confuse between their profession and Ethics Committee. Now we are discussing the framework, on the table it's about risk benefit, and *everyone* talks about that. Not how you do surgery, that's your expertise. We should have the same goal: credible review. Each one contributes a different aspect. I contribute expertise but I should listen to the social aspect. At the beginning that was tough, but they got used to it.

The ideal social situation in an ethics committee room is, Juntra admits, out of the ordinary for many committee members. Imagined as a set up for the enactment of an 'open and inclusive process', it is also a de-professionalising move for the medical professionals, who are used to being listened to and respected.[70] While Juntra asserts that '[e]veryone in that room has the same right to say anything,' a 'right' does not always translate into an action, hence the Survey's criteria for observation during the surveyed committee meeting's board meeting: does the layperson participate? Still, she reports 'improvements.' Since the SIDCER recognition lasts three years and the program has been running since 2005, renewals, or 'resurveys' are now being done with a number of the early adopters. Now, she says:

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[70] I draw a parallel here between the expertise role given to medics in the ethics review process and that of the modest witness given by Boyle to gentlemen in the English 1600s. As Shapin and Schaffer put it, '[w]itnessing was regarded as effective if two general conditions could be satisfied: first the witnessing experience had to be made accessible; second, witnesses had to be reliable and their testimony had to be credible' (2011:336). For the former, the principles we see here. For the latter, see Chapter 7.

> Committee members talk about something reasonable. Everyone should be able to follow the discussion. Its not just two people discussing and the rest just sitting there. And the lay person has to understand too. Before, we'd see the layperson intimidated not really saying anything. Now [in the resurveys] they're participating! Before they were afraid, scared to ask a "stupid question," but now they want to give their opinion. Perhaps they see their contribution making a significant difference.

While the laypersons may now speak (and this listed as a measure of the success of training) this is of course not proof that they are listened to. As Jasanoff argues for evidence in a courtroom (1998), it matters not only what evidence is presented, but also that the 'eye that frames [it] must be certified as authoritative' (1998: 714). When laypersons speak in the ethics committee, they are supposedly 'equal', their thoughts given 'equal respect.' But this does not happen automatically. Juntra tells me that the trainings 'gave room for [the layperson] to contribute, and grow. Before there was no room. Without training, committees said "I need a layperson," but they let them be!' In her view, committees cannot just 'let them be'; indeed 'growing' the layperson has been one of FERCAP's main interests. Creating a 'role' for the layperson is an aspect of this. As one trainer commented:

> After the training they realize there's a role for this person, not just for the sake of requirements. Because others don't know what [their] role is about. Once everyone has the same training [it works better]. If only one person goes to training, how can they come back [to their committee] and say '[the layperson] has a role'?

The question of how a housewife can debate with a philosopher is reversed: what is at stake now is not how the housewife can become sufficient to the philosopher's demands, but how the philosopher can learn to hear the housewife. Measurement, however, is never far away: 'I think training brought about change [but] there is the question of how to prove it,' Juntra says.

> When you observe an EC meeting, you look at the dynamics. If she doesn't speak her mind… You look at what they do. We [also] look at protocols they reviewed and see how they deal with each protocol. Say we review 20 sets of minutes and none of them mention this aspect of layperson, its never in the minutes.

She also notes that the Survey recommendations usually contain a note for the laypersons:

> We always say [they] should ask the layperson to review the consent forms. Then they have their own checklist, we say 'a not medical' person should comment [on consent forms]. That defines a very specific role for them.

That 'very specific role' does not, however, require a very specific person. Explaining the layperson to a group of trainees in the Philippines, Cristina said:

> A layperson doesn't mean someone literate. Can be a lawyer, a monk. […] In some countries they use a patient representative. 'Layperson' means someone who does not

> belong to the field of medicine. Define it in your SOP so it will not be difficult to find.[...] In guidelines you need a layperson, and an unaffiliated. If that person is not there, you've not got quorum. You cannot make decisions if there is no layperson and no unaffiliated. They can nullify your decision.

Cristina is less concerned with the detail of the layperson than with defining a role for them. They cannot 'belong to the field of medicine' but their difference from medical members is less important than their presence. Without them, legitimate decisions cannot be made. Although Cristina says the layperson may be illiterate, the examples she chooses are highly qualified professionals. I want to tentatively suggest that, though she does not use the term, her choice of these professions stems from a particular way of thinking about 'society.'

In the previous section I showed that in informed consent we see hints of the legacies of theories of 'the individual' and 'society.' As we saw, ethics struggles with community consent because it cannot decide whether persons are members of communities or individuals first. In Strathernian terms, informed consent struggles because of the primacy of individuals over relations in Euro-American ways of thinking. In the same way as informed consent makes this primacy evident, I suggest that the 'role' of the 'layperson' too is revealing; a site that makes evident the concept of 'society' at work.

Strathern's work shows how the English theorising of 'society' produced their idea that '[s]ociety allotted roles to its members' (1992:158). Cristina revealed the results of the allocation of roles at the conference in her offhand definition of 'capacity building': '[c]apacity is always specific to a role. You have to define, like each person has his role in society. You cannot be good for all, you do a specific role.' Society is the basic metaphor here: capacity as specified into roles, is made thinkable by a pre-existing model of society organised in terms of roles. The original context of her definition came vis-a-vis the 'role' of ethics in a global system of research. In invoking a 'role in society' in her explanation, Cristina moved easily between a role in society and the role of ethics in a global system of research. The idea of 'role' is clearly operating in multiple contexts, on multiple actors, at multiple scales. I suggest this same mode of thinking about roles applies to the ethics committee. This particular abstraction of society about which Strathern writes 'proliferated others — religion represented society, law represented society' (Strathern 1996a:52). Cristina's invocation of 'a lawyer, a monk' uses professions which descend from these commensurate domains, repeating precisely the other abstractions proliferated by the society abstraction. The lawyer or the monk are, *because of this way of thinking*, able to stand for 'society' on the ethics committee.

ii) In Practice

We have seen what the guidelines and FERCAP *suggest* for a layperson. What about those who serve under this designation? In May 2010 I interviewed Jaya, a trainee lawyer in Colombo, Sri Lanka. She had been attending committee meetings for a few months when we spoke, and she classified herself as a 'layperson.' In her answer to my question about what that meant, she told me:

> It's like this. A person from [a] high background doesn't really understand what goes on in normal people's lives. In my office, there is a senior lawyer, and he went on a bus for the first time *in his life* the other month. It was a five hour journey but he'd always traveled in a private car. He was saying that there were people crying, [he was] complaining about the music, people with baggage, being sweaty. And I thought, 'That is just once in your life, we face it everyday!' That sort of person, until they actually face it, doesn't understand. You need people who are sensitive to that issue! So we are people [on the committee] who represent average people in society.

For Jaya, her life experiences marked her as 'normal', in contrast with the doctors on the committee she attended. She likened the lawyer in her office to the doctors who, due to their 'high background' could not understand everyday reality. The 'difference' of the layperson's thinking seems to be the mark of their contribution. At trainings, lectures tell medics, 'You should be proud to help a lay person,' 'they need to be empowered.' And when laypersons addressed one another, they said:

> we should be proud of what we are and what is our perspective [...] It's not about clinical practice, it's about research ethics. The technical part is the clinicians. Research ethics is where should be no difference between a clinician and a lay person [...] What you study is not how to do better surgery, it's about beneficence and justice. You should be at the same level as far as those principles are concerned.

But it is difficult to keep the conversation in these domains when certain knowledges triumph. While 'different thinking' is valued, they cannot be too different. For some, it can be an uncomfortable position to sustain. Harsha, the Sri Lankan layperson whose comments opened Chapter 4, said:

> Medical people, they humour us when we ask layman questions. But they may not respect and consider us if continue to ask dumb questions. If our questions are well informed and human, then its OK but if they're completely ignorant, idiotic - I always wonder if what I'm about to ask is idiotic -then they'd like to discuss it and educate us. We always think twice though, it's not kids play, we need respect of equal stature, or what you say won't matter, we could be brushed aside. [...]The fear of inadequacy is always there.

The question Harsha is asking herself is 'how naive is too naive?' What kind of naivety will result in the loss of her status as useful layperson, and render her voiceless? How can she maintain her

fragile ideal of equality? Her position is not enviable. Harsha is, in her day job, a successful advertising executive; she is clear in her thoughts and articulate in her answers to my questions. Her education brings her into the circles of the doctors who invited her to participate on the ethics committee and while she maintains that she thoroughly enjoys the meetings, there is a shadow of something that she cannot collapse into. Her role is to "represent" laypersons, and she can do so because she is one, from a medical point of view. But she cannot provide *too good* a representation of them; she cannot be 'completely ignorant.' For all her 'ignorance' can be seen as an epistemic competence (Maranta et al. 2004, see also Michael 1996), her ability to continue to interact with the 'medical people' demands a certain fluency: she must remain 'well informed', or risk losing the (necessary) respect of the medics.

Other 'lay' members foreground their capacity for empathy as knowledge, such as Barbara, who worked in translation and marketing in Taiwan:

> Sometimes, I feel very angry about the doctor, not concerned about the patient. It's not their fault, they go through a science point of view to see the experiment. I'm glad I'm an IRB member so I can help the patient, to protect them. So it's more like a mission for me now.

Her friend, who was sitting in on our conversation over a cup of tea, raised her eyebrows. Barbara laughed.

> She [the friend] knows, I'm kind of picky about some details. Too picky maybe. Why don't they *think* about research? Because they think it should be more cold blood, more science style, more powerful. Sometimes, if want to do research think the patient will listen, so you should be grateful I'm going to help you in the future. 'Cos I'm doing for your own good, so you should do whatever I tell you. Sometimes I think they believe its no harm - this is everything I do every day, easy, not harmful. [...] Its like a mouse, white mouse. How can they create those strange clinical trials?

This is not protection of a human subject who can "vote with his feet" (Noah 2004:384, see Chapter 4 above); in her foregrounding of the relation between an investigator and their patient, Barbara is reminding us of the particularity of the relationship between patients and *doctors* in this part of the world (e.g. Chin 2002). I suggest that the paternalism which informs patient-doctor relationships cannot be upset by 'layperson' in a committee, and that in the attempt to formulate committees which take on board the 'lay' view, what they actually reinforce is the attitude of *custodianship* committees have over patients.

At the end of the opening conversation about the water bottle, Cristina inserts Heijan's image of the blind men and the elephant. This is the same story Heijan used in Chapter 2 to explain the

operation of the Survey to trainees in Beijing. There it was used to suggest that through teamwork, Surveyors could form a whole overview of the committee under study. The Survey could take the different parts of the committee into the different parts of itself, and at its final meetings, re-compile them. In Heidi's words, this might bring them to 'truth'. But when Cristina mentions it here, we are not talking about the Survey. We are talking about a committee, its meetings, and its decisions. The image has leapt scale, in part because the 'reality levels' (Latour and Callon 1981:298) in use by FERCAP do not hold; the 'level' at which the Survey takes place (overviewing the Committee) mixes with the 'level' of the Committee itself since the techniques they apply to their objects are so similar.[71] When used to talk about the ethics committee rather than the Survey the social mathematics of the parable are different; the change in scale matters. While the story is used to point to the partiality of knowledge, also it relies on an external position of knowledge: the elephant is standing in for an unknown, since we and the King both know what it looks like. An *image* (glanced-at-and-understood) of the *story* (told in linear time) exploits the difference in knowledge between the viewer and those depicted. Only the king and the viewer of the image are equal; everyone else is 'blind'. Cristina's use of it as an image equivalent of Juntra's water bottle example simultaneously equalises and differentiates the different participants in the ethics review; they are each equally blind to the elephant, they each hold a different part. As an organising metaphor for the ethics committee, the story of the blind men draws out the simultaneous equalisation (all the men are blind) and differentiation (each has a different, unique part of the truth). However, as I have attempted to demonstrate, this is a state of ideal contradiction which is difficult to achieve in practice.

A tale of two microcosms?

The sections above detailing who should be on a committee, and why, illustrate how the ideal committee is contested. Does one convene a committee which, in Carl's words, 'isn't a committee that is looking at the community and making decisions for it but that it is a committee *of* the community'? Does one emphasise the equality of participants, aiming for a conversation in which everyone is of equal standing? Or does one emphasise the need for scientific expertise, in the

[71] I have remarked before on the way in which ideas are replicated and shared between the Survey and the Ethics Committee. I return to this observation in the Conclusion.

knowledge that unless research is scientific, it is not ethical, a principle commonly cited by FERCAP. While ideal committees are being designed, ideal circumstances cannot answer.

The term I want to use to denote the activity I perceive in the committees resulting from the two priorities above is 'microcosming.' 'Microcosm', from the Greek *mikros kosmos*, or little world, is used to describe something 'encapsulating in miniature the characteristic qualities or features of something much larger,' (Oxford American Dictionary), of imagining one thing miniaturised inside another. This term I propose to use as descriptor of a strategy applied by my informants: to be clear, I intend it as a means of drawing attention to *their* sets of strategies or techniques, in the way Callon and Latour intend the term 'macro-structuring' (1981). The logic of the macro and the micro *is an artifact of the logic under study*. While the term is mine, it describes a productive strategy, attentive to replication, scaling and the movement therein. Microcosming not only contributes to making 'society' as a partner with whom 'science' can converse, as an aggregate that can be represented, but it is also constitutive of the scales upon which 'society' and the 'individual' are thought to exist. Furthermore, it attends to the relationships between them. Microcosming becomes about making a macroscale object present at the interpersonal scale. How can you bring 'society' into conversation with a person? The presence on the committee of a particular version of 'society' is perceived as a miniature, drawn from a 'larger' imagined externality.

Building on Chapter 4, I want to suggest that there are two types of microcosming going on in FERCAP's engagement with committees. The first concerns the *committee* itself as a microcosm. The second involves an image of 'society' contained within a *person*, who comes to represent society on the committee. In the work of microcosming, committee members simultaneously bring into being society 'out there' and its presence in the room, either as the committee or in a person. I am talking of two different techniques to materialise this macroscale entity in a face to face situation. One is to see it in the layperson, the other is to see it in the committee itself. They result in ways of doing an ethics committee which, I suggest, are distinct from one another. The sections which follow reflect on the implications of the distinction I am drawing.

i) Cross sections and non-experts

At a FERCAP training in Chiang Mai at the 2009 Conference, a trainer sought to highlight the 'synergies' of committees which, she said, were 'supposed to be a microcosm of society where people have different backgrounds and trainings.' In this description, the ethics committee is

explicitly imagined as a 'microcosm,' albeit an ambiguously faithful one, of 'society.' Why is 'society' being microcosomed in this way?

Social historian Duncan Wilson writes that, following *New York Times*' 1972 revelation of the Tuskegee study in the USA, 'Yale lawyer Jay Katz argued that fundamental questions needed to be asked about the nature of authority assigned to physicians' (Wilson 2011:199). Katz claimed that 'doctors possessed no unique expertise that justified making them the sole arbiters of medical ethics, and proposed that patients and experimental subjects should be safeguarded through 'the more active participation of non-scientists in research decisions' (Katz 1972a: 606 and Katz 1972b: 1, cited in Wilson 2011:199). Arguments such as this, Wilson argues, led to a profound shift in the locus of governance over biomedical research.[72] Within two years of the Tuskegee revelation, Wilson observes,

> President Nixon responded to controversies over human experimentation by establishing a fixed-term national commission for the protection of human subjects in biomedical and behavioral research. The act that established the commission notably stipulated that no more than five of its eleven members should be doctors or scientists, with the majority drawn from philosophy, law, theology, sociology or the general public (Wilson 2011: 126).

In the USA today, debate continues about the 'politicization' of bioethics (Brown 2009, see also Moreno 2005, Caplan 2005). In defending the President's Council on Bioethics (PBCE) from accusations of politicization, Leon Kass, its former chair, stated that:

> The Council has been "in microcosm, and in the best sense of the term, a *political* body," because of the way it has sought to incorporate diverse perspectives, avoid expert jargon, and engage the public (Kass 2005: 247; 228, original emphasis, in Brown 2009:43).

I suggest that it is a version of this model of a bioethical council which led the speaker at the Chiang Mai training to frame the committee in the way she did. While publics have not been the focus of my research, nor of this chapter, in my observations of the way a committee is imagined as microcosmic there is — implied — a macrocosm from which that microcosm is drawn. When bioethicists look for 'public opinion', 'representative' committees are convened, or specified sections of 'society' consulted (Strathern 2005b). Here, the ethics committee needs to sufficiently make whole a fragmented outside whose diversity needs to be 'represented.' When representatives are found and arranged onto a committee, it can be thought that in the single voice of this committee's decision, 'science' and 'society' speak together Strathern however (2005b: 476) remarks that

[72] The further repercussions of which I discuss in Chapter 7.

> we would do well to be wary of the kind of co-production of knowledge that hypothecates *society* as a partner [...] An abstract notion of "society" [...] is pre-emptive. It demands demonstration rather than investigation; it will require performance, representatives and evidence of its presence in people's calculations.

There is a further dimension to this recurrent tension in the normative democratisation of expertise (Weingart 2008, Jasanoff 2003), and I want to analyse it by returning to the jury comparison made in Chapter 4.

Cristina argues that ethics should not be a specialist activity, that it should be the kind of conversation that everyone on the committee can follow. In this committee the different backgrounds of members are valued, a 'cross section' is sought. In discussing the jury in the previous chapter, I raised the importance of classifications of persons and their knowledges. In 2007, UK barrister Helena Kennedy represented Shuja Mahmood, a man accused of involvement in a plot to cause explosions in London using ammonium nitrate fertilizer. The BBC reported her closing speech to the jury: 'because you are drawn from the public at large you represent something more — you signify law is not left to lawyers or judges; it is not some specialist preoccupation' (BBC 19th February 2007). Kennedy's concern that 'law is not left to lawyers or judges' repeats a distinction made in ethics, when Juntra says an ethics committee meeting 'is not about your profession' (p.177). Both juries and ethics committees must deal with hierarchies of expertise, types of person and knowledge. Sometimes, both insist on the value of non-specialism. Let me unpack.

While the jury is a great deal older than the ethics committee, they hold in common a Euro-American tradition of equal civic participation. It seems as though both Cristina and Helena Kennedy are arguing for the same principle: that both the law and research ethics should be accessible to everyone; it matters that they are decisions that could be understood by all. Through their principles of composition, both the committee and jury contain the essential fiction that 'society' can be made to speak. What differs is who it is that makes up 'society' in each of these groups. It was because a jury was supposed to be a 'cross-section' that, when in early 2002 in the UK, Louis Blom-Cooper QC 'argued that defendants should have the right to be tried by a panel of experts instead of a jury' (BBC 16th April 2002), there was a rapid response from civil rights groups and barristers (Home Office 2002). Blom-Cooper had claimed that 'the question of evaluating evidence in the courtroom is a professional job, it's not for amateurs' (BBC 16th April 2002). During the response to this suggestion, the Bar Council framed this as a matter of public trust: 'the public trusts the jury system, the government needs to show it trusts the public' (BBC

14th July 2002, The Observer 14 July 2002). Public trust and confidence is precisely what Coleman (2004:49) and Koski both desire for science, and ethics committees are posed as a route to it. I suggest that as states borrow from science techniques of knowledge for their legitimacy (Ezrahi 1990), the technique of transparency is beginning to be applied to ethics review committees.

The reason usually given for the 'closed' nature of an ethics committee meeting is that of confidentiality. However, pursuing the jury analogy, Coleman argues that confidentiality concerns 'should not be used as a shield to limit the public's ability to participate in and oversee the decision-making process' (Coleman 2004a:50). Indeed, he goes as far as to claim that 'both IRB deliberations and their written opinions should be open to the public' (Coleman 2004a:50). In the USA, committees *are* federally mandated (Stark 2011b:72) and like Coleman, Stark speculates on the closedness of IRB meetings (2011b:35-37). She writes that '[m]any questions raised about declarative bodies as a tool of government have gone unanswered precisely because administrative bodies work outside of public view' (2011b:36) and argues that:

> decision makers are persuaded by different forms of evidence for administrative choices made behind closed doors than in decisions made publicly, with doors flung open, TV cameras rolling, and full transcripts available (2011b:36).

In Shapin and Schaffer's account of early experimental science, Hobbes and Boyle famously disagreed over what counted as public witnessing. Haraway writes that Boyle's 'open laboratory' and its offspring evolved as a most peculiar 'public space' with elaborate constraints on who legitimately occupies it (Haraway 1996:431): 'What in fact resulted was, so to speak, a public space with restricted access' (Shapin and Schaffer 1985:336). That questions are starting to be raised about the closedness of ethical review is significant when one remembers Stark's succinct summary: they can change what can be known in their review and revision of protocols. The consequences of this I develop in the analysis below.

ii) Laypersons and Expertise

If the committee itself can be taken as a microcosm, what of the second kind of microcosming? I suggest this was seen in Colin and Wedika's comments on the inclusion of 'laypersons' on their Sri Lankan committees. In his study of the 'epistemological commitments underlying American conceptions of individualism, politics and public action,' Ezrahi (1990: 201) notes 'the idea that

the life of every individual is in some respects a microcosm of the life of the community.'[73] This imaginary of society/community-in-the-person allows commentators to turn away from the imaginary of 'segments' of society being represented on the committee to a person 'in whom' society/community is contained. Ensuring the presence of 'society' in ethics committees then takes the form of the layperson: a person whose expertise is precisely their inexpertness, their normality, everyman-ness. In the section on the significance of the terms 'reflect', 'represent' and 'have knowledge of' above we begin to discern that *who one is*, and *how* one knows something both matter. The detail of the slippage in discussion shows two outsides: the professional realm of medicine, which seeks representation though expert knowledge, and the remainder, imagined as society, with its cultural and 'lay' specificities. Making standards that describe a committee sufficient to both of these is, as Vasantha notes, practically impossible.

This microcosming has a 'type' of committee associated with it, one more concerned with the scientific soundness of research. The problem of scientific soundness arose during the discussion related above (p.172), where Vasantha commented that, in India, they expected research to have gone through a technical (or 'scientific') review prior to reaching the ethics committee. The tension has been noted before, most clearly in follow up discussions to the Nuffield Report on the ethics of research in developing world settings. The follow up document reported that

> During discussion, there was broad agreement that both the scientific quality, and the ethical issues raised by the proposed research should be reviewed but there was disagreement as to how this should be achieved. Ideally, and where feasible, it was suggested that these review processes should be separated (Nuffield Discussion Paper 2005: 48).

Desirable though the separation may been, it is not always 'feasible'.

> In Kenya for example, a scientific committee usually reviews the scientific protocol before it is submitted to an ethics committee. If the scientific committee does not have enough expertise, an external Kenyan expert is sought to review the protocol. In a much smaller country such as Fiji, there are not currently enough suitably qualified experts to make it possible to create two separate committees. One suggestion was that it might be more appropriate to specify that a REC has a duty to ensure that there is adequate review of both the ethical and the scientific aspects of a proposal, rather than stating how this should be achieved (Nuffield Discussion Paper 2005: 48).

During my time with FERCAP, trainers repeatedly argued that if research is not scientifically sound, it is not ethical; that no risk to participants can be justified if the results will not be

[73] With a remark which has relevance to the struggles members of committees found with voicing their views, Ezrahi (1990:202) quotes the Americanist Sacvan Bercovitch (1981:13, 32) stating that "elsewhere, to be independent was to challenge society, in the United States, it was to be a model of consensus[...] representative selfhood bound the rights of personal assent to the rites of social assent.'

scientifically valuable. In several countries where FERCAP works, national bioethics committees have little force, there is little legislation, media coverage of biomedical issues or litigation. In some places, hospital or institutional ethics committees may be the only point through which international applications for research pass. As such, the scientific members and their expert knowledge come first, upholding the maxim that unscientific research is always unethical. The priority of this version of the ethics committee is to oversee *good science*; create publishable papers, monitor research coming into a country from overseas. Ethics committees' attention to matters considered scientific can frustrate: '[c]linical researchers are exhausted by the demands of ethics committees that seem more concerned with the science (which they cannot necessarily judge) and editorial control of patient information sheets than with ethics' (Warlow 2004: 241). How, and where the distinction is made is an ethnographic question. It is of the committee in this mode that Juntra is thinking when she expresses concern about the lack of doctoral qualifications in some countries where trials are to be held, or when Chatura, a committee member in Sri Lanka tells me that they spend most of their time discussing methodology, criticizing proposals:

> When you think about it, [research ethics is] a highly technical subject. You can't just walk off the street and be a good ethics committee member. Just because they are clergy or a teacher, doesn't mean they can come. I don't agree with taking one of each kind and saying everyone is represented [...] Some methodologies are unethical because if research is not scientific then it is unethical to subject people to risk.

As Shapin and Schaffer (1985[2011]:336) note, 'democratic ideals and the exigencies of professional expertise form an unstable compound.' At the same time as FERCAP works to bring perspectives together on an ethics committee with the principles of equal contribution and common discussion, it also re-creates the separateness of those views. Shapin and Schaffer's witnesses of science acted as 'transparent spokesmen [...] whose only visible trait was their limpid modesty, they inhabited the culture of no-culture. Everybody else was left in the domain of culture and society', writes Haraway (1996:431). The separateness resurfaces in Chatura's comments on the technicalities of research ethics. It is the extent to which committees, through witnessing the ethics of a protocol, are acting as modern-day witnesses to science (Shapin and Schaffer 2011 [1985]) that causes complaints of censorship (Hamburger 2004). Stark's work '*Behind Closed Doors*' is a valuable contribution to the study of how committees do make decisions. However, when the witnesses of ethics are *also* witnesses of science (Nuffield 2005: 48), when their decisions not only *rely* on the scientific expertise of members but are also *about* the science, we see arise a situation which gives double meaning to the making of 'good science.'

In closing, I want to draw attention to the question of what (and where) gets chosen for one's macrocosm. It is a question suited to empirical study. Laura Stark's work on committees as 'declarative bodies' concerns itself with the way they are 'empowered by governments to make decisions without consulting citizens' (2011a:233). In my own work with FERCAP, I have not found it to be the case that 'citizens,' 'the public' or 'society' are invoked or thought of as needing to be consulted; nor that the committee is a device which, though its decisions, is used to make science accountable to society. The authority of most of the committees I worked with did not come from an imagined ability to represent the considered opinion of a population. 'Society' is present, nominally, in the second microcosming, laypersons, but the work of the committee is more akin to Noah's peer review mechanisms (2004:291).[74] In Singapore, Holden and Demeritt (2008) expressed concern that the focus they encountered on 'the international marketability of research results' and the 'highest international standards' (2008:81) drew from a macrocosm which was, for Singapore, mis-located and mismatched. As they write,

> the bioethical model being put into practice in Singapore anticipates a certain state-society relationship in which the populace is invested with a series of rights, both individual and participatory, such that it can give active asset to new and novel forms of science and technology (2008:82).

When Holden's interviewee, who worked for Singapore's national ethics committee, pointed out the absence of 'autonomy', replacing it instead with 'respect for the individual,' Holden and Demeritt were — at their own confession — 'flummoxed': what, they asked, was ethics without its 'guiding principle' of autonomy?' (2008:82). They argue the 'the mapping of ICH guidelines onto Singaporean society defies the very logic of those guidelines,' that it was not about the meaning of 'autonomy' for committees or the Singaporean state: 'as long as the consent forms are signed and the paper trail is clear, there should be no qualms about what it all means' (2008:82).

Here I am concerned with the meaning already in the making of the paper trail. In comparing an ethics committee with a jury, I found that neither in judgement nor discussion are all perspectives equally valid, even if they 'should' be. This is also what Stark finds in America (2011b:38):

> Is everyone equally an expert in IRB meetings? In theory, the answer is yes. In practice, however, the answer is no. [...] Cordoned off from traditional avenues of public oversight, declarative bodies have been imagined as democratic by virtue of their design. Each member is expert in his field; each member is equally valuable.

[74] The proximity of peers to one another causes the problems we have seen in previous chapters.

While FERCAP works to 'educate' committees on the role of the layperson and tries to measure the impact of their approach in terms of whether or not the layperson speaks, this cannot be an indicator. The layperson needs to be "heard" and this is difficult to measure. We have seen that both 'laypersons' and scientists or experts need to 'learn.'[75] Thus I would suggest that the capacity FERCAP builds is a matter of seeing problem as they are framed by the makeup of the committee.

Concluding Remarks: Limiting Endpoints

When Dr Dipika asserted that a monitoring checkup on a trial from 'an ethics perspective' was both a right and a different kind of monitoring from that carried out by Clinical Monitors she prompted a discussion which revealed limits to her actions as an Ethics Committee member that would otherwise have remained invisible. She prompted others to define and delimit areas of action considered to fall within the role of one set of actors or another; a 'cleavage' in knowledges (Mol 2002: 20-21), here between *ethics* as 'lay' knowledge and the expertise of clinical monitoring. I have attempted to show how a version of this cleavage between 'lay' and 'expert' operates also *within* the committee. Like the idea of 'role', and the image of the elephant, it moves (scale). The committee emerges as a means of controlling the formation of perspectives, holding things in place. It is bound by time, particularly in Asia where committees are made up of volunteers. It is limited by those chosen to be on it, those who sit in the room. As a form it contains multiple views but in acting as a committee it must arrive at a decision: a committee decision. The 'one voice' (Chapter 3) with which the ethics committee speaks takes a single body, sometimes the Chairman, sometimes the stamp of "The IRB" (cf Stark 2011a: 235). This both lends authority to the image of combined and considered views, and conceals the identity of those who have swayed the opinion in the meeting. In this "corporate" sense, the committee members are less themselves and more the features of many.

Many scholars remark on the Western origins of bioethics. Part of the impetus for this study was to examine the consequences of the fact that, as the ISBC proposal put it, 'most of the concepts and international regulatory principles in use continue to be derived from Western cultural

[75] After arriving at this analysis I became aware of the conversation between Mol (2011) and Strathern (2011b) on this point (see also Jensen 2012) but do not address it directly here.

values' (Hess 1995, 2007, Nader 1996, Harding 2006)' (ISBC 2007). 'So long as all the ethicists are in the North and the South is just the recipient of ethical principles, nothing will change!' writes Bhutta (2002:118). As an example of how it is not just principles but processes which are affected by Western cultural values, Maori health researcher Tupara (2011:374) notes that with regard to collective consent, 'ethics committees are unlikely to facilitate arrangements for collectivity if it is not part of their standard assessment protocol or accepted practice.' I have developed her observation through my focus on the form of the research ethics committee, arguing not only that its form, composition and ideals of operation owe a great deal not only to Euro-American ways of thought, but also that it replicates the tensions that constituted anthropological analysis for a large part of the 20th century: the micro and the macro, society and the individual, local and global.

Furthermore, I have explored the implicit distinction which treats the *form* of the ethics committee as separate from the 'western' origins of ethics *content*; as though it were in some way neutral. My analysis points to the effects of form, the way the 'committee' organises and creates the conditions for a behaviour that is recognised as 'ethics'; work I have sought to make visible. When regarded as a frame for action, this is not the limiting endpoint of the research ethics committee, but its limiting starting point.

As a prelude to Chapter 6, let me extend my focus on limits. In my analysis I have suggested that the capacity being built is not just to do with histories of ethics or even modes of thinking, but with the inseparability of those modes of thinking from the form of the committee. What emerges is sometimes imagined — as Wedika put it — as a dialogue between those who speak for everyday people, and those who, through their training in medicine have 'lost' that way of thinking. In its purpose and modelling, the committee simultaneously assumes that viewpoints are comparable, and works towards ensuring that they are. The possibility of misunderstandings at the committee table was expected, indeed desired. Misunderstanding and discussion would contribute to debate, considered as a necessary component (measured in the Survey) of what an ethics committee was. But that the misunderstandings might not be the *same* misunderstandings is not something that can be entertained or desired (Viveiros de Castro, 2004:9 cf Roy Wagner 1981:20, see also Crook 2007 and Strathern 2011b). Instrumentalised, misunderstanding could always be resolved, viewpoints were always comparable. There was an implicit understanding of misunderstanding as reconcilable. Put differently, differences could be resolved. I turn in the next chapter to how

FERCAP handles this resolvability, by looking at the arranging work difference is made to do and how differences are themselves arranged.

Chapter 6: Comparison makes a difference

Respect for cultural and socio-political differences is important. Members involved in the work focus on the common task, rather than on their political and cultural differences. They begin to see each other as friends and co-workers despite their divergent political and cultural background. Asia is a land of contrast and diversity but the FERCAP experience is about a common goal.

Reflections on the FERCAP Experience: moving forward with partnerships and networks.

Cristina Torres 2010:52

To 'misrecognise or fail to recognise (cultural difference) can inflict harm, can be a form of oppression, imprisoning someone [or a group] in a false, distorted and reduced model of being, research cannot be "difference-blind".

Charles Taylor, 1992, cited in *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research*, NHMRC, 2003, Australia.

What is the 'cultural difference' referred to in the quotations above? In this chapter I explore the idea of cultural difference in FERCAP's work, how it comes to matter and how it is used. In Chapter Two I used Sam's idea of a house for the region, calling the living room a common space. Here, I look first at the making of Asia as a region, and the role comparison plays in this activity. How does FERCAP hold the region steady?

'One thinks of comparisons because other people do,' writes Marilyn Strathern (2004: 69). Though she is thinking of the work of other anthropologists (Leach and Leach 1983, Herdt 1984) what captures my attention in this chapter is the comparisons FERCAP members are making amongst themselves, about themselves and between themselves. 'And how is *our* ethics?' was one of the first questions asked of me during my fieldwork, as I spoke to a Sri Lankan about my interest in dual-ended (UK–Sri Lankan) ethics review. It was a question of comparison which might have prompted me to embark on a series of my own comparisons using the implicit units of the question: nation states, and the 'cultural and socio-political differences' therein. I could also have fallen back on obvious categories, comparing the operation of ethics review committees, national legal and regulatory frameworks or others used by FERCAP and its surveyors — indeed,

comparison (with their own committee, the committee they know) is one of the ways in which surveyors envision capacity building taking place.

During fieldwork, I reached a point at which these questions — and the world of graduated achievement and evolutionary progression they implied — appeared obvious and natural. I had gained an ethnographically informed understanding of 'how things are', but as I moved between places I became concerned about the kinds of assumptions I was carrying, courtesy of this imaginary. Certain places seemed more central to ethics, other places more peripheral. Sometimes this was because there were more people, sometimes more committees, sometimes simply a single person with a lot of energy. Jensen (2007) remarks that the apparent size of a place — large, small, central, peripheral — comes from correlating the large with importance, something 'regularly taken as a solution to the problems of sorting perspectives when one moves between contexts' (Jensen 2007:837). 'The idea' he writes, 'is that if relevant scales were observed, the many different places, opinions, and contexts visited could be properly sorted and evaluated' (ibid). This was a model of knowing places that I recognised, and as a pattern of thought it had consequences: centers appear as obvious sites of knowing 'more.' This chapter attempts to work through the consequences of de-centering these models. What are alternative ways of approaching the comparisons made within FERCAP, without replicating the co-imbrication of space and importance? How to pay attention to the instrumentality of similarity and difference, their un-fixedness, and the role comparison itself plays in the making of geographies of similarity, difference and significance?

I take as exemplars Mol and Law (1994), Riles (1995, 2002) and Jensen (2007), in whose work there is a consistent effort to challenge academically accepted descriptions upon which arguments and interpretation are built. Mol and Law (1994:641) describe theirs as 'a paper about the topographical presuppositions that frame the performance of social similarity and difference,' a paper I take here as a sampler over which to sew not narratives of a varying disease, but the pre-packed notion of 'cultural difference.' Jensen (2007) builds on Strathern (1991), Wagner (1991) and Callon and Latour (1981) to consider the scales adopted by anthropologists and sociologists in coming to terms with social activity, with the reminder that 'the researcher is no better located to observe the proper scales than any other actor is' (2007:847). Using Callon and Latour (1981), he argues that the challenge is no longer that of traditional social theory: 'how to sort good from bad representations of society' or achieve 'calm observation and distant overview' (2007:847). 'Rather than being neutral observers of scales', he writes, 'sociologists, as are all other actors, are

inevitable participants in the construction of scales — in their very efforts to analyze and describe those scales used by other actors' (2007: 847). When the anthropologist starts paying attention to questions such as why, and to whom size is important, without the reliance on the stories that seemed to explain these features away as obvious, new vistas emerge. The languages of both scale and comparison start to look like instruments employed within the ethnography itself.

There are certain things that comparison 'makes', almost immediately. Thévenot opens an essay (2002) on the mutual implication of 'things' and 'persons' in moral or political evaluations with a quote from Hannah Arendt.

> A seance where a number of people gathered around a table might suddenly, through some magic trick, see the table vanish from their midst, so that two persons sitting opposite each other were no longer separated but also entirely unrelated to each other by anything tangible... a world without things that are between those who have it in common, as a table is located between those who sit around it, a world with no in-between which relates and separates men at the same time (Arendt 1998:53 in Thévenot 2002:53).

One of the problems with dealing in terms that denote, foreground or are themselves 'difference' is that difference is usually taken as a separating notion. One thing is not another. It is different from it. Thus difference is posed as a barrier to common goals. One tactic has been to 'celebrate' difference, in order to turn upside down the potential problems that it causes (Strathern 2011a). But this is always slightly surprising to commentators, who are working with, rather than against, the implicit values in words like 'relation' (Strathern 1995c) or here, 'difference.' When Choy (2009) comments on Mathews' (2009) ethnography of 'unlikely alliances' between Mexican scientists, nature spirits and indigenous industrial forestry (1926-2008), there is a hint of surprise that the research has demonstrated 'how a global alliance comes together through — not despite — cultural, epistemological, and geographic difference' (2009:89). A common language, can, of course, conceal.[76] When FERCAP says it is not doing bioethics (see Chapter 1), not only is it refusing questions of moral philosophy which appear to have no answer, it is also sidestepping bioethics discussions that center on difference. I suggest FERCAP's approach is instead to create a space in which the detail of cultural 'difference' may continue by foregrounding the detail of other aspects of ethics review. Returning to the table in Arendt's image, the region operates as the separating-yet-joining object around which members of FERCAP are gathered. But how is such a situation created and sustained?

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[76] 'Co-ordination' in higher education, for example, facilitated between European countries by the Bologna Process sometimes creates differences which then become disguised by a common Bologna language (Dahl et al. 2009). As with the 'common language' of GCP, plans have been made to export the Bologna model (known as Bologna Global) to other parts of the world (Zgaga 2006)

Regions (networks, and fluids): an Asian Bioethics?

What if 'cultural difference' were to be considered the anaemia (Mol and Law 1994) of FERCAP? In their paper, Mol and Law ask questions about anaemia by asking about blood, space and anatomy, about textbook definitions, numbers and measurement. Most of all they enquire into the *location* of anaemia. Where does it get located, when evoked? (1994:644). How does it travel? They look at Africa, they look at the Netherlands. They look at the different equipment, people, haemoglobin concentrations. In analysing the work that goes on in stabilizing 'Asia' as a region in more than geographical terms, I will look at the different committees, surveys and trainings. As Strathern has long remarked, the making of difference is a social act (1988:96) — something also achieved through comparison. 'If the social is indeed made in the associations (and separations) that people make,' she writes, 'then comparison itself is one way of making the social. Not making it appear but *making* it. It is at once a social activity and an act of social analysis' (Strathern 2009:17). It is with these thoughts and questions that we might begin to get at some 'critical approaches' to knowledge relations (ISBC 2007) as we trace the 'associations and separations' (Strathern 2009:17) built up in how the idea of 'cultural difference' circulates in FERCAP.

The first of Mol and Law's topologies is 'regions', in which 'objects are clustered together, and boundaries are drawn around each cluster' (1994: 643). Leo de Castro, a philosophy based bioethicist who served on the first FERCAP steering committee in 2000 and as FERCAP's Vice-President in 2003, begins his article '*Is there such a thing as Asian Bioethics*?' with a question which clusters: '[w]hat would it take for a bioethics to be Asian?' 'Two things seem naturally to come to mind,' he says. 'Firstly, Asian bioethics must be peculiar (or contain features that are peculiar) to Asia. Secondly, Asian bioethics must be common to Asians' (De Castro 1999: 227, see also Sakamoto 1995). Within the 'region,' however, difference 'in bioethical thinking' proliferates. He finds other scholars there before him: '[h]aving identified distinguishing features of East Asian and Ibero-American bioethics, both Fan [1997] and Drane [1996] are quick to point out the variation in bioethical thinking *within* each region' (De Castro 1999:229, emphasis added).

When Mol and Law ask whether there is such a thing as anaemia, they trace it through references, objects, comments and locations. They ask how regions are generated and boundaries drawn, such as the 'Africa' where anaemia is both more frequent and more severe than in the Netherlands. They answer their own question with the reply that 'when a region is defined, the differences

inside it are suppressed. They are minimized, or 'marginalised' (Mol and Law 1994:646). In order to create an 'Asian bioethics,' work must be done on generating a region, but the emergence of differences 'within,' and their suppression, complicates. As de Castro comments,

> Being peculiar is necessary because, if Asian bioethics - more particularly, the features that make it Asian - were not peculiar to Asia or to Asians, there would not be much sense in distinguishing Asian from non-Asian bioethics [...] It seems natural also to suppose that Asian bioethics should have features shared by Asians. For if there were no such features, there would be no special reason to speak of a bioethics as Asian. There would be nothing to unify Asian bioethics. But, how far can these requirements be expected to hold? How much peculiarity and commonality can there be? (1999:227)

For de Castro, 'the existence of variations or of different orientations and divergent views across countries within a region' (1999:229) raises some questions about the idea of a shared regional perspective. 'Of what importance are the shared features', he asks, 'if they do not amount to a unified theoretical system or a single coherent perspective?' (1999:229). Hongladarom, a Thai philosopher who has participated in bioethics symposia, struggles with the same framings as de Castro. Recalling an event on 'Dialogue and Promotion of Bioethics in Asia,' he comments that he said

> that there was no such thing as Asian bioethics because Asia was a very large continent containing highly diverse cultures, histories and traditions that made it very difficult, if not impossible, to find common elements that could define the 'Asian' in Asian bioethics (Hongladarom 2004).

With 'Asian bioethics' explicitly foregrounded, both commentators find it difficult to adequately 'suppress' the differences within the geographical region in order to create a sense of region. They are faced with the question of where 'cultural differences' begin and end. De Castro tells us he is not the first to struggle: prominent Hong Kong philosopher bioethicist Ruiping Fan (1997) 'acknowledges that Buddhism, Taoism and Shinto have all combined to bring about variations in bioethical thinking from country to country, or from area to area' (cited in de Castro 1999:229). We are now not only dealing with countries, but trans-national belief systems variously 'combined'.

Nonetheless, my interviewees demonstrated the utility of thinking in terms of regions. Moving identification 'up' a level from nations to 'Asia' not only allows for but also enacts the encompassment of difference. If I am told that 'AAHRPP doesn't understand Asian people's thinking,' then the speaker, to draw out the difference, has called on a region, against an (American) organisation. 'Asian-ness' was considered both as a FERCAP asset, and an explanatory device for its success. In the world-system of SIDCER regions, between which comparisons were

made, dire conditions 'in Africa' were usually evoked (though this did nothing to detract from the need for improvement felt and generated amongst FERCAP's members). As one employee of TDR who attended the 2009 FERCAP conference put it,

> We're not so worried about Asia. Or South America. They're GCP compliant, most of those countries already have laws about clinical research. In Africa you have these committees that just sign and they don't know what it is they're signing to. Ethics isn't just about learning to write, it's having it in your mind and that's not the easiest thing.

At the same time, such comparisons render 'difference to that other' the thing which is held in common. Countries in Asia, goes the thinking, have more in common with one another than they do with any part of Africa. Asia, 'clustered' (Law and Mol 1994: 643), is not 'like' Africa: a boundary can be drawn. Occasionally during fieldwork, lunch tables provided an arena for trainers to be implicitly compare Asia with Africa through their criticism of training and capacity building work there, where they saw foreign groups and individuals who threw money around, traveling business class, expecting per diem expenses and taking advantage of one another. 'The fortunate ones - ones who go abroad, get an education, do well, they are not caring for their people. They are using the people to get more money for themselves they talk a lot'. Through this, trainers reinforce 'Asia', and thereby FERCAP, as different.

Mol and Law tell us that '[h]aemoglobin levels are not the same all over the world. In one region *more people* have anaemia than in another. And these anaemias are also *more severe*' (1994:646). They then tell us that these are regional facts, formulated in a topology, 'a topology in which there is one region in which anaemia is "oh, well," a region which is distinguished from another where it is a 'very concrete problem' (1994:646) How can this help us think about the enrollment of 'cultural difference'? Let me return to the activity to which research ethics is a response: scientific research. Scholars of western scientific practice and discourse have remarked that the sciences occupy a particular space, thought of as 'cultures of no culture' (Martin 1997, 1998; Traweek 1988) in which facts are discovered. Despite work in STS which shows how facts are made, mobilised, and allied (Latour 1987) in western discourse on science, the space of debate for ethics hinges on the 'legal and social', not 'culture'. Science is 'unmarked', its cultured view (Haraway 1988) disguised, its natives in the West homogenised. Concerns about 'culture' arise when science 'travels,' particularly in multi-sited clinical trials (EMA 2012). In other words, the discourse of western bioethics is a topology in which 'cultural difference' is 'oh, well', but in these elsewheres (such as Asia) 'culture' is invited to be a 'very concrete' problem. This is what seems to be at stake in the question 'Is there an Asian bioethics?' Yet de Castro observes that the pursuit of a coherent

Asian bioethics against 'the alleged imperialism of Western concepts and bioethical principles' sets up a trap:

> In the attempt to characterize an Asian bioethics that is significantly different from Western bioethics, we can easily commit the mistake of universalizing (among Asians) a single Asian ethical perspective (1999:234).[77]

FERCAP's regionality causes two seemingly opposed challenges: to make particular the international guidelines that circulate in small silver (WHO 2000, 2011) and blue (WHO 2002) books and to support, if not articulate, Asian approaches to these guidelines as each country under its gaze seeks to establish and run committees. The use of Taylor's work in the opening quote from the Australian report — to fail to recognise (cultural difference) can inflict harm — reflects the potential with which FERCAP deals. Indeed, a committee's 'localness' and attention to 'difference' is part of the agenda which seeks to build ethics review capacity in the first place (Lancet 2003, Nuffield Council on Bioethics 2002). One might imagine that given the difficulties of finding 'common' elements, FERCAP's solution might be to simply not talk about difference within the region. But this far from the case. Invoking differences and similarities in differences and similarities can have social effects: again, as Strathern puts it (2009:17), not making the social appear but *making* it. To ask when the nation matters and when it does not, for example, is to ask when the scale of the scaling-device 'nation' is relevant. The national is but one type of difference, easily enrolled but strategically flattened. This is where Arendt's table is useful. Countries in the region are thought as are separated yet joined, and this, I argue, is what is at stake in FERCAP's 'Asian-ness', in its talk of family (Chapter 1). Thus as Mol and Law write of the 'complications' in pinning down anaemia, certain differences 'can simply be treated as a complicated and ever-present backdrop' (1994: 647). But the finding and use of difference is not a neutral activity. Gregory Bateson (1972) noted that humans use a wide range of different differences, and I would add that it is at different times that different differences come to matter.

[77] Drane (1996:56) points out that universalising (among Westerners) also occurs, and that within what is known as Western bioethics 'different orientations and divergent views co-exist and compete with one another' (1996:56); it is not as though 'Ibero-American bioethics is [...] a self contained unified theoretical system providing a single, coherent perspective' (de Castro 1999:229).

Physical Space: on centers and peripheries

Mol and Law's second 'space' is 'network space', in which 'distance is a function of the relations between the elements and difference a matter of relational variety' (1994:143). In this space, 'proximity isn't metric.' '"Here" and "there,"' they write,

> are not objects or attributes that lie inside or outside a set of boundaries. Proximity has, instead, to do with the identity of the semiotic pattern. It is a question of the network elements and the way they hang together. Places with a similar set of elements and similar relations between them are close to one another, and those with different elements or relations are far apart (Mol and Law 1994:649).

The way in which SIDCER breaks up the world into regions such as FERCAP allows regional space, but at the same time, within and between these regions, network space brings places closer together and further apart. In network space, for example, New York and London are 'closer' to one another than London and (say) Durham — despite geographical distance. I want to add this sense of network space to Jensen's request that we (as readers) suspend our 'commonsense notions of scale' (2007).[78] In an article on the development of an electronic patient record system in Denmark he uses three interviews: one with a representative of the Danish National Board of Health, one with a nurse, and one with an informatician at a hospital. The reason he wants us to suspend our commonsense notions of scale stems from the automatic 'size' of the actors listed above. He observes that plans for the patient record system are conceived of as formulated in political offices (macro), in order to be disseminated ('rolled out') at hospital wards (micro) (2007: 883). Jensen points out that the people in his story do not 'seem equal':

> One actor seems large, connected to things powerful and important, which has to do with the 'macro' development of the national health infrastructure, related as his work is to issues of policy and bureaucracy, whereas another actor seems small, her work comparatively mundane and trivial in its 'micro' concern with drawings on cardboard (2007:834).

He explains that in the history of sociological thought there have been many attempts at connecting the separate poles of macro and micro in order to get analytical purchase (2007: 834). Efforts have been directed at reconciling the poles, or exploiting their 'interactive potential' (2007: 835). Indeed, we find a similar concern in discourses of research ethics and bioethics (Simpson

[78] I have also taken inspiration from Annelise Riles' analysis of legal letters pertaining to land claims in nineteenth century colonial Fiji (1995), an essay in which she attempts to manufacture for the reader 'a rhetorical situation that will allow us to apprehend our taken-for-granted notion of scale' (1995:41). Riles aims to show how scalar language, encoded in the expression of English and American lawyers, reformulated 'far off' issues as relevant and important to the (then) nascent field of international law.

2004a). The 'macro' and 'micro', the international documents and how things are 'on the ground' (to use a common Sri Lankan phrase), seem doomed to separation. In this space, an anthropological account might be of value. It is, but perhaps not in the way we expect (i.e. throwing 'local' light on 'global' problems). The next part of my argument draws on fieldwork in Sri Lanka, where I employ Mol and Law's 'network' space, in which distance is a function of the relations between elements (1994:143) alongside Jensen's suspension of commonsense notions of scale.

From a village in Sri Lanka, I knew that Colombo was the center for research ethics. Scaled 'up' to the region, the center became Bangkok, and 'up' again Geneva, or the US NIH. In thinking about my own movements in the region, I developed a discomfort with my easy acceptance of these stories of center and periphery as I had come to understand them. During a presentation on the concept of FERCAP to a Chinese Ethics Review Committee interested in taking part in the recognition program, I heard Cristina neatly lay out the 'natural topography' of ethics in biomedical research:

> The whole idea is to develop capacity of ECs so they'll be able to comply with regulation requirements because drug development is a very much regulated activity and in GCP the ERC is supposed to play a role. The Survey will help you comply with regulatory requirements related to drug development. The guarantee for a good clinical trial is oversight, but it's hard to do at the regulatory level. For example, China is such a big country there is no way the SFDA will be able to monitor each and every one. But the Ethics Committee is institution based, so it makes it possible to guarantee grass roots level quality in a Clinical Trial. So we say the foundation of a good clinical trial is really ethics, so we try to convince. Its a duty based ethics, [we] say its a duty to be ethical, scientific. I think the idea is that we police ourselves, not that the regulators tell us what is wrong with us. We form a group of Ethics committees and act together to ensure we act ethically and ensure ethics is being carried out in each institution. That's the concept. It's a purely voluntary initiative, we've been quite successful in the region. We're expanding our presence in China, we've started some ECs in China, India, Sri Lanka, Thailand, Korea. All this together we adopt some common standard and we try to evaluate each other.

The 'levels' of this statement seem obvious: a big country, difficulty monitoring 'grass roots' level activities. Cristina shows how FERCAP tackles this problem, first through 'policing ourselves' and second through 'acting together.' What the naturalness of these suggestions obscures is the very (Western) understanding according to which `different levels of information' really exist out in the world: for example, between one level of the (large) national organization and another of the (small) nurse in the provinces (Jensen 2007: 838). The levels westerners (and anthropologists) habitually use appear under examination, particularly when juxtaposed with Melanesian knowledge practices (Jensen, 2007: 837, citing Strathern 1991:xiv). Jensen suggests that we follow

'how different places and different people are variably connected and how actors engage in a constant deployment of their own scales' (2007:833). Calling this a 'fractal' approach, he reminds us that it is 'crucial to refrain from relying on a specific prioritized scale with which to evaluate all other actors, for the point is precisely to learn from those others about the intellectual, practical and moral scales they work with in order to build social relations and spaces (2007: 883). Returning, then, to Cristina's comment, she moves from the observation that 'China is such a big country,' to the Ethics Committee as institution based, before arriving at 'convincing' people of their duty to be ethical, to be scientific. Here she reduces the 'size' of the object she is dealing with, from the nation to the individual. It is a scale-in-the making that would be easy to miss, since it so closely resembles how a social scientist might go about 'contextualising' the work of one ethics committee within a national arena: of course the committee is 'smaller' than China, or the SFDA! One is linked to the 'macro', the other to the 'micro'. Were the framing and description changed, the SFDA might, in other circumstances be cast as large, powerful. Yet here it is distant, small, made so by Cristina's focus on the physical size of Chinese territory, and the suggestion that it would be unable monitor 'each and every one.'

John Law has remarked that 'we need to understand the *where* as relationalities too.' 'Euclidianism,' he comments, 'is simply one version of the doing of location' (Law 2008 on Woolgar et.al. 2008). My ethnography is full of moments where location is non-Euclidian, where the decisions of doctors in Tuskegee (Rothman 1991) or Woo-Suk Hwang's use of his laboratory assistant's ova in his research (Hwang 2009, Kim 2009) become part of a canon recounted over video-link connections to rooms in Sri Lanka; 'macro' issues in 'micro' settings, 'small' events made 'large'. These stories become collected, housed as Latour (2005) would observe, in offices, video archives, course materials, textbooks. Jensen's fractal approach demands that 'belief in such distribution of the large and the small, according to obvious and commonsense social scales, is suspended' (2007:837). The consequence? 'Importance, relevance, size and scale would then viewed as enacted categories' (ibid). Let me illustrate from experience.

My research in Sri Lanka was a thread of physical continuity in the social continuity of following FERCAP surveyors around Asia. With four separate arrivals and a research period totaling seven months, the structure of my research in Sri Lanka provided ample opportunity to examine changes both in the field-site and in my perceptions of it. The renovation of the ethics committee room between my first and second visits, for example, was all the more dramatic for my absence (see Chapter 3). As I became more familiar with the work of FERCAP, the questions I asked of

ethics committee members and researchers in Sri Lanka became informed by a perception of absence, generated by my increasing familiarity with ethics committees elsewhere. This sense of absence mapped onto a sense of peripherality, an elsewhere informed not only by the ethnographic desire to be where things were happening, but also the sense that things come from elsewhere. Sri Lanka, a key research site and locus of much of my research activity, had become "small," less important. Although I did not realise it at the time, that sense was also being reinforced in the interviews I was conducting. The image of a capital and its periphery comes complete with a ready-made conceptual schema of international, modernising cities and protected rural backwaters.

Sri Lankan public discourse carries its own temporal mapping of the country, largely reinforced by nationalist Sinhala desires to protect the villages (Spencer 1990, Brow 1990). Speaking from Peradeniya, a University town in central Sri Lanka, one researcher explained that the distance to the capital Colombo was marked not only in kilometers but time:

> To go to a one hour meeting, you have to spend four hours on the way there, and four on the way back [in your car]. Colombo is only 100 kilometers, it shouldn't take that long. But it's a busy road, you get caught in school traffic.

It seems like a very practical issue: the distance grows as the quality of the roads reduces. The time required to make the journey grows with the volume of traffic, it results in inconvenience. Participation in events from locales outside Colombo drops. The Peradeniya researcher above tells me he was the only person on either of the committees he attended who wasn't based in Colombo. Events organised for training in ethics, such as those run by FERCAP's 'child' in Sri Lanka, FERCSL, often suffer similarly low attendance from those based outside the capital. As one researcher based in Galle[79] said to me, 'they send it [the announcement] across, but people don't often go, it may be that we have to organize it here and get a resource person to come'. Researchers in Galle were more explicit about how the distance affected their interaction with and understanding of ethics. 'It's easy for people in and around Colombo,' said Renuka, a member of a southern Ethics Committee,

> but for us, Colombo, it's one whole day, three and a half hours up, three and a half hours down, for a one hour meeting. So that is how far behind we are, with them briefing us. Not in learning, sharing of information. It is a drawback, that geographically we're not in the

[79] A city on the south-west coast of Sri Lanka, approximately 70 miles south of Colombo by road. At the time of research the coastal road took between 90 and 120 minutes, or almost three hours by train. Since the end of my research, a new Southern Highway has been constructed, which may speed up road travel between the cities.

> same place. For example, on Saturday, there's a workshop on clinical ethics, but none of us are able to attend.

We are beginning to see what Mol and Law remarked upon as the way 'network elements hang together' (1994: 649). If people don't travel, the speakers say, then neither does knowledge of research ethics. It gets stuck because of the roads, because of the school traffic. 'Three and a half hours' becomes a measure of how far 'behind' the geography makes them. In this mapping of knowledge onto distance, and the mapping of distance onto authority, if Colombo was a centre, then there were more distant centres, greater than it, referred to often as the 'outside.'

Recalling the early days of research ethics in Sri Lanka, Renuka told a story in which 'people recognised the importance, meetings and things came from the outside. It became a popular thing.' But it is difficult to keep the interest up. For the committee in Galle to function well, Renuka said she would like to see '[us] all coming under one umbrella, being focused and uniform, and it would be nice to have two people dedicated, participating in conferences and keeping up to date.' The temporary (1-2 yrs.) nature of committee appointments, as well as the fact the work was additional — and often secondary — to existing research and teaching burdens meant that she did not feel ethics was the 'primary concern' of anyone involved. 'None of us are really committed to this. We all have our own primary work, this comes after all that, concurrent'. She thought progress might come through designated personnel, but, she said:

> it requires a huge mind shift. It depends on progress in other parts of the world. If Colombo is going to progress rapidly, we can't lag behind. They'll be a parent body, we'll be a sister institution and partners. The problems we have we can refer to them, while maintaining autonomy. For example, having a statistician.

The progress-spatial map is drawn directly here: from Galle the view is of progress elsewhere, rapid progress in Colombo and a fear of being left behind both by the capital and other countries. But what might that progress look like? Further interviews revealed a reliance on those who travelled internationally. 'I learned a lot from Dr A. She has traveled in the region on the subject', said Bartholomew, a pathologist on an ethics committee in Galle. 'She's always coming back from Bangkok, saying "I was there and they had these documents. These were the protocols that had to be maintained."' Proximity isn't metric. In this reckoning, Galle is further from Colombo than Bangkok, since the latter two are regarded as sites of ethics knowledge. To repeat Mol and Law's point, 'places with a similar set of elements and similar relations between them are close to one another, and those with different elements or relations are far apart' (1994:649). For Bartholomew, individuals traveling to conferences elsewhere was one mechanism, people arriving

was another. 'There should be some standards coming from somewhere', he said. It is to the nature of that 'somewhere' I now turn.

Measuring up

As I have demonstrated in previous chapters, a good deal of American literature, training and standards circulate in the region. Due to the International Fellows training program, amongst those with whom I worked, Western IRB in Olympia, Washington, is viewed as a centre of the "gold standard" of ethical review. The US NIH are developing Asian centres of clinical monitoring, and the US based non-profit organisation AAHRPP is exporting its accreditation scheme. FERCAP, as outlined, maintains an awareness of these processes and procedures, but distinguishes specifically *American* laws and regulations from *international* standards and declarations. The influence of the UK, according to one FERCAP trainer, was limited. Comparing it with America, he said 'America has Fogarty, Harvard, they are sponsoring and spending millions establishing training programs abroad. The UK? No.' Countries were seen to make centres, in the institutional sense. Funding patterns for centers were associated with particular types of human resource management, which were perceived as having national characteristics. Sumalee, a Thai researcher who had worked in laboratories in the US, UK and Thailand in Bangkok and received funding, compared the attitudes of British and Japanese funders to international research. 'Wellcome is really for the British working overseas,' she said.

> Their centres are still controlled by British scientists, not local. In Bangkok, it is still a UK base because the center's top director is British. Why can't it be Thai? In Vietnam, it's the same. It's controlled by the British, why not the Vietnamese?

She queried the objectives: 'why not increase the capacity of the people in the country to be able to do that, to collaborate with scientists in the UK?' she asked:

> Maybe it's the nature of the British. I think the Japanese let go. In Africa, they let locals take over and collaborate from their country. [They] give freedom for [the] center to work with others as well. It should be that way. You should not feel you raise this child for yourself - you should raise the child for the world — let the child choose what is best for them.

The point being made by Sumalee is about capacity building through research, phrased as 'developing' and also about how scientists are 'measured up' on scales of scientific development (e.g. Royal Society 2011). I suggest we can usefully view comparisons made by and within FERCAP

as a means by which one thing is measured against another. In the section above, I showed how seeing '[i]mportance, relevance, size and scale… as enacted categories' (Jensen 2007:837) gives us purchase on how social space is actively made, and makes us attentive to comparison. So how is 'resizing' done? Here, I take three examples of the resizing of relating, or comparing. The first concerns FERCAP and the Asian branch of UNESCO, both based in Bangkok. One would assume that UNESCO would take on a 'large' presence, but here we find it reduced. The second returns to the relationship between FERCAP and AAHRPP, and links in to national ambitions. The third concerns FERCAP's relationship to the WHO and its authority to recognise, or accredit ethics committees.

During research, I noted that UNESCO was very active in Asia with bioethics education programs, conferences and meetings, (e.g. Ten Have et al. 2011) but the one of its main contributions, the 2005 Universal Declaration of Human Rights and Bioethics (UNESCO 2005), was not often part of FERCAP trainings. When I commented on this, people shrugged. 'They want it cited,' remarked one trainer,

> but my problem is that there is very little about *research* ethics. They are initiating bioethics committees, meaning every country should have a bioethics committee, not a research ethics committee. And the bioethics committee would consider things like environmental ethics, education ethics, health would only be one of the things that should be subsumed under bioethics.

Sensing that the breadth of bioethics meant health would become too 'small' (a proportional resizing), I pushed the point. Why did this matter? The trainer recalled a 'stakeholders workshop' in Geneva:

> Everyone was there. WMA, CIOMS, FERCAP, AAHRPP, UNESCO. We [FERCAP] were saying that the World Health Assembly, the health ministers of the countries of the world, that they should come up with a statement that they'd uphold research ethics. UNESCO said, "You don't need that, we have the declaration. We have covered everything." For me, they are coming up with motherhood statements, statements for the common good. "Universal declarations" don't address our concerns related to whether you should allow *this* trial or not.

The tension between 'bioethics' and 'research ethics' is evident, but what I want to press is the comparison which aims to make the 'universal' smaller. The declaration simply does not do the job she needs from it, the 'motherhood statement', deemed to have 'covered everything'. As its supporters try to make it 'bigger' in Geneva, it is being 'reduced' in size by the trainer in conversation with me. Its ambition makes it *too big* to be relevant. We have encountered 'sizing' before, with FERCAP compared with, and, in places, falling short of the American accreditation

association AAHRPP. Proportional logic is an evaluation employed to demonstrate, and make, importance (Corsín Jiménez 2009, 2010a 2010b). In Chapter 2 Cristina described to me a conversation she had had with AAHRPP's Marjorie Speers, explaining that it was the WHO that were 'important' to FERCAP:

> That is where we derive our... reputation, and some amount of, how to say, some sense of importance. In the WHO set up, they do things vertically. So the left hand doesn't always know what the right hand is doing. You've got a Malaria stream and HIV and TB and so on. They make it an issue. Say we're not actually WHO.'

Is is this last question, another matter of proportional reframing, which catches my interest. Discussion around the question of whether FERCAP 'is' WHO turns on a distinction between the two terms[80] 'accreditation' and 'recognition.' I probed this distinction further in an interview with a FERCAP surveyor in China, who came up with another reason:

> Well, inspection is something that is done by a regulatory authority. And an audit... may be, well it's more in depth. It is trying to analyze what went wrong. Now, accreditation, that is more in terms of compliance with good practices, but in FERCAP we call it recognition. Partly because they ask us from whom did you get the authority to accredit?

Who is 'they'? I ask.

> Oh, people. So now, it is more politically correct to say recognition. So we do not threaten the national authorities. They say local authorities are to do the accreditation, and it is the work of national regulatory authority. In China, there's even an issue that what we're doing is illegal!

FERCAP's authority to 'recognise' was also brought into question through the relationship between Taiwan and China. Taiwanese involvement in FERCAP has been extensive, its uptake of the recognition program swift. 'Taiwan is with FERCAP and they don't like that,' comments the Surveyor. Where Taiwan aims to be recognised as outside of China, separate and distinct, that relies upon FERCAP being part of, or 'inside' the WHO. To my interviewee, this provides another motivation: 'People ask them why they trust FERCAP and they object to Taiwanese involvement [in FERCAP].' The doubt, perhaps, stemmed from it permitting Taiwan such free involvement. My discussions with Taiwanese participants in FERCAP led to the revelation that while few international organisations would recognise Taiwan, or deal with it separately from mainland China, FERCAP did. Added to this, Taiwan had far more committees recognised than mainland China, which in the eyes of some was an embarrassment. In a struggle to be 'large,' China is geographically large but with (comparatively) few committees recognised, whereas Taiwan

[80] Much like the tension between clinical monitoring and site visits which provokes the response to Dr Dipika's conference presentation which opened the previous chapter.

is geographically small with (comparatively) many committees recognised. The question of who encompasses whom works both for China and Taiwan and for FERCAP and the WHO.

As Cristina said above, the WHO is a vast complicated organisation and there is no 'right answer' to whether FERCAP 'is' the WHO. She acknowledges it is in part though WHO-TDR funding that FERCAP derive their 'reputation', but it is telling that as we conclude our conversation, she dismisses the question: 'I never claimed that I am a WHO employee!' What is interesting for this analysis is how the comparisons make a difference.

In these three stories, the fate of UNESCO's declaration, AAHRPP and Taiwan, we have examples of proportional resizing with consequences. In his attention to the resizing work of proportions, Corsín Jiménez takes as his reference point Galileo Galilei, whose discovery of the moons of Jupiter had relativised the importance of earth and man. In old age Galileo lies in bed, blind and infirm, with the reported lament that he, 'who had enlarged the universe 100,000 times,' was 'shrunk to the size of [his] body' (2004:1) Corsín Jiménez comments that 'the universe may be of the same size for all but not all people measure up to the universe in the same way' (2004:16): sometimes, as with Galileo, 'measuring up hurts' (Corsín Jiménez 2004: 16). This measuring (up) can be applied to the way countries were assessed for their degree of 'development'. As a development oriented, capacity building organisation, FERCAP is, as Cristina states above when she contrasts her organisation with AAHRPP, 'trying to help [committees] achieve a level of competence.' But all those who volunteered as trainers or surveyors knew of huge regional variation. Cristina told me she tried to 'articulate the perspective of a developing world country.' She was aware of how she could 'adjust her language' to serve her purposes:

> Like when I'm in Korea, I say 'You should help. You have a model, you should help other countries in the region.' I don't say which ones, but since you have an advanced economy, you should play a leading role in setting up models, developing a better system. The developed ones are Taiwan and Korea. China is developing, or what they call an 'emerging market'. I have to modify the discourse and do presentation. I always tell developing countries that there should be no difference in quality of review. It is not an economic issue not a technology issue. But you do have to modify they way you present.

On matters of regional hierarchy, those who do not participate in FERCAP can tell us almost as much as those who do. One researcher I spoke to listed Singapore, Hong Kong, Australia and New Zealand as 'non participants'. He could understand Australia and New Zealand not showing much interest, he said, but the other two? 'Well, they are very good,' he said, 'maybe because they were British colonies, they have no problems for the language'. 'Too high up', said one ERC member, of Singapore, deploying height as a language of superiority.

Japan was termed a 'different case' within FERCAP. Personal friendships had led to individual members being involved — such as the chairperson — but no surveys took place. Criticized for being more bureaucratic than ethical, one FERCAP surveyor commented that she 'didn't get the impression that they looked into the essence of the protocol. The paperwork was perfect, but not the content. It's process, not just procedures on paper'. Another pointed out that since Japan had national guidelines, a FDA which monitors, 'they don't think they need it. They took part in the ICHGCP, along with the EU, USA and Australia, which aimed towards harmonization among those countries.' I probed the notion of a 'different case' with some questions. In response, he initially suggested I ask why committees in South Korea and Taiwan had sought recognition, since to him, the trials those three countries sought to host were the same. Gradually a sense of hierarchy emerged. 'Well, it's partly pride. They can't take being criticized by a lower country. It would be an insult.' A Taiwanese man, he had participated as an international surveyor on the FERCAP survey, and said '[t]hat's what happened in Korea. When we saw speakers from Philippines, Thailand, audience just went out of room. "Why should we listen to these guys, from countries not as good as ours?"' This brought him round to the point he had been struggling to make about Japan's lack of participation. 'They'd never allow people from South Asia to survey them!' he concluded, slightly exasperated at the anthropologist for forcing him to state the 'obvious.' 'They're Number One! For their self pride, they couldn't have surveyor from India. USFDA but definitely not other Asia[n] countries. That would be intolerable to them', he said flatly.[81] 'The top can improve by USA FDA but not by India or Thai.' He had visited Singapore, and reported that he once asked them, 'Why are you not active in FERCAP,' to which he received the response '"We are a developed country!"'

> So I said so are Taiwan, and Korea... but they [Singapore] only like to be seen affiliated with the US. That's why they have AAHRPP in Singapore and Hong Kong! And now they [AAHRPP] are also entering Korea... Some big professor from Korea asked me, 'Why [do you] stay with FERCAP, they're not better than us.' So they propose to go to AAHRPP. So there may be a competition.

In this sizing and re-sizing of countries, just as Cristina is aware that she can talk 'up' to countries with funds and well-established research environments, she is also aware that she has the capacity to foreground similarity, as she does in the quote with which I opened this chapter. This is a technique I saw used elsewhere, particularly during a Survey in Beijing, when a surveyor had remarked with great respect on FERCAP's arrival in the Chinese capital. Aware of tensions

[81] Another instance of fractality, where social hierarchies within committees transfer without difficulty onto hierarchies between countries.

between China's capital and second city, Shanghai, where FERCAP had already become established, she threw an arm out to her co-surveyors from the Philippines and said:

> We all have our Asian roots, and many of us have Chinese roots… Maybe our only difference is our language we speak — if you look at us, we all look the same. We share the same goal and values and would like to protect human subject in research, and do scientific research!

Here the Surveyor is drawing on migration between countries in Asia as a basis upon which to highlight shared goals. In a moment of tension, it levels. Another powerful leveller is the idea that ethical review is 'not a technology' (Chapter 3, see also Torres 2011:52). Where I heard this view reinforced, it was usually surrounded by contrasts between countries which categorized degrees of development, within and outside of Asia. These differences in degrees of development meant that while developed countries were considered capable of financing their own capacity building, developing countries required support. As the FERCAP Research Fellow Arthur put it,

> The standards are the same, whether developing or developed country. Developed countries, they can finance their own capacity building, but developing countries need support. We can try to facilitate money for Nepal and Bhutan. Doesn't matter if [the country is] developed or developing, [it] can be of a par with Western standards.

Surveyors who had traveled with FERCAP to other countries sometimes expressed surprise or shock at what they encountered, or the orientations one country seemed to have towards another. The comparisons which members of FERCAP undertake contribute to and build on its developmental ethos. When a surveyor from Taiwan thinks about the funds required to support a survey team, he tells me 'that kind of money, for Johns Hopkins it's a piece of cake, but for Cambodia? It's so expensive.' Thus FERCAP work to subsidise Cambodia's participation. How FERCAP 'measures up' to AAHRPP depends on where one is looking. If committees in South Korea and Taiwan move to AAHRPP, it diminishes FERCAP's ability to subsidise countries like Cambodia, and it in this sense that measuring up 'hurts.'

In this illustration, comparison and scaling matter in FERCAP's exercise of capacity building. Munro reinforces the point:

> Scale does not exist autonomously as it does with the western conception of levels of wholes, such as the tripartite set of society, institution and individual to the contrary, it is

> arguable that changing scale — the effects of 'magnification' or 'diminishment' — is precisely a demonstration of 'capacities' (Munro 2005: 257).[82]

I suggest that the comparison done by FERCAP members as constitutive of Mol and Law's third space, 'fluid space', in which 'difference….isn't necessary marked by boundaries. It isn't always sharp. It moves….[in] a fluid space, elements inform each other. But the way they do so may continuously alter. The bonds within fluid spaces aren't stable.' (1994: 662-663) I explore this further below.

FERCAP's comparisons

FERCAP's Research Fellow, Arthur, worked with Cristina in Bangkok, assisting with the ever growing documentation, administration and organisation of Surveys across the Asian region. His experiences had given him cause to reflect on the differences of the countries he had attended or arranged trainings and surveys in. 'The idea,' he said,

> is you get to know an idea of the context of the countries in terms of how do they go about ethical issues? Concepts like justice autonomy and beneficence, but what do these concepts mean for these countries?

The comparisons made by FERCAP resemble certain versions of anthropological approaches to comparison. Commentators like de Castro, and implicitly FERCAP, pose the region as a site of difference to an external other: western ethics. In a recent anthropologically informed collection, analyses grouped together under 'Asian Biotechnology' (e.g. Ong and Chen 2010) take on national characteristics. Wahlberg's review (2011) provides a concise summary of chapters that include 'an analysis of the:

> 'Koreanness' of fallen stem cell scientist Hwang Woo Suk who had suggested that dexterous Korean chop stick users had sharpened the cell work done in his laboratory; capacity building efforts to bolster an 'Indian' clinical research infrastructure as a way to attract lucrative multi-centered clinical trials to the country; … [and] the demarcation of 'Chinese DNA' as a measure of 'Chineseness' where the 'introduction of genomics since the 1990s…adds another spin to the discourses and practices on China's ethnic categorization (Wahlberg 2011: 492, references removed)

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[82] Corsín Jiménez offers us a description of this process through his own writing: '[y]ou may be reading this and thinking 'this is not very interesting'. If that is so, you are in fact re-proportioning your ideas against mine by 'sizing down' my views' (2004: 16) He attributes the movement in the proportioning to capacity: 'You are… *moving integrally* through such orders with a *sense of capacity* (and the term is not arbitrary, for capacities are magnitudinal categories) (2004: 17)

In our interview, I listened as Arthur talked about how his training in history informed his work. 'Histories give you a broader contexts on why these things are happening,' he said:

> In the Philippines, when we talk of ethical issues, it'll always be rooted in how the Spaniards or Americans did health research. The first ethical issues will always be rooted in a colonial experience. For Japan, their particular context is from WWII, they have ethical issues that may be traced, connected to WWII Japanese experiments. If you look at Korea, Dr Hwang is a product of how they do academic atmosphere and culture in Korea. There, everyone needs to discover, and so there is a lot of research and not much… basically there are particular contexts why.

What interests me here is Arthur's final comment, 'a context why', giving context as reason. It may be a turn of phrase, even a slip, but in the historical lens, the contexts (unlike in Frazer's work (see Strathern 1987: 266)) are precisely that which is juxtaposed, and, in a curious reversal of the assumption that contexts contain cultures, *culture* forms the ground for the idea of *context*. It is this which, I suggest, aids FERCAP in sidestepping 'cultural difference' for 'common goals.' Let me explain by way of an example.

Jenny Reardon's work (2001, 2005) on the Human Genome Diversity Project (HGDP) reveals the challenges faced by scientists as they sought to 'sample and archive human genetic diversity' by collecting specimens from 'distinct indigenous groups around the globe' (Reardon 2001:357). In the controversy that followed, Reardon found, it was the framing and bounding of groups which caused endless problems, demarcations on a complexly 'structured field of competing differences' (2001:361). 'Populations' could not be kept stable, since the boundaries between 'society', 'culture' and 'biology' (boundaries which Reardon observes 'did not exist in the world' (2001:366)) all produced different answers to the question of what a 'population' was. Wastell's findings on 'diversity' offer a germane critique:

> there is no such thing as a diversity that does not emanate from a project of measurement'… Diversity is 'not something that is 'already out there' waiting to be described and ordered. It is made by systems which operate through the estimation, valuation and proportion of entities - as apprehended by the system itself (2001:186).

These systems — which can be projects, (the HGDP) professions (the medicine which treats anaemia) or organisations (FERCAP) — shape what is differentiated, and how. For example, also discussing the Human Genome project, Strathern observes 'an organisation of knowledge whose aim is totality generates instances of its own descriptive process (mappable places)' (1995: 163). In the chapters above I have demonstrated the generation of instances of 'mappable places.' They are not genes, but offices and practices, efforts that encompass, or come to be encompassed by, national or regional agendas. For Strathern, what is interesting about the HGDP is 'not so much

that natural science creates universal objects of knowledge out of local instances; rather in that incommensurability disappears.' (1995:163). What is held constant — the similarity — is that there will always be a context; that there *are* contexts is what is alike. This is what Arthur reveals when he brings 'context' forward. 'You cannot have a black and white view of things when you don't understand the context, the country,' he said, of surveyors.

> Some trials which would in one country be considered risky might be seen to be beneficial to the population, depending on the context. There's not a universality of particular instances and issues. [There] should be contextualization according to country. For example, FERCAP cannot just get people to sit and comment on how an EC do their job without knowing the country context.

He allows the fact that there are 'contexts why' to stand as the figure against a ground of 'cultural difference'. Context aids this 'fluid space', it allows for a 'difference [that] isn't necessary marked by boundaries. It isn't always sharp' (Mol and Law 1994:662) since the FERCAP system does not set out to foreground that difference. I return the quote of Cristina's which I opened: the FERCAP experience is about a common goal (Torres 2010: 52). Here I have shown how that experience is choreographed. In this shift from 'cultural difference' to 'context,' we are also encouraged to focus on similarity over difference, or 'common goals.' In the concerns of the Survey and in the borrowing of techniques of standardisation and measurement from natural science, in the rooms of ethics, incommensurability disappears. In this observation I realised, as Sarah Green realises in her ethnography of ambiguity on the Greek-Albanian border, it was 'the ambiguous sameness that made the difference, not just the differences' (2005:14). In Epirus where she worked, the growth in number of European Union funded signs in their landscape signifying development projects which bespeak a break in 'how things are and how things seem' (2005:37). 'Whereas in the past, it might have been nations and their nationals', she writes,

> now it seemed there was a particular standard for evaluating the aesthetics of the diversity of culture and nature, a standard that made it possible to 'package' each people and place into something distinct and unique, which could nevertheless be classified and would be of interest to tourists to visit (2005:37).

Anthropologists have begun to research the implications of this 'packaging', with Herzfeld (2004:2) writing that 'even 'diversity' can become a homogenous product... the particular is itself universalised.' Is something similar occurring through research ethics?

Gaps

Let me return to the opening of this chapter, where I refused the obvious form of comparison between countries, a form that would probably be of use to those wanting to know the status of ethics compliance across different countries.[83] I rejected it in order to study a form of comparison ongoing in the material. We have seen countries compared. What, then, does the 'cultural difference' in the quotes that opened this chapter become? What happens to it? I turn to Annelise Riles' review of an ethnography of Alternative Dispute Resolution (ADR) (2002), in which there is — as in both bioethics and research ethics — a strong sense that context matters, the 'local' is valuable, and culture is the object to which one pays attention in order to understand a situation. Here are her observations on different kinds of frames for ethnographic knowledge:

> Consider what happens to ethnographic knowledge in the hands of the ADR expert: The authors point out that the ADR rhetoric of commitment to contextual understanding of the cultural facts of disputing is rarely honoured in practice. This in turn creates a rhetorical problem for the authors: If their essay actually engaged with the ethnographic literature in great contextual detail, it would become unintelligible to its target audience of ADR of practitioners because the latter are interested in general arguments about the nature of their engagement with the particular, not in the particular per se. What we have here is an example of the aesthetics of user-friendly expertise: Detail disappears and is replaced by a gesturing toward detail (2002:617).

I am not suggesting that a 'respect for cultural difference' is mere rhetoric, or that committees who work with FERCAP do not honour the idea. I have shown that they do. But FERCAP's problem resembles that of the authors whose book Riles reviews: committees are not so interested in the particular. As we saw in the previous chapter, their members are not bioethicists, few have 'bioethics' training. They are primarily doctors, who have trained in research ethics. And although the details of research ethics are very much what FERCAP works on (the details of SOPs, the details of offices and of meetings) in matters of 'contextual understanding of the cultural facts' (Riles 2002:617), I suggest that *gesture towards detail is precisely FERCAP's tactic*. Rather than prescribing in the domain of 'cultural facts' or exploring 'cultural difference,' it works with the detail of the form of the committee: how the discussion should take place, who should be on a committee, what its offices need to have. The 'recipes' — in the form of SOPs — acknowledge 'context.' It is the premise upon which 'local' capacity building is founded, and as such, forms the ground, not the figure of FERCAP's work. It is this which constitutes the separation between

[83] As the Bhutanese delegate perceptively noted when commenting on my nascent research plans during the 2009 FERCAP Conference.

bioethics and research ethics, so that learning about doing ethics review can happen anywhere. As one conference delegate tells me,

> We can learn from FERCAP or US NIH, program, any, so we don't actually have to have FERCAP people go abroad to learn nowadays. People get PhDs in London, the Hastings center, this kind of bioethics more and more people for them its not a big deal, if you have so many successful models such as WIRB. So we have seven fellows, in Korea 30-40 fellows from WIRB. Of course they have to modify it when they come back to Asia, that's not difficult.

To bioethicists such as de Castro working on the 'details' of cultural difference, the idea that modifying ethics learned in the West upon return to Asia is 'not that difficult' would be hard to fathom. But such a statement is possible, plausible even, when cultural difference remains the background against which FERCAP can foreground models, SOPs and the form of the committee. Returning to ADR, Riles suggests that it is not (just) that

> standardised solutions have replaced specific ones. Rather, in these new technologies we encounter the standardisation of the specific: The expert's manual become a kind of formal tool of its own — one can take it anywhere — but it acknowledges and even points to its own gaps; it makes room for the inclusion of local conditions and specificities. It incorporates in advance the critiques of the anthropologist by gesturing at repeated moments to the local, the particular, the need for translation and adaptation, and by translating our analytical perspectives [...] into technical factors to be taken into account by the expert [...] The particular becomes quite literally a gap in the expert form, something imagined, prefigured by expert knowledge itself (Riles 2002: 617-618).

Riles describes here the 'gesturing' which the anthropologist looking at the rolling out of 'ethics' across a region might conduct, perhaps through comparing its uptake in different countries. I suggest that the ADR 'experts manual' has kin in the template SOPs which FERCAP supplies to committees. These templates 'acknowledge and even point to [their] own gaps' (Riles 2002:617). This has the effect of neutralising 'difference', and making it the concern not of FERCAP and its surveys but of the committees themselves. It may even be something assumed to be already in their possession. As something the apparatus of ethics review already takes into account, 'difference' *lies in the gaps* (Riles 2002). This happens again, in ethics committee discussion. These gaps are also built in to review, in part again through SOPs and in part through learning the form in which ethical issues are to be discussed. The format of thought is visible in trainings on ethics review, as one trainer states:

> In Western societies autonomy is of higher value but Eastern societies sometimes we give higher value to beneficence. So now the culture of the community is going to take effect. What is of higher value to the community, that's how the ethical dilemma is resolved. For example, X finished her bioethics degree in Australia. One of the ethical issues that was

> presented to them was whether you should take care of your parents. She said, "In my culture it not an ethical dilemma, it's a duty." [Your] perspective is different depending on the culture where you come from. The decision is going to be different.

When the trainer proffers the ideas of autonomy and beneficence she is citing the principles of the Belmont Report (HHS 1979), an inaugural document in American bioethics, which recommended the measured balance of justice, risk, nonmaleficence and beneficence. It recommends an evaluation of balance between those who bear the burdens of research and those who benefit from it, the maximization of benefit and the minimization of harm. The focus of the speaker is on the *difference* of the decision, what one committee decides is not the same as what another decides. But what is also evident is that this difference can be rationalised into the framework of proportional balance: the *mode* of deciding is the *same*. The duty of caring for your parents translates into beneficence, autonomy is rebalanced. 'Duty', which may have quite a different quality cannot be calculated in this pre-existing equation. Recall Cristina's comment (Chapter 3) to a trainee wondering about consensus, and the possibility that both sides might have an equally valid point: 'you cannot be deadlocked, you must make a decision.' The ethics in FERCAP's capacity building program, like development, has ends (committee decisions, GCP compliance) in sight. Rather than endlessly opening up possibilities, questions, and the problems with which this chapter began, the need for 'action' requires that they be closed down (Riles 1998, 2001, Yarrow 2011:171). The critical purchase afforded by the approach I have taken has no such goal in mind.

Concluding remarks

Viveiros de Castro (2004: 11) declares that 'since it is only worth comparing the incommensurable, comparing the commensurable is a task for accountants, not anthropologists'. Strathern suggests the anthropological 'trick would be demonstrate noncomparability' and in doing so, 'cancel any easy assumption about anthropology's own self-sufficiency as a single analytical language' (Strathern 1988b: 95). I have tried to cancel this sufficiency assumption by another means: by demonstrating that it is ethics committees who must be accountants, not anthropologists.[84] It is they who must make commensurable, and be commensurable with one another. The former, as I have attempted to demonstrate, is an activity achieved through language and comparison; the latter is part of FERCAP's work of standardisation through its recognition

[84] It is here too that the difference between being an auditor and an ethnographer lies. See p. 53.

program. The comparison of this chapter is not the kind of comparison in which members of FERCAP, or the medical ethics world, are engaged. In the dissertation so far, I have attempted to show how much of what happens is dependent on the ability to make-comparable. By this I mean that comparison for FERCAP is a means of organising difference, an organisation which operates by removing the focus from it. Made attentive by Mol and Law's work on anaemia (1994), I have been able to explore the co-existence of spaces formed by the scaling, sizing and proportioning work of actors in the field.

I have shown many ways of doing comparison, and shown that they do different things. An anthropological response is to see what is produced in the juxtaposition, the employment of a 'critical pause' to see what happens when one thing is placed next to another (Gingrich and Fox 2002, Strathern 2002a). It is clear that members of FERCAP use comparison - deliberately and not - to shape the social world of research ethics. In *not* comparing the countries to which this research took me in the same language of scalar achievement as used in the field, my attention was opened to a different way of 'doing knowledge.' Yarrow's comments on anthropologists amongst development workers are apposite: 'differences between academics and development experts,' he writes 'are not simply disagreements: they are not simply different views or perspectives on 'the same' basic questions and issues' (2011: 171). For him what is '[a]t stake are different ways of making questions and issues apparent; different ways of ''doing' knowledge' (ibid). In the separation of research ethics from bioethics, the prioritisation of form over content makes FERCAP's international project possible. But if this is an arena of standardisation and measurable, auditable ethics, what happens when ideas, such as that of duty, don't fit schemas?

Chapter 7: Locating Ethics

> Making codes is one thing; transforming them into forms of life, quite another.
>
> Jasanoff 2005:175

> People is the hard thing. If they don't have a quality culture, its very difficult. People tend to do the same old thing. And they cannot change. It has to be a long time, starting when you're young perhaps.

Juntra and I were conversing in Bangkok in late March 2010, a time at when "Red-Shirts" (National United Front of Democracy Against Dictatorship) had filled the city and would, in the weeks to come, occupy large parts of the capital's commercial center. We were discussing quality, a theme in the trainings we were attending that day. She drew on contemporary events to make her point:

> I want to go to the market, how do I go? There are demonstrations, how do I get there, what are the possible ways I can go? I need information. Are there any obstructions? I choose the best one to get there according to the situation now. So I get information, where are the demonstrators now? I look at a map. I look at the risk of the three ways to get where I want. I choose the best. It may not be perfect. How can I manage to go there in the shortest time. Quality culture - that's the culture of your *thinking*. The shortest time, and the cheapest way.

She gestured around us at the university buildings.

> There is a quality culture of people working here: when they go home, they switch off the fan. If there is no quality culture, they wouldn't do this: 'I don't care.' Quality culture is about the whole organization, not about you. People say, 'I use a piece of paper and then I throw it away.' Quality culture is to reduce waste, it is an organisation on top of your thinking. I use two sides [of paper]. Whatever you do, you have it in mind. It's very hard, hard to define quality. But you have to define what it is. *I have to get quality culture into each person.*

What is Juntra talking about when she says she wants to get quality 'into' people? What is this thing which is not 'about you' yet must be 'inside' the person? Scholars have paid attention to the language that has accompanied the growth of audit, but few anthropological writings have addressed 'quality' directly. We see critical engagement with 'Best Value' (Miller 1998) and audit itself (Power 1994, 1997; Strathern 2000) but other terms languish, like 'good' or 'best practice',

perhaps because of their apparent obviousness, being taken 'at once as evidence of [themselves] and perceived as a layer added to others' (Strathern 2004b:10, although see Riles 1998). Quality —or in this case, *strategic* quality — is another of these self-evident terms. To unpick its meaning, we might ask why and how Juntra would try to get quality 'in' to people. What might this effort require, and what might be the result?

In previous chapters, I have explored how ethics comes to be located in standards, minutes, rooms, protocols, decisions. This chapter explores the 'ethics' people locate in themselves and others, how this is imagined, and its effects. In Chapter 4, I began to highlight a division in the discussions surrounding the relationship between law and ethics. In thinking about methods of governance, there is a move between external measurements and internal. Quality, as Juntra describes it above, exemplifies the phenomenon: she offers a divided union between an internal disposition ('the culture of your thinking') and an external measurable which can be tested and judged. Might the success of 'quality' as a rhetorical instrument lie in its exploitation of this dichotomy? It is measurable, but it also depicts an internal attitude or state: 'the difficult thing is the people.' This binary also pervades much of the contemporary commentary on governance. The status quo is summarised succinctly by Simpson (2012:157):

> Within the rationality of neoliberalism, the objective is to re-position government such that it no longer governs the people but governs the governance by which people govern themselves. Rose, following Latour suggests such 'action at a distance' is achieved through an intensification of surveillance, management, monitoring and the use of expert discourses on the one hand, and on the other, the creation of new subjectivities shaped by the urge to empowerment, responsibility and autonomy in all spheres of life.

While producing a further comment on the workings of neoliberalism is not my intent, the material presented here does speak to the concerns articulated above. It also offers a critique, wary of the antinomy into which an analytical divide between interior and exterior might fall. Established as independent fields, ethics and bioethics have their own disputes, narratives and commentaries. What I aim to bring to these discussions is an anthropological reflection on invoked modes of virtue, moral knowledge, conformity, responsibility and accountability; re-framing old questions upon which extensive anthropologies of the twentieth century have been written (Douglas 1992, Evans-Pritchard 1937, Frankenberg 1972, Gluckman 1972, Barth 1959, James 1988). The dichotomy of interior and exterior itself — a split replicated in the ethnography and in analysis — must ultimately come under scrutiny.

Quality

In Chapter 1, the story of Coast provoked the comment that in Asia, 'the system does not exist.' As such, audit-like regimes are introduced in the knowledge that FERCAP must first convince and persuade, rather than adjudicate[85]. As Cristina put it in her summary of FERCAP's activities, 'EC/IRB members need to be convinced about the importance of their task for them to exert their utmost effort' (Torres 2011:52). In convincing, it must get things 'in' to people. Quality has further qualities: it can be called upon in management. In her role as the head of the TDR's Strategic Quality Management (SQM) Unit,[86] Juntra not only favours the term 'quality', she can push its use in the World Health Organisation. 'There is a clear need to implement the principles of strategic quality management in health research to prevent failure, maximize the utilization of available resources and ensure consistency and credibility of results,' she writes in *TDRnews*, the organisation's newsletter (Karbwang 2010:24). In the biomedical research industry, quality moves closely with audit. As Bhatt and Pradhan (2007:15) put it, 'the fate of a drug molecule depends on the quality of the research data generated…[and] an audit of a clinical trial provides the sponsor an independent review of the quality data generated by the trial.' Both quality and audit are now moving closely with ethics. I asked Juntra about how she thinks about ethics and quality, trying to understand in what way they occupy the same frame. She used herself as the example through which to explain the relationship:

> I should learn from mistakes, but maybe I don't see it. I forget. So have to measure performance. If I don't perform well, I should improve. I need to measure. If I correct unsystematically I don't know which is wrong. […] I may train people but is the training good enough? You need to see evidence. If not, just do training and think its OK, because you just wanted to "do training". If I give a lecture on the principle of good practice in ethical review, what is my measurement of you? How do I know you have learned? I can ask you, give you an exam or an exercise. But I have to define what I expect, what is my learning objective[…] A lot of time don't know what we're looking for, so its difficult to measure. Same as going to the market - you're buying dinner, if you have a list, you go to this section, buy this, that, fast and get what you want in a short time. If not, you buy things and you don't know what to do, [it] doesn't make a meal, [it] becomes junk. If you don't have anything in mind, [you] buy many things, [but you] don't get what you really need.

Measurement is clearly key. Juntra's recursive descriptions pass from the measurement of the activity (ethical review) to the measurement of the learner ('how do I know you have learned?') to

[85] They are not yet in the realm of 'coercive accountability' (see Shore and Wright 2000 for an account from higher education).

[86] Responsible for the quality of TDR–supported studies.

the measurement of the training (is training good enough?) to the identification of learning objectives. Quality is potentially present at any of these moments; an orienting principle for designing and implementing the survey, in addition to being the thing that surveys seek in committees surveyed. In other words, quality is a measure of ethics, and ethics is a measure of quality.

We might say that here, ethics is 'part' of the Strategic Quality Management efforts, of SIDCER's 'Strategic Initiative for Developing Capacity in Ethical Review.' Through Juntra this principle and priority has been taken up by FERCAP. Using language which recalls the images of fragmentation in Chapter 1, Juntra observed that:

> until now, quality management was often fragmented. For instance, there was a quality check at the start of a new research project in the grant selection process, and another at the end through peer review publications. But during the balance of the research process, quality management was frequently left to researchers and their institutions (Karbwang 2010:24).

During revisions to the standard operating procedures for survey teams, Juntra used a metaphor to describe the way in which the group doing the revisions should *aspire to quality in their definitions of quality*. 'Do not just say "I will make a pen,"' she said. 'I will say:

> "I want a yellow one with a red bottom, five inches long." It's not [an attitude of] "any pen will do," we want *that* pen. And if we're talking about surveyors, we need to define the quality of the survey and the surveyors. Otherwise its just another routine thing.

Juntra would perhaps have got on well with Geertz, for whom culture 'is best seen not as complexes of concrete behaviour patterns — customs, usages, traditions, habit clusters —... but as a set of control mechanisms — plans, recipes, rules, instructions... — for the governing of behaviour' (Geertz 1977:44, cited in Strathern 1985: 111). SOPs are a good example, described as 'recipes' in Chinese Ethics training documents (Figure 29). Thus when doing ethics depends on quality, surveyors take up the language of quality improvement with gusto. At a FERCAP training prior to a Survey in Manila, April 2010, I heard this statement from a Surveyor: 'We believe in continuous quality improvement. Therefore there is no perfect EC, we will always find something, some weakness that we will make recommendations about.' FERCAP surveyors have passed this language on to committees seeking renewal of their recognition status.[87] On a visit to an IRB in Taiwan, I received an office tour, and the secretary handed me a thick folder filled with the

[87] Committees must be re-surveyed every 3 years.

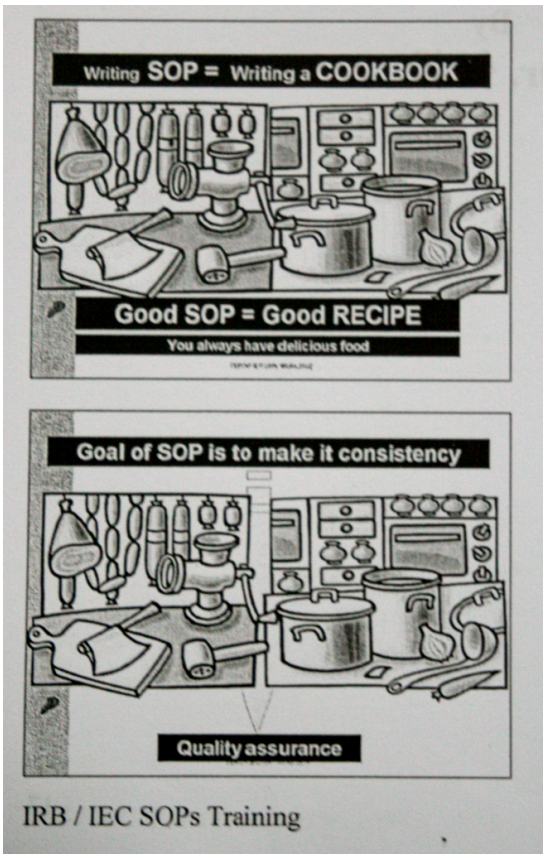


Figure 29: Image taken from Chinese Ethics Training Book

documents from their recent Survey. The hospital's powerpoint slides listed the IRB's SWOT analysis:

> W [weakness]: continuing dialogue between the PI and IRB needed to ensure the PI's positive attitude toward IRB functions and responsibility.
>
> T [threat]: owing to tightened standards reinforced, the number of research protocols submitted to this IRB for reviewing may be reduced temporarily; for the long run, however, we believe that the sponsor and PI would recognize, appreciate and benefit from our continuous insistence on quality.

These tensions between IRBs and PIs I have discussed already (see Chapters 3 and 4). What interests me here is the 'continuous insistence on quality': quality is something that must always be striven for, but chained as it is to the terms 'continuous' and 'improvement,' it can never be arrived at. The term used to describe FERCAP's work, 'capacity building,' suggests a kind of linear progress. This is how Surveys first appear: as efforts to see committees reach a certain standard, be recognised through the FERCAP/SIDCER program, and then continue to work towards re-recognition. But the introduction of higher standards and changes in regulations and guidelines suggests that this process may not easily be considered complete, indeed, if no committee is ever

perfect, then their condition is one of infinite improvability. The sociality of this potentially infinite project is visible in the operation of the Survey (Chapter 2), when the Surveyor announced there was no perfect ethics committee. But it is also visible in trainings on trials, as illustrated in this comment in a Philippines GCP training:

> Should results of non-GCP compliant studies be published? It boils down to GCP. From the research protocol up to publication [...] Remember, there is no study that is perfect. Who can do a perfect study? Nobody except God probably. No investigator can claim that his study is perfect and fully, fully 100%. *Sapagkat kami ay tao lamang*, because we're just people.[88] We're just human beings. We're bound to make mistakes.

In this researcher's experience, GCP monitoring, of the kind which was the subject of debate at the opening of Chapter 5, also prompts a sense of judgement and blame. The researcher explained how he had felt when a monitor came to visit his site during the conduct of a multi-sited clinical trial in the Philippines.

> The first time we were monitored we hated it. We were debating. 'Why are you doing this?' we asked the monitor, 'Your role here is to help!' But they did want to help — so in the end it becomes good, a good study. We were like that for the first visit, but then there was a second visit. [...] You start blaming each other in front of the monitor. There was a third visit, and by the fourth visit, we came to like the monitor.

Just as Surveyors declare there is no perfect committee, GCP trainers declare there can be no perfect study. This is, in part, because it is the same people who are doing both. The researcher above who initially hated his Clinical Monitor is a member of an ethics review committee. Their clinical experience informs committee decisions about clinical trials but, I suggest, it also shapes the way in which 'ethics' is developed and implemented.

While my discussion so far has focused largely on ethics review committees themselves, the economics of research and narratives of personal and national productivity are never far away. One trainer told me that she aimed to motivate her students: 'By the end of the session, '[I want them to] think "[There are] many things I have to do! Many things in need of change."' Juntra remarked that at trainings, there is an imperative to pay attention:

> You are contributing to your country, using resources properly. People who come and don't want to learn should feel ashamed, they are wasting their nation's resource. If I go and I don't pay attention, I feel guilty because the organisation has paid for me. You should feel it *yourself*. I'd like that to happen to everyone. Shouldn't wait for people to evaluate you, but evaluate yourself. If I've been sleeping, I should feel bad.

---

[88] Lecturer's translation, taken from a popular Tagalog love song.

The neoliberal commentary with which I began encouraged the link which this section has developed: between measurement and morality. Porter's work (1995) has so clearly shown that measurements are far from apolitical. Where there is morality in the measurement, there is also measurement in the morality. Quality, like ethics, becomes a value to believe in, and something to be advocated for. Made deliberate, conscious, it can be practiced. But what is that is being appealed to, such that this move to quality consciousness might happen? What might be 'in' committee members already, being elicited or invoked? Following on from these questions, the next section explores the concept of duty, first invoked in this thesis' opening vignette in Cristina's remark 'If you do not do your duty, you are not a good professional.'

Duty based Ethics

> The duty-based approach in research ethics was also clearly understood in the East Asian setting that is clearly steeped in the Confucian tradition of beneficent governance and grounded in the Buddhist principle of selflessness (Torres 2011: 48).

While we have seen above that Juntra would like to get quality 'in' to people, I also want to suggest that FERCAP trainers aim to elicit something from them. Cristina calls on Confucianism and Buddhist principles to suggest that duty was 'clearly understood': perhaps 'getting things into people' is dependent on something already being there. The language of duty-based ethics prevalent in FERCAP is perhaps supported through Dr Koski's presence on the SIDCER advisory board, and his participation in the Forum's conferences. When Koski describes the finely woven silk cloth which I used in Chapter 1, he says '[t]he individuals and entities engaged in human research constitute a matrix of overlapping roles and responsibilities that together serve to ensure that the *duties* are satisfied' (emphasis added). His subsequent slide (Figure 30) draws duty out from its Kantian roots towards the Belmont Report.

East Asia is not the only place where FERCAP works, and existing emic uses of the concept of duty within the countries covered by the network has received longstanding, if intermittent, academic attention (Doniger O'Flaherty and Derrett 1978, Lassoff 2009, Peletz 2011). This work on duty in the region stands in contrast with the rights based discourse which, scholars note, has been foregrounded in bioethics (Annas 2005, 2010, Fenton and Arras 2010; see also Bhatia 2000 and Carnegie 1996). Given this, we cannot assume that the 'duty' invoked by Koski resembles that which will be understood by FERCAP members or effective when invoked in trainings. Perhaps rather than a 'boundary object' (Star and Griesemer 1989), the term is more usefully imagined as

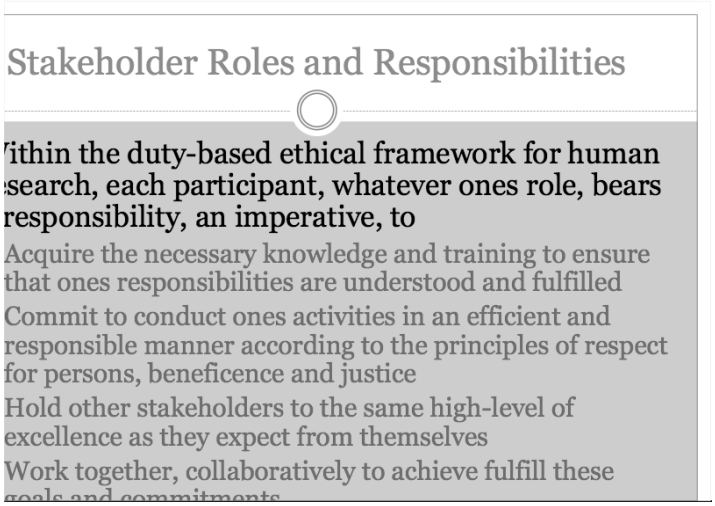


Figure 30: Dr Koski's Stakeholder Roles and Responsibilities slide.

a boundary concept (Allen 2009, Löwy 1992), employed as a idea around which different parties can congregate, 'plastic enough to adapt to local needs [...] yet robust enough to maintain a common identity across sites' (Star and Griesemer 1989:393). Furthermore, duty as a boundary concept operates as 'a means of translation [...] key in developing and maintaining coherence across intersecting social worlds' (Star and Griesemer 1989:393). Despite their emphasis on making things explicit and their attention to detail, FERCAP do not say much on how they intend the concept of 'duty' and I suggest that by leaving its meanings implicit, and using it only occasionally, the idea of 'duty' helps FERCAP achieve 'coordination without consensus' (Kimble et al. 2010). I would suggest that Cristina is aware of this, and her linking duty to Confucian governance and Buddhist principles reveals only one part of the boundary concept's properties. The specificities of the invocation of duty across the region in which FERCAP operates will be diverse.

Recalling Noah's argument that perfect documents mean nothing unless the researcher has 'bought in' to the process (2004:292), one committee member commented 'Yes I've done six months at WIRB but unless you keep it in mind, the training is nothing. It is up to you.' I suggest then, that the idea of duty is a resource that FERCAP draws upon, and I am interested in what 'duty' appeals to. FERCAP's capacity building work extends beyond documentation, Surveys and training, they seek to build capacity through appealing to duty and responsibility; in some places, such appeals are practically the only tools available. Speaking of a Surveying trip to Francophone Africa, one Surveyor said:

> They have practically nothing. No PhDs. So in the Ethics Committee of the National Health facility, they make decisions on what drugs to come in for testing, which ones to say no. I ask how they decide which to have, but they have no evidence to support their decisions and drugs for testing are everywhere. There are no standards. I said, 'Maybe you need some people?' The most that they have is a Masters degree: can you imagine, you'd be the authority of the country? How can you expect others to take responsibility? That's what ethics is about. Even in daily life. It's about responsibility. Before you accept responsibility you have to know what [your responsibility will be] about. If its beyond your capacity, you have to gain that capacity first. You should ask, 'How can I best contribute?' That's why in GCP you have to state very clearly what each [party's] responsibility is about. So the person can see, 'For me to take responsibility I need this training.'

This Surveyor's configuration of a committee member looks for responsibility towards others (trial participants) in the framework of GCP, which in turn foregrounds responsibility for oneself. The Surveyor's comments evoke the idea that in duty 'it is not specific conventions that are the object of the exercise but a specific orientation of the person' (Strathern 1992a: 153). From this sentence two separate paths emanate. In this thesis we have seen how measurements are only considered effective if their goal is pre-specified. These are the conventions which can at once be measure and goal (Hoskin 1996). But in the same way as research ethics separates form from the content of bioethics, Cristina's use of duty releases ethics from 'specific conventions,' focusing instead on the orientation of the person. One orientation she knows they have in common, and the direction of her appeal, is the professionalism of the professional.

Professionals and Professionalism

Here is an extract from my field notes.

> *We need some consensus, otherwise we stay in a grey area where decisions are not made. Ethics is very important for society, but it shouldn't be a stumbling block for decision making.*

It is July 13th 2009, and we are at the National Science Foundation in Colombo, Sri Lanka. We are trying to discuss the formation of ethics guidelines for the professions. "We" are scientists of differing stripes, architects, medics, engineers, microbiologists, and we have been talking for some time. Our objective is to ascertain whether cross-profession professional ethics can be established, and if so, what they will look like. But this 'consensus' is proving elusive and it is hard to find ways to make decisions. 'Decisions can be made depending on the values we agree upon in the society,' offers someone. But this is difficult too, because 'society' is not thought to be present. We have only professionals, and scientists. We brought them here to

formulate principles they consider internal to their disciplines. Another speaker tries to find new common ground.

> *When trying to discuss guidelines on the formulation of ethics I think its easier if we take a common thing. I feel there are two main things. One, will the outcome harm society? If yes, then it is not suitable, it's not ethical. The other is will it harm the environment? On these we can base our effort. Then it comes to transparency. Then the right to information. Next piece is accountability. An individual is accountable to their boss, to a university head, to ministers, to the president. At the end, the president is accountable to society and the people, as an elected leader. So, basically the question is whether we are maintaining social responsibility.*

Social responsibility, however, opens a new set of issues. Ethics and responsibility, the speaker has suggested, intertwine, and the presence of the president in the chain of accountability configured by the speaker causes further problems still:

> *In totalitarian regime, questions are not asked, because we'll be shot. You implied we're responsible up a chain to the president, to the public. No! We're responsible to the public, otherwise it is like a totalitarian regime, where if we have to be prepared to go public on something which differs from what the president wants to say, once in a while, one of us will be shot.*

Locating and fixing ethics, as found by those in the discussion above, is no easy task. As an opening on my discussion of professionals and professionalism, it presents a slice of what was a heavy, complicated discussion, raising more questions that I can hope to answer here. But its richness is suitable, since it reveals what is at stake in the dichotomy between professionalism and audit: are ethics 'in' s/he who is willing to speak up, even at the risk of being shot, or are they 'out there,' in the powerful abstraction of 'society'?

Ethics committees, Dyer and Demeritt remind us, 'are part of a wide sea-change in the governance of professional conduct. Until recently,' they claim, 'research ethics were treated as matters of personal and professional integrity' (2009: 47). Professionalism is presently enjoying something of a renaissance (Friedson 1994, 2001; Miettinen 2001a, 2001b, 2001c). Creuss et al. (2004) draw on the work of William Sullivan, a medical sociologist, to support their view that:

> [n]either economic incentives nor technology nor administrative control has proved an effective surrogate for the commitment to integrity evoked in the ideal of professionalism (Sullivan 1995:16, cited in Creuss et al. 2004, see also Freidson 1994).

I say renaissance, because there was a time when being (a) professional was not enough. Looking at the UK, Duncan Wilson, an historian of biomedicine, has charted the factors that 'fostered outside scrutiny of medicine,' with an aim to show 'how particular individuals fashioned

themselves into "ethics experts"' (Wilson 2012:195). 'The new regimes of external oversight, like bioethics, were not simply the product of the conservative demands for audit and accountability', he writes, 'but also depended on the presence of individuals and professional groups willing to define themselves as the new arbiters of best practice' (Wilson 2012:196). In the USA, Stark traces 'how the moral authority to decide how to treat research participants was relocated from professions to the state and reinvested in procedures rather than ethics principles' (2011b:7), although she suggests that 'group review was invented, justified, and expanded less by "outsiders" like bioethicists and activists than by researchers themselves' (2011b:7). As it professionalised (itself), bioethics kept intact the idea of the profession, to which research ethics is now returning.

Koski, whose image of a finely woven silk cloth opened Chapter 1, began a webinar with the complaint that 'there is little direct, measurable evidence that the heightened burden [of review] actually increases the effectiveness of protecting human subjects, or improves the quality of the research itself' (Koski 2011). He turns to an article by Taylor (2007) which was published in the industry circular *IRB: Ethics and Human Research* in which Taylor concludes, based on interviews with members of Canadian IRBs, that:

> in the absence of empirical evidence regarding the quality of REB review, those interviewed said they rely heavily on the integrity of the researchers and professed a cultural norm that the integrity of researchers not be questioned (Taylor 2007:11).

In their research on review boards, Beagan and McDonald write that though '[a]lmost all of the participants believed, often passionately, that ethics review is effective [...] the empirical evidence offered for or against such claims was scant' (2005:66). Sugarman (2004: 495) would produce an evidence-based ethics that, '[s]imilar to evidence-based medicine,[...] would emphasize the importance of data in informing decision and decision-making about the ethical issues inherent in clinical medicine and research.' Thus Beagan and McDonald find it 'paradoxical that those in the health professions base their practice on evidence-based standards *except* in the case of ethical review' (2005:67). In his webinar, Koski, rather than developing the measures Sugarman, MacDonald et al. require, concludes that the absence of 'evidence' actually brings something else to the fore:

> [W]e simply have to say, all right, if we're really talking about integrity, if integrity is what we're falling back on in hope that that's what is actually going to protect human subjects, [then] of course that's what Henry Beecher[89] says. [I]t's really the integrity, the well trained, well intentioned investigator, doing the right thing, that provides protection for human subjects, not a committee, not regulations. It's the individual integrity of scientist, and of

[89] Henry Beecher (1966) wrote a now famous paper revealing ethical problems in American research.

> course, if we think that we're going to be able to continue to do things the way we have for 30 years and expect to come up with a different result, we're deluding ourselves, and we're legitimately criticised on both sides of this debate that we're really not being rational in what we're trying to do.

For Koski, not being "rational" means not paying attention to the "evidence":

> The professional investigators have perhaps the most important role of all. But the system we have developed over the years has somehow in a sense conveniently overlooked that. To put it another way, some have argued that ethics committees themselves, or the IRBs/REBs have in fact taken over the responsibility for the ethical dimensions of research at a time when we should be looking to our physician scientists to take on more responsibility.

One way for physician scientists to take on that responsibility, he says, would be to undergo an examination as an 'ethics professional'. Separate from reviews of the committee, in this model individuals are certified for their competence in ethics. He advocates a shift from a 'culture of compliance to a culture of conscience,' and his talk focused on how that might be achieved.

> Where we are today is in the compliance domain, where so much of what we do is driven by our desire to ensure that research is going to be reviewed and performed in compliance with regulations. Regulatory compliance is the floor for all Human Subject Protection. Because if you go below that you're breaking the law. That means you're a crook. And certainly this is not where we want to be, and yet this is where we stay 'cos its the only thing we've known how to do. It's not where we want to stay.

The result of a move from a 'compliance domain' to a 'true performance domain,' he says, would be trust: research that is trusted 'not only by the participants but by society, sponsors, everyone.' His statements here are part of his formulation of a move from 'compliance to conscience,' developed during his tenure as the Office of Human Research Protections (OHRP)'s founding Director in Washington (Koski 2001; Whalen, et al. 2003):

> Under a professional system, investigators who fail to meet their responsibilities lose their privileges. If you don't do it right you don't get to do it at all. That seems to be a very powerful way to motivate people to do things right, it works in medicine, it works in law, and other fields, there's no reason it wouldn't work in research. [...] There would also have to be personal accountability. Rather than shutting down an IRB or suspending a FWA, thats not the issue it really needs to get back to the individuals who are doing the work who need to be held accountable for how that work is going to be done.

As Busch remarks, linking certification arguments to trust and the management of risk (2011:203), certification can be thought of 'as a displacement of trust as predictability' (2011:214). At the webinar, Koski sees 'certification of individuals, accreditation of institutions and programs' and other 'validation tools and 'instruments' as 'crucially important':

> These are tools that the public has become comfortable with and come to rely upon in terms of knowing that a system upon which they must depend, either for their own personal safety or their health, even though they may not know all of the intricate details, they know someone who does know all of the intricate details is overseeing things.

Koski is talking about certifications such as the Certified IRB Professional (CIP), an American professional certification I first heard about from Edith, a secretary of a committee in Taiwan. She had taken the exam but failed. 'There are 250 questions on the exam!' she told me. When we met, she was trying to decide whether to sit the test again. When I asked her why she wanted it, she paused. 'To become a professional? When I'm in the IRB, I want to have the test, but its been two years [since I was a WIRB fellow]. I can't remember the US regulations,' she told me. She was quiet for a moment, then said,

> Just like IRB, this qualification is just for the name. In Taiwan, 5 people here have the CIP, and they tell others it is *very* difficult. Many tried and failed, even famous profs who have conducted Clinical Trials. [They] just thought 'Its just about clinical trials and ethics.' I think they failed 'cos CIP is about CFR, which is US regulations. So, not very important for Asia people. But if you say you have it, people will think you're good.

The CIP is promoted by the American professional association Public Responsibility In Medicine and Research (PRIM&R). Originating in dinner groups of people trying to stay on top of burgeoning regulations in the 1970s 'when there was no such thing as a professional research administrator' (Selwitz 2009) the organisation has seen 'management of [...] human subjects committees become not only an accepted but also a respected profession' (Selwitz 2009). 'PRIM&R are different from FERCAP,' Edith told me:

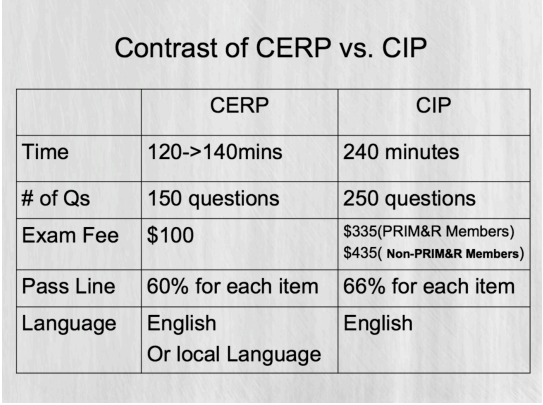
> They really provide education, and they earn lots of money [though doing it]. One day can cost $600USD! They know how to make money, they go to each state, they provide Ethics 101, 201. And they encourage the CIP. It costs $438. You need to prepare, study. No Americans fail, only foreigners, because of the language barrier.

Since the CIP was based on US regulations, neither Cristina nor Juntra had taken the exam, 'they said it's not so important for an Asian country,' remarked Edith. But last year, she said, they had 'tried to imitate the CIP, make an exam model' (Figures 31 and 32). This was the CERP, Certification for Ethics in Research Proficiency, proposed during the FERCAP conference in 2008. Based on 'credentialing' and focusing 'specifically on the individual' and their 'current knowledge in an international and specialised area of practice' (Lee 2008), passing CERP would allow successful candidates to use the designation after their names.

But it didn't work,' said Edith, 'nobody wanted to take it. There was a meeting in Taipei, but only a few people came. There were more speakers than audience!' Edith thought while it was a good

ELIGIBILITY REQUIREMENTS

CIP	CERP
A Bachelor's degree plus two (2) years of relevant IRB experience within the past seven years	
Four (4) years of relevant IRB experience within the past ten years	
Currently certified as a CIP	
Completion and filing of an Application for the Certification Examination for IRB Professionals.	Completion and filing of an Application for the Certification Examination for IRB Professionals.
Payment of required fee.	Payment of required fee.
Service as an IRB member is not, in and of itself, sufficient to fulfill the requirements for experience.	PI/Board member/Staff



Contrast of CERP vs. CIP

	CERP	CIP
Time	120->140mins	240 minutes
# of Qs	150 questions	250 questions
Exam Fee	$100	$335(PRIM&R Members) $435(Non-PRIM&R Members)
Pass Line	60% for each item	66% for each item
Language	English Or local Language	English

Figures 31: slides from Lee 2008.

idea, the low uptake was largely because it was not (yet) a formal requirement. This reminds us of something not made obvious in the direct comparison between the CIP and the CERP: that research ethics is not a profession in Asia in the same way as it is in the USA. In appealing for FERCAP members to be good professionals, I suggest, Cristina is referring to their existing professional identities, as medics and scientists.

Let me return to the opening vignette from the Sri Lankan National Science Academy, where scientists gathered to discuss cross-profession ethics. They were troubled by the location of ethics. Is it found 'out there in society', sought and found through survey or consultation (Strathern 2005b) or does — should — it come from within? To the 'levels' of Euro-American thinking (Callon and Latour 1981, Strathern 1985) these are sensible questions. Indeed, not only does ethics — in its language of informed consent and 'benefits to society' — echo it, but anthropologists too replicate the dichotomy, resting arguments upon the notion of 'levels' at or between which actions can occur (Callon and Latour 1981). This they owe to a twentieth century imagining of sociality, laid down initially by Durkheim:

> Society was held to inhere in the "level" of organizing principles, not in what was being ordered; levels were literally conceived as of a different order from persons concretely imagined as so many individuals. Hence the central problematic of midcentury anthropology: the relationship between individual and society. Each comprised an irreducible perspective on the other (Strathern 1992b:105)

This irreducibility left the speakers in the National Science Academy at an impasse. In a Durkheimian frame, it was possible to view society as the source from which morality — or the 'general' ethics sought by the vignette's speakers — should spring. Society, like the professions, could serve as an 'external constraint' (Durkheim 1995[1912]). FERCAP's duty based ethics and

"moral force" is an appeal to professionals; a response to an environment where a call to uphold (professional) integrity may have greater effect than a call for accountability. Accountability requires an agreement between those who hold a committee accountable and the committee's recognition of that authority. Despite talk of a 'return to the professional,' faith in the regulatory capacities of 'the professions' in some countries where FERCAP works is slight. As an interviewee in Sri Lanka put it, 'most of the time, the professional association isn't there. Most of the time, it's just conscience. The Medical Association cannot go behind every single person.'

If I have argued that Cristina's appeal to professionals is aimed at their existing professions, it is due to the fact that ethics committee work is an activity overlaid upon people's existing jobs. However, this is not to say there is no activity recognisable as professionalising. As Edith said, she wanted to sit the CIP herself, to become a professional. In an essay on 'Remaking the moral person in China: implications for health,' Kleinman observes that the medical profession, 'like the legal, architectural, engineering, and other professions, is self-consciously professionalising with greater attention to best practices, training standards and public responsibilities' (Kleinman 2010:1075). This version of professionalising — best practices, standards — was only one of the kinds of professionalising I observed during my fieldwork. There was also something far more interesting going on: with their understanding of how committees 'work' across the region, FERCAP's project with ethics committees was beginning to specify — in informal spaces — the kinds of skills and attitudes that will aid the realisation of their vision. A pre-conference training in Chiang Mai in 2009 brought under discussion the personal and professional qualities and responsibilities of the two parties most directly responsible for the management of ethical review committees: Secretaries and Chairs. About sixty people from across the region had gathered in a side room of the Imperial Mae Ping Hotel in Chiang Mai, Thailand to hear each other present. The South Korean Expert Secretary General had included in her presentation certain personal qualities that secretaries were encouraged to possess or develop in order to do their jobs effectively:

> [Must have] Responsiveness: act quickly and reliably.
>
> [Must do] Balancing: IRB is actually a compromise activity in terms of ethics. If you have high abstract standard you can't approve any proposal. You must have a good sense of balancing.
>
> [Must be] Gentle: keep people around you happy, but be strict.
>
> [Required character involves] Integrity: it is very hard to have authority. You need discernment, accountability, sense of balance. I talked about attitude, virtue ethics or principle. If you have good virtue character you will be a good secretary.

These are qualities that blur the boundary between professional and personal characteristics, describing the ethics-of-the-self characteristics of those who would administer the work of committees. I explore this inculcation (Noah 2004) through looking further at what FERCAP trainings aim to achieve.

Belief in Ethics

At a FERCAP Strategic Planning session in Shanghai, June 2010, meeting attendees were preparing powerpoints for use in trainings. During the first session after lunch, Juntra was comparing versions of the FERCAP logo in order to select one for a standardised powerpoint: 'This one is nice, but the letters are not nice. When the proportions are wrong, it's not the logo anymore! It should be a flame, like this, it should go up.' I took the opportunity to ask about the logo in more detail. 'It is the flame of enlightenment,' she told me, 'to revive and fan a passion for ethics and research.' Her description encapsulates how 'ethics' can be simultaneously thought of as an international system of committees and a *state of mind*. 'It's the same as when you change your paradigm,' she told me. 'This thing may be obvious for some person, but others can't see it until they cross that line.' We were sitting opposite one another around a table at the workshop, and she put her hands on her laptop screen that formed a barrier between us. 'It's hard to explain when you don't cross [gesturing to her side of the screen] when you're on this side [gesturing to my side of the screen]. However much I tell you, it doesn't mean anything until you cross the line.' My face must have betrayed confusion, because she continued with another example. 'Do you ride a bicycle?' I nodded.

> You can ride a bicycle now, but before you could, why [was it] so hard? Do you remember that first time? That moment, the first time you ride the bike, you remember. That's why I try to find examples, what does it mean, when you can't do it, you can't do it, you can't do it, then you suddenly can do [it]. Take that moment.

Some trainings were thought to produce this effect more than others. Cristina, who had been following our conversation, warned the others present not to expect the participants to reach this understanding immediately.

> At the beginning the participants wouldn't care. Then they start to listen. It [the workshop] is one of the most transformative. At the beginning they don't care, then they hear… You see them change.

FERCAP trainings are not merely targeted at making students realise their own ignorance and seek to overcome it, rather, the aim is a transformation of attitude, or in Juntra's terms,

'paradigm.' Many of my interviewees agreed with this view. During a lunch-break on a GCP course in Chulalongkorn University, Bangkok in April 2010 I was talking to Cathy, a committee member from Bangkok about the presentations we had seen that morning. My head was full of the changes that were taking place institutionally to accommodate international recommendations, and some of the difficulties experienced in implementing rules and regulations. Cathy nodded along, but in a pause, she pointed out something she thought I hadn't quite grasped. 'There is one thing you haven't mentioned', she said: 'the integrity of the researcher':

> No rule can write it all, to cover every aspect and every speech of the doctor to the patient. Only the integrity of the doctor and that will control good or bad science and research. Regulators cannot do what integrity and the culture of a faculty can do.

It was this institutional 'culture' which Cathy hoped would be passed between members in her institution:

> When you are young staff, and you haven't come to an ethical issues course and you don't know much. Still, if someone told you 'This is the rule,' even if you don't know yet you will not avoid a rule or do something against it or behind the backs of others. So first you recognise that it is a rule. Then someone says there are ethical issues, and if someone has a good integrity, to be a good doctor, they will go to the course. And start to understand it. That's when they start to understand ethical; you *become* ethical not just in your rules but in your life and your mind.

What Cathy makes very clear is that there can be no rule that governs social interaction, for wherever we look — the conference, the room of the ethics committee, the survey and of course (most obviously) doctors and patients — the relationships cannot be reduced (to rules). More is hoped for in this enculturation than rule following; in my focus on standardisation I had — for Cathy — missed the point. 'Regulators cannot do what integrity and the culture of a faculty can do,' she said, 'people need to want to be good.' Her reaction to the standardisation we were learning about in our GCP sessions was to root action in the staff, not in the rules.

In FERCAP trainings, learning to see ethics, to really understand, is felt to lie beyond their activities implementing and training committees. We have seen hints of this already: this thesis began with a moral value placed on acting through belief, not through policing. Sri Lankan bioethics advocate Sumathiupala pushes for education, but not just a change in how much is known:

> By creating awareness among the research community, this ignorance [about ethics] can be defeated. This can be done by guiding researchers to do quality research because they *believe* in the ethical framework: you should promote ethics because ethics produces good research

> and you should become an ethical researcher because you believe in it and not because somebody has started to police you (2006:S78).

This idea of *belief* in an ethical framework interested me. At the opening of a Surveyors training, one Surveyor described his transformation and how FERCAP had helped him 'see' ethics in these terms:

> Well, before 2005, I'm just like you, some of you. I sit in the audience for the first time when Cristina came to [City X] to give a symposium on SOP. I was not an IRB member in that moment, so I had no idea, though I knew what it [ethics] was. Then I had a chance to learn a lot from Dr Torres and Dr Juntra. So thanks to them, we had the opportunity to visit WIRB for six months. And after that Cristina gave us a lot of chances to visit other IRB, a kind of field trip. So we learned from the book then we learned from reality.

These moments, in conjunction with the language of 'belief,' prompted the single occasion on which I addressed ethics and religion directly with Cristina and Juntra. We were having lunch together in Bangkok between training sessions and I asked about their experiences across the region with religion and ethics. Cristina responded:

> Each religion is thinking about the common good. No matter what your religion, it's about the good for the other person. In the Philippines, I say its *not* about Catholic dogma. The idea in EC is to respect how a person thinks. *That's* autonomy. Respect his conscience, how he thinks. *How you relate it to your belief system, well that is one area Asians are different - things are not in boxes.*

In emphasising the *distinction* between ethics and 'Catholic dogma' Cristina was focusing implicitly on general principles abstracted from religions and applied in an ethics committee setting. Commentators point out the difficulty of separating religious and ethical thought, even down to the language used for the concepts (e.g. Hongladarom 2004 on the Pali roots of Thai ethics language). What interests me is the expressed need for this distinction, the claiming of a space for ethics which is not conducted in the language of religion. Previous chapters have shown there are a great deal of parallels between the spaces of thought of ethics and religion: justice, right and wrong, fairness, balance, empathy, compassion, even conversion. In many ways it is not surprising that modes of thought and behaviour that resonate with the religious should be seen in the way people talk about ethics. Merographic thought (Strathern 1991, 1992) makes ethics seem part of both the secular (medical) and religious domains, fully encompassed by neither.[90] The domain of medicine and the activities of biomedical assessment and audit are a site of unusual

[90] Humour is one means by which I saw this communicated: Catholic surveyors who attend churches while abroad on surveys joke that 'you can follow the same all over, you know where you are, it has SOPs!' More intriguingly, teacher-pupil relationships bind with ethics when a student asks whether eating a *balut*, a fertilized chicken egg with a nearly-developed embryo inside, was unethical. A Surveyor asked whether he had managed to reverse the unethical side of having consumed his own by eating himself the one his teacher had refused.

convergence, a place where one's personal ethics and ethics of the self (Laidlaw 2001, Foucault 2000a[1981], 2000b[1985], 2000c[1988]) can be brought in to comprehend and enact the form of ethics in use by biomedical research.

The medical interventions that ethics committees assess are, after all, interventions on the body. Discussing Rosalind Rey's work on pain during the enlightenment, Asad (2003) argues that 'the secularization of pain signals not merely the abandonment of a transcendental language ("religious obsessions") but the shift to a new preoccupation - from the personal attempt at consoling and curing (that is, inhabiting a social relationship) to a distanced attempt at investigating the functions and sensations of the living body (Asad 2003:48 cited in Hirschkind 2011). This shift is perhaps evident at the intersection of research and treatment, particularly in countries newly adopting multi-sited clinical trials, with their requirements from sponsors and auditors. As Simpson and Sariola put it for an Australian sponsored trial in Sri Lanka, '[d]octors, who might otherwise follow their disposition as healers [...] are no longer operating in craft-mode but are recast as mechanical and meticulous monitors of the body and its functions' (2012:565).

But perhaps a 'transcendental language' is not as abandoned we might imagine, reappearing through ethics not with religious obsessions but those of quality, audit and monitoring. Much of what is described above is what we would recognise as self management, where 'the manager...gets internalised: externally imposed control becomes internally generated motivation' (Martin 1997:241, cited in Strathern 2004: 10). The internalisation — a relocation — of control, and change into motivation — a conversion — has not gone unnoticed by scholars. Those attentive to audit (Power 1994, 1997; Strathern 2000; 2004, Pels 2000, Brennais 2006), organisations (Foucault 2004[1977]) and work policy (Martin 1997) have remarked on this re-placement. However, there is a prior question that governance demands: in order to govern and in order to make people into what you want them to be, you have to have an idea of what those who you wish to influence already are. You possess an idea of what was long termed 'human nature.' As Sam put it in the car as he drove me from a noodle bar where we had eaten breakfast, 'America has Belmont, Europe has Helsinki. We have Confucius. It just depends if you want to do it or not.' In his equation of the declarations of Belmont and Helsinki with Confucius, Sam is elevating them to the status of philosophies which provide resources through which to understand 'ethics.' However, Sam's view, these documents revealed profoundly different reasons for having IRBs in Asia and in the West, focusing on the fusion of personal character and regulation. What he

argued, as he approached this statement, is that Americans have a different idea of what rules are *for*:

> In USA [they] use IRB to limit and regulate research because [they] believe humans are bad, personality is bad. In Chinese, we believe the personality is good but sometimes we need to have regulations. So we give a lot of regulations for people because everyone knows regulation is good for research subject. But in our education system we already put ethical education in our primary schools, through to university.

In Chapter 4 I showed that not everyone with whom I spoke agreed that Law, as a separate realm of social control, was where ethics should lie. Interviewees in the preceding chapters have opined eloquently on ethics coming from 'within,' ridiculing the notion that ethics should take documented, fixed form. One scoffed at the idea that it ever could: 'it's like saying someone is beautiful...How can you prove you are right?' While both Koski and this speaker are applying the standards of evidence to ethics, the former seeking proof that 'ethics' — the committees and their procedures — are working, the 'ethics' spoken of by the latter latter does not lend itself to such methods of proof. If, however, ethics is viewed as a set of measurable processes, then it *can* be proven. It is on this distinction that FERCAP's work hinges. It does not seek to prove it is 'right' about the content of decisions: its trainings are concerned with 'sensitization.' Instead, it audits, measures, codifies and checks the processes. Providing evidence for an ethics review is the focus of the survey; providing evidence for the efficacy of ethics review is another concern (McDonald and Cox 2009). But the other focus made evident by Koski is the changed practitioners. FERCAP's objective is not merely to measure, reorder and record; they seek to transform people by 'putting things into them,' 'making them see' and eliciting a personal response.

What the ethnographic moments presented reveal is the way in which these terms simultaneously rely on, and collapse into one another. 'Ethics' is slippery. What, for example, holds quality and ethics apart? We see how both quality and ethics are infused or made possible by "belief," how ethics itself can be thought of as a form of belief or state of mind resulting in a transformation; how GCP and ethics map uncomfortably onto one another. In his ethnography of derivatives traders in Tokyo, Miyazaki (forthcoming) stretches the concept of 'arbitrage' as far as he can, in order to find its edges, examining its 'extensibility' by extending it to a point at which it is no longer extensible. This he describes as an analysis that takes arbitrage as a '*modality of engagement* in a historically specific location and time' (ibid). Here, I have placed ethics in an analogous role to arbitrage - a term that marks an activity conducted as part of one's professional working life, but also that people also apply to their own lives. Similarly, the chapters of Miyazaki's ethnography unfold, we find traders discussing not just trading in terms of arbitrage their lives, futures,

interests, from UFOs to hypnotherapy clinics. By drawing attention to this spread, Miyazaki shows how 'arbitrage became a principle, that is, a principle of capitalism and even of life and mind' as it extends 'from external objects to internal matters,' following through the 'epistemological and ontological problems that have shaken the integrity of the category itself' (forthcoming). I would suggest that what is called ethics does not support the integrity of the category, rather, its successful uptake is precisely because it can be renamed according to requirements. In appealing to quality or duty, trainers can still be understood to be talking about ethics. But the 'extensibility' (Miyazaki's term) of the category means that reflection upon it challenges a clear separation between one's professional *working* life and one's personal values, beliefs and priorities. Exemplifying the challenge ethics poses to clear categorisation, one conference presenter commented, 'Ethics is not definable, not implementable because it is not conscious. It involves not only our thinking but also our feeling.'

While there are 'IRB professionals' in certain parts of the world, for most in Asia, the role is a voluntary one, on top of existing duties or work. In an historical view, during the 1980s ethics emerged as a defined field outside of medicine, initially as bioethics in the US and UK, subsequently research ethics (Wilson 2010, 2011). Such an exteriority Wilson argues (2012) is part of the exteriorisation associated with audit. If making ethics into a profession is not what is meant, and the desire for personal qualifications seems low, then what is FERCAP's engagement with the professional about? I suggest that the critical public, thought present Euro-American models through the 'accountability' function of audit, are substituted by the professions in Cristina's invocation. The profession model encourages accountability to one's fellow professionals, something of which one is *already* a part. The mutual implication of committees in the survey take is another example of the way in which professionals become constituted through others, becoming what one might call dividually professional. Such a model requires of them not only the enactment of a form of public accountability turned inwards, but also a form of personal transformation, rendered most memorably in a description of a chairperson I heard during the 2009 conference: 'A chair cannot tell people to be ethical if he or she is not ethical. You cannot be having an affair.' Turner reflects that for Durkheim, '[m]orality and moral force is always to be discovered in 'something that goes beyond the individual, and to the interests of the group he belongs to' (1992:24). I suggest that this is what, in her recourse to 'moral force,' Cristina is pushing for. The good professional is a good compromise: it can accommodate both the scientific goal oriented measurement, and appeals to duty based ethics. Duty can be invoked in a way which employs the 'moral force' of a (professional) community, be that the nascent community of

FERCAP's ethical professionals, or the biomedical professions from which most members of committees come. One way of reading the placement of ethics as a duty in her statement 'if you don't do you duty, you're not a good professional' is to see that Cristina's ethics *is* professionalism, the separation collapsed. For all the work of externalising ethics 'outside' of medicine and the concomitant rise of audit, idea of ethics is shifting back towards ethics as something located *within* the practicing professional.[91]

Pels' (2000) analysis of the shifting ground of anthropological ethics makes it possible to better interpret the narratives of the professions here. He argues that the ethical code which attends to the ethos of self-auditing is aligned in some cases with the production of marketable selves. While this is already the case in the USA, it is also becoming so in Asia. The example of the CIP serves different 'technologies of self' from those addressed to professional duties oriented towards a public domain. It is also the division which has implicitly structures the thesis, moving from ethics committees as an "external," recognisable form of governance) to 'ethics' as people's "internal" reactions and convictions. Drawing upon MacIntyre (1984), Pels reminds us of the concept of an ideal towards which every person would strive, which he suggests is missing from contemporary ethics. Where striving for ethics blurs with striving for quality, I suggest a dimension of MacIntyre's 'lost element' pushes forward. Quality demands that when committees are surveyed, they commit to being 'the best we can be', in a regime that recognises no possibility of completion or perfection. The concept of concept, the language enrolled is that of belief, as in the powerpoint closing statement from a Taiwanese committee: 'Our belief: To pass the accreditation of SIDCER is to affirm our IRB's unceasing improvement.' Unceasing improvement harnesses ethics and hope in anticipation of and engagement with an infinite project, a project which is not just an abstraction. Inspired by the materiality of ethics it becomes anchored in specific futures, materialised in dreams towards which people work. These I explore in the next, and final, section.

Dreams

> Technocratic thought goes hand in hand with dreams: dreaming is an act of setting oneself apart from the world as it is lived day to day. It is small-scale personal utopianism, predicated on a distance between the world as others see it and the world as it could be (Riles 2011: 178).

[91] Compare, for example, the Reith Lectures of Ian Kennedy (1981) and Onora O'Neill (2002), the former using them to argue for the place of outsiders in 'establishing standards which doctors must meet' (Kennedy 1980c:2), the latter using them to claim that systems designed to ensure public accountability simply deepened the mistrust they sought to remedy.

In order to draw together the themes of this thesis, this closing section juxtaposes dreams for the future of ethics review held by ethics committee members in Sri Lanka, America and Taiwan. As with Chapter 6, the intent is not national comparison, rather the nature of the dreams themselves, these acts of 'setting oneself apart from the world.' I suggest that together, the dreams reveal more than the imagined systems or structures of an international research regime; they reveal a desire for certain kinds of people.

Boyer complained in 2008 that few anthropological studies 'took seriously the place of desire, fantasy and anxiety in the production of expert knowledge' (2008:43). Two recent publications address this absence. In *Collateral Knowledge* (2011), Riles pays close attention to the legal documents that make up the 'collateral' on financial agreements between banks in Japan and the rest of the world. She also pays close attention to the hopes and dreams of Sato, her key informant. The event which structures her narrative is the introduction of a new technology in banking transaction, Real Time Gross Settlement (RTGS), which for Japan was 'part of the path to an advanced economy regulated according to "global standards" (Shukuwa 2002) (Riles 2011: 174). The parallels to medical science are hard to miss; the economy around biomedical research is substantial, growing and efforts to standardise standards of quality and evidence to serve the internationalising aims of drug development companies have been evident since the opening chapter of this thesis. What has also been evident is the flexibility, or the 'elasticity', the extensibility of the word 'ethics.' Miyazaki (forthcoming) has conducted long term research amongst Japanese financiers, and he too has met dreamers. Tada and Aoki, the pair we follow through his book, are arbitragers in a derivatives trading team. What Miyazaki carefully draws out of their dreams is the way the central concept in their working lives - arbitrage - overflows its 'work' based meaning and comes to structure their relationship to capitalism: their belief in it, commitment to it, and ways of abandoning it.

Ethics, I suggest, runs a similar course, threatening (as it has in the chapters above) to collapse into other terms. As an activity, it is flooded with risk assessment, balance sheets of benefits, conflicts of interest yet we have seen the 'belief' in ethics which FERCAP employs to foster support. In his work, Miyazaki shows that the 'virtuality of finance theory (such as arbitrage) produces a second order of virtuality (such as personal dreams).' I suggest that the virtuality of research ethics, abstracted even out of bioethics, also gives rise to a 'second order of virtuality': the dreams below. A vision of the world 'as it could be' comes forth as a strong motivator in this ethnographic material. We are now familiar with Juntra's vision in which, through SIDCER,

FERCAP incorporates good ethics as part of a system approach to clinical trials, themselves contributing to improved medical research and ultimately better quality of life for patients. As she put it herself, 'that's always your vision. In 2012, when I close my eyes…I have energy because I want to see Ethics Committees in different countries recognised by criteria we set out. Every year I count and I am happy when it increases fast.' In Riles' view, a collision of dreaming and technocracy is not as unexpected as one might think. She observes that this kind of thinking fits well with what Geertz long ago termed a "model for" rather than a "model of" (1973:93). For her interlocutor Sato, much of the appeal of the RTGS project lies in the 'effects on the character of *people* in the market' (Riles 2011:175, emphasis in original). Let us take a further look at the kinds of people the dreams of those involved with ethics reveal.

Bartholomew's Dream

Dr Bartholomew Shar served on an ethics committee in Sri Lanka. During our interview, it became apparent that his ethics review committee work was strongly influenced by the training he'd had in a branch of standardisation: not GCP but ISO — International Organization for Standardization.[92] Working with genetic and laboratory data, he knew a great deal about ISO standardisation and the effects it could have. If figures were wrong, not only could there be consequences for patients and public health policy in the country, any research being done might suffer. Inaccurate figures could, however, be fixed. Our interview charts the mingling of two dreams. What is of interest is the way ideas from the first, more realised, dream of laboratory standards in Sri Lanka seemed to make possible — and desirable — his second dream: standardization in ethics.

I began our conversation by asking Dr Shar to describe what he did on his ethics committee. 'Well, we take a file like this,' he said, holding his hands four inches apart to indicate the volume of paperwork. 'I review in my area, how much blood needs to be collected, what is routine, volume and timing issues, transportation, genetics and social issues.' The remit he has just reeled off is an expanding chute, beginning with vial of blood and ending with 'social issues.' To illustrate, he links those 'social issues' to a particular case, re-grounding the concerns of his committee.

[92] According to their documentation, the ISO is a network of the national standards institutes in 164 countries, coordinated through a Central Secretariat in Geneva, Switzerland. It is a 'non-governmental organisation that forms a bridge between public and private sectors' (ISO 2012).

> For example, a thalassaemia[93] carrier. Someone comes with a proposal to detect, but are they going to inform those from whom they took the samples? The garment factory girls, they have a [thalassaemia] prevalence of 3% or something, but when you really do have that prevalence data, what will you do? If you convey that they are a carrier, there is no counselling adequate. It affects marriages. Sri Lanka is…a very Asian country. Marriage and these things are very serious. Once you are having an affair, it seems you will marry, the social pressure is there. If you are married, even though probably there will be dispute, or you are not matching well, the majority choose to continue marriage even though it's hell. It's not like in your country where it is not necessary to suffer for life. The question comes because of sociocultural differences between countries. When we consider ethics, it's similar to something hand in hand with human rights. Whether it's Australia, Africa, US, UK, I think research ethics should be the same internationally. It's a sort of standardisation of research for an acceptable level. So for example, if there's a lab diagnostic test, we have accreditation - it comes from the Sri Lanka accreditation board. I'm an assessor. If we accredit, the certificate will be accepted. It's ISO15189, the standard for medical quality of diagnostic tests for that lab. It means its the same as any lab, anywhere in the world.

What I want to emphasise in the extract above is the transition in this narrative from thalassaemia to diagnostic laboratories, via a standardised model of ethics. Bartholomew was not simply making a *comparison* between the systematisation afforded by ISO standards, he was making the processes of standardisation *equivalent*, thus changing the capacity of those objects for variation. Put differently, in his view, a scientifically designed manner of measuring and controlling laboratory machinery had produced a desirable state of global inter-changeability, accountability and trust. Despite his emphasis on the difference in marriage and courting practices ('It's not like in your country'), he seems to suggest that the same would be appropriate for ethics. Consider the things that an Ethics ISO would solve for him:

> [For the laboratories] we get international recognition and when you come to hospital, don't have to worry about the quality of the service. If you have your own level of guidelines, of you differ from other countries, how much the gaps can be a problem, not be acceptable. Expect standard up to when diagnose diabetes should be same, between USA, UK, Sri Lanka. So its the same with ethics. If we try to stick to own principles and guidelines, we'll try to avoid some aspects of guidelines practiced in other countries. This might be advantageous for our researchers in a way but considering internationalisation and globalization, will it be acceptable internationally?

Again, in the crossing over of biomedical models (the diagnosis of diabetes) with ethics, Bartholomew is applying principles from ISO training to what he regards as an equal problem of international standards. He went on to tell me how his training in laboratory standards had come about. A cabinet paper, presented under the Ministry of Science and Technology, had established a Sri Lankan accreditation board, (SLAB), which received funding from a Swedish Government

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93 A group of inherited blood disorders affecting the production of red blood cells. Occurring at a high frequency throughout South Asia, the disease poses significant challenges in terms of public health.

grant (Swedish International Development Agency (SIDA) via the Swedish Board for Accreditation and Conformity Assessment, (SWEDAC)). Trainers from Sweden arrived and stayed in Sri Lanka for three weeks, assessing, guiding and supervising. They offered qualifications, through an examination which Bartholomew described as 'continuous surveillance.' 'They were behind us when we were conducting assessments, walking without saying a single word. At the end of the day, they would say, "These are the inadequacies." They raised all the nonconformities, and we corrected all of these things.' Bartholomew qualified as a technical assessor and consultant. He began accrediting laboratories in September 2009, in accordance with ISO 15189, an international standard for the quality of laboratory testing. But the mutual recognition that the training and assessment had ensured would expire. 'You can do this, but next year, even in the next six months, you have to improve,' he said. The acceptability of variation in laboratory accuracy and ethics fits his vision of how research in his country is changing:

> We are a fast developing country. The next step is research. We need to characterise our patients, diseases, compare the therapeutic efficacy of drugs invented elsewhere. Lots of factors can influence each disease. Even for reference ranges we depend on a textbook. We chose the Western figures from these books — is it correct? We can see from experience [a blood measurement is] usually 12-14, but we don't know if it's nutritional, or due to ethnic difference.

The interview had moved rapidly in the direction of his research, but he seemed to think we were talking about ethics. I listened:

> If you're going to publish research in thallasaemia, you need HPLC[94] to label a patient as thallasaemic. It's the diagnostic, all over the world, an accepted method. What's available most of the time [here] is a semi-quantitative method, cellulose acetate. So then we can't publish.

'Why not?' I ask him.

> The diagnosis remains only a *possibility*. It's not a confirmation. [...] We need that final diagnosis, so then it can have an impact at national level. [...] When we go internationally, especially for journals, they maintain the highest standard, the research published is of good quality. Suppose that we have a machine that is not calibrated, not certified, not maintained as per the manufacturing instruction. But it gives results. So I analyse blood sugar. Using my machine I may be *near* my target value. But I may have an accuracy error and this error will be there for all, everything I measure. So you need *external* quality - you don't know the value, the external body does. It will interpret and send a report, [they will say] 'Your value is out of range, so repeat and confirm' [...] Even a pipette has to be maintained and standardised to get accurate values.

[94] High Performance Liquid Chromatography Testing, used to separate and identify compounds in mixtures.

As Mol and Law point out as they look for anaemia in Africa, 'it is *possible* to arrange things 'there' [Africa] so that numbers about the population are created' (1994:650), but as one of their interviewees says,

> [i]n tropical medicine as a whole the laboratory is a problem, because a laboratory isn't just a laboratory. It is a *system of people* who work there, who are stimulated, controlled, a system of quality checks (1994:651).

Busch notes that 'development organizations have begun to realise the difficulty of keeping standards for things and those for people apart' (2011:26) (see also Brunsson and Jacobsson 2000, Loya and Boli 1999). Extrapolating from his experience with ISO quality review, Bartholomew insisted that the ethics review committees should themselves be reviewed.

> We have a lab here, we get accreditation, they come and see if the accrediting body is sticking to guidelines and protocols. Do we have protocols to start with? I am sure if we're to say we're an ERC, to give approval on projects, we should also be reviewed. They'd have to see if we're doing it in a proper way. Those things — chemistry protocols — will have to be there. Sometime researcher might find fault with members of committee. To be transparent, we need proper documents there.

Suddenly, the link is back:

> If it's in a document, we can say, if the checklist fits it'll be correct. If these things are uniformly maintained, one researcher won't be annoyed. If we come under the umbrella [they will say] if you're going to be our member, you need this. They give us the documents. That should be uniform to the country, region, globally eventually, one fine day, if you had applied to any ERB, if one granted, then all others should have granted. Should be uniform, nationally, then regionally, then globally.

I pushed Dr Bartholomew a little further on his vision for 'uniformity':

> There's uniformity with FERCAP. The Colombo ERC has links with various outside agencies. They'll be very big body and we'll come under them. If they say 'You need this or that,' they'll help us make sure we keep up with standards that regulatory body would want. It's a big job providing technical know-how.

His concern was that, without this, different committees would become known for their decision-making tendencies and the phenomenon known in the USA as 'IRB shopping' (Candlis et al. 2006) would emerge. 'You might say Galle ERC very strict but if [you] send to Peradeniya, much more lenient, maybe a similar project [would be] given approval.' He had a plan for counteracting this effect.

> The first step should be the national. Central ERC or board - some system should be there. When we have national standard, then should go internationally.

Arguments have been made for ethics as a technology of imperialism (Angell 1988, Benatar 1998, Nundy and Gulhati 2005, see also Lurie and Wolf 1997) suggesting that when committees make decisions based on or compliant with international principles, they are not taking 'local' values sufficiently into account. Sometimes it is suggested that committees do this to attract research, at other times committees are cast as ignorant, ill informed, corrupt or simply for show. Responses have come from those onto whom ethics is considered imposed. Edward K Mbidde, Chairman of the AIDS research committee on the Uganda Cancer Institute suggested it was somewhat 'imperialist' of Angell and others to think that they knew what was best by seeking to override decisions made by local ethics committees (Mbidde, cited in Macklin 2001: 25, cited in Simpson 2004a):

> Thus, the idea that local ethics review bodies may produce verdicts that are inconsistent with those that would be produced in Western contexts has prompted the suggestion that the experience and competence of local ethical review boards may be lacking when it comes to dealing with issues thrown up by research on human subjects or the introduction of new technologies. Such an assessment fails to recognise that local bodies may arrive at different outcomes than their Western counterparts, yet do so using competences that are more closely linked with local cultural values. However, this is not to say that just because decisions are made locally that they are good or right decisions (Simpson 2004a: 8).

There is a distinction between all committees having the same structural procedures and all committees making the same decisions. One of the risks of reducing guidance to the 'mechanics' of decision and leaving the content of 'ethics' to others is that in this split between 'Bioethics' and 'Research Ethics', the standardisation of form also becomes the standardisation of content. Dr Shar's dream, it seems considerations of locality would be done away with altogether. Is it possible to imagine ethics as an 'immutable mobile,' turned into a set of rules, or a scientific analysis? Dr Shar is suggesting such a thing is possible, and that a model from scientific medicine can be trans/imposed upon values in the same way as it can upon blood cells. 'African medicine is quite like medicine in the Netherlands if haemoglobin measurement is transported in proper working order,' write Mol and Law:

> If the bits and pieces within the haemoglobin network are held in place. This is the point of the immutable mobile. The laws of Newton are as true in the Gabon as in London *if* the structure of bits and pieces that makes it true in London is successfully transported from Europe to Africa' (1994: 652).

They are building on Latour's *Pasteurization of France* (1988) in which he demonstrates that 'the laws of inoculation are the same in a farm in Pouilly le Fort as they are in the École Normale Supérieure in Paris so long as the farm is turned into a research laboratory' (Mol and Law

1994:652). What network must hold for the regional surface of ethics to be folded? In Dunn's study of the normative power of EU standards in Polish pig slaughter, she notes that the standards

> have become key tools of the 'transition' in eastern Europe because they claim to have a kind of disciplinary power that makes economies and producers commensurable. By using a single metric (here the ability to transmit regulation from international bodies to the level of the firm) to compare and rank states, firms and goods, standards make unlike things into comparable units (Dunn 2005: 183).

I have suggested that while FERCAP work hard to avoid prescription, as we have seen in Chapter 6, its orientation to detail is specifically targeted. Meetings designed to seek consensus on ethics, in the case above around the need for professional guidelines in Sri Lanka, face numerous difficulties. The 'location' of ethics became a problem in a different sense, revealing the dichotomy in thought between locating ethics 'in' the person or 'in' 'society'. In discussions which seek to take in the 'international', as we saw in Chapter 6, the difficulties encountered become based on national and cultural distinctions. It is by reflecting on these that we see how finely FERCAP walks between proscription and standards. Comparing biomedical ethics to Wilson's description of human rights as 'one of the most globalised political values of our time,' Simpson anticipates a comparable rise for biomedical ethics, 'a transnational logic that aspires to universalism and consistency of application that can be found in the spaces between and above nation states' (2004a:9). In FERCAP, the consistency of application comes from principles that seem like neutral management issues: SOPs, quorum recommendations, the writing of minutes. They do not advise on what they term the 'moral philosophy' or 'bioethics.' Bartholomew, in his mapping of biomedical accuracy onto ethical standardisation uses the reliability gauges of laboratories as a metaphor for relativity. He is describing the problems encountered by Mol and Laws's anaemia doctors, when they write that '[h]aemoglobin measurement, it turns out, is not immutable. As its devices and techniques move from the centre to the periphery, their truths become progressively less "reliable"' (1994: 652). His chosen analogy collapses the standardisation of measurement in laboratories becomes the standardisation of ethics in committees around the world. When 'smooth ethics' is tied to innovation and industry, other imaginings can emerge, such as Dr Koski's below.

Dr Koski's Dream

Standardisation, whether GCP or ISO, is open to comparisons. The analogy below I first heard Koski's dream as part of an online webinar held in December 2011.[95] He was developing his point about professionalism which I referenced in Chapter 7:

> To my mind, its not with IRBs, it's really a responsibility that should be borne by those who do the research, sponsors, institutions, and investigations, rather than the EC. We all know that having rules and regulations can't by themselves protect human subjects from risk and potential harm. It's only how these rules, regulations, guidance, principles are actually applied. Whether or not they're taken seriously by those who are doing the research.

Developing his point about how this could be achieved, he asked audience members to imagine another kind of system.

> I'm going to ask you to just suspend your disbelief for a minute and imagine the possibility of a global network that includes perhaps 120,000 clinical research sites, each one of which is fully accredited by independent accrediting agencies, according to international standards, standards that are established by the public working in conjunction with regulatory authorities, ethicists and others, so we have a truly global standard for quality and safety that's accepted around the world. Each of these accredited sites would be staffed by a fully trained and certified professional research team. These sites would be connected, interconnected through a very robust webpage information system that would allow realtime capture of important performance information but also important safety information so that we're continually watching to see how things are done, continually monitoring adverse events, pharmaco-vigilance, in order to truly do something that if there's an early signal for potential harm to research subjects with a class of drugs that we identify those before harm is done and take steps as appropriate to fix that. All of these independent sites would operate under a fully integrated and accredited human research protection program, the exact model for that we don't know but perhaps something that would involve various levels: a central review in combination with local review, not that there'd be dual ethical review, but perhaps a centralised ethics and scientific review that would work in tandem with local review to determine whether or not its appropriate to do a study in a particular location. We'd start with the assumption that any research study that might be done globally in fact would be ethical everywhere that it's done and the only question would be not whether its ethical or scientifically sound but that it be appropriate for the standards prevailing in local community and the resources available to do it. The model that I've just described to you in terms of a global network is in fact very much in the limelight these days through an initiative we started about 2 years ago, called ACRES, the Alliance for Clinical Research Excellence and Safety.

This description of a dream network is the outcome of the macro-structuring I described in Chapter 1, the smooth running international research with global reach. Koski continued, like Dr Shar, developing an analogy by which his dream could be understood.

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[95] The audio was made available through Xtalks, an online archive, and what quotes I use were transcribed from there.

> ACRES is working to build this kind of global clinical research network based on a model that's derived from the global air transportation system. You know, back in 1945, the airlines realised that in order to be able to fly planes safely around the world, and get people to be comfortable flying on them, they were going to have to be able to have a global network of airports that allowed for planes to take off in Boston and fly to Brussels before they go on to Mumbai and Singapore and know that every place a plane was going to take off and land it was going to be handled through the same kind of SOPs and procedures that are accepted by all of the stakeholders to ensure that it's going to be done safely and it doesn't matter there's a system so there's no confusion about how its done. Over the years the organisation known as IATA, the International Air Transport Association has worked to build this kind of network and we know today that although the global airlines are every bit as competitive as the global pharmas, you know. We know drug research today is very much an international endeavour. If we had a new system that was based on the model of professionalism that I've described before, with the adoption of standardised policy and procedures for safety, we'd have the opportunity to completely revolutionise the way clinical research is done around the world today.

The analogy is not unique. During the FERCAP Conference in 2008, Dr Beat Widler, then working for Roche gave a presentation on 'Promoting Human Subjects through the Risk Management Approach.' He opened with the familiar Time Magazine slide ('From this image of perception'), moved to an image of Florence Nightingale ('to this assurance') and followed with this:

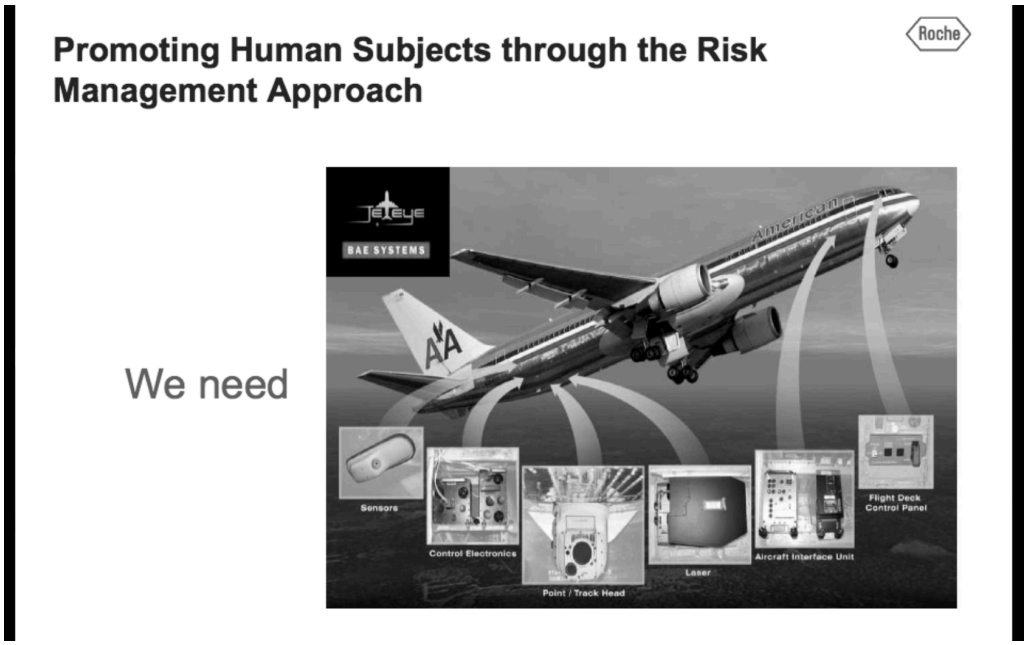

Figure 32: Dr Widler's 2008 FERCAP Conference Slide on Promoting Human Subjects through Risk Management Approach

Where Ethics shifted to measurement through Dr Shar's analogy in the dream above, here it is elided with safety. Its absence from the acronym (ACRES) is only part of the shift. In Dr Koski's comparison with global air transport, as with Dr Shar's comparison with ISO measurements, concerns are regarded as *so* analogous that differences between them are erased. Here, the unspoken concern alongside safety is trust, the trust of the public, thought lost. The real time reporting of data and the safety of planes offers a working model. In his linkage of air transport and ethics, Koski is putting forward three principles: 'Technology, complete and accurate information, and trust.' This is a triangulation Corsín Jiménez (2011) observes in the work of DiPiazza and Eccles (2002) on corporate ethics and reporting *and* Max Gluckman (1972) on African divination and the allocation of responsibility. He remarks that we anthropologists have long puzzled over these concerns.

While in this thesis I have demonstrated some of the ways that objectivity has been sought, made, manipulated as a technique both of scientific and of political power, the machines of objectivity in this dream far surpass the mimicry in Surveys or even ethics itself. The network is not one of active people but of passive watching as the technology reports. While we can not call Koski's dream '*small* scale personal utopianism,' such as that possessed by Sato, it certainly supports Riles' claim that dreams sit along side technocratic thought. In an imaginary where human components face standardisation at every stage, is it really any surprise that it is a machine that, in the final measure, looks over them? Koski knows that 'integrity' of researchers has previously been the focus of reports on the conduct of research (IOM 1989; NAS 1989, 1992, 1993 and 1989;, National Research Council 2002; Wellcome 2005[2002]). Much of what he recommends has been said before:

> individual scientists in cooperation with officials of research institutions should accept formal responsibility for ensuring the integrity of the research process. They should foster an environment, a reward system and a training process that encourage responsible research practices (NAS 1992: 13).

Yet *integrity* is hard to measure, what standardised test can chart something which only offers hope because of its exteriority to the logic of audit?

Sam's Dream

During interviews with ethics committee members at the Tzu Chi General Hospital in Hualien, Taiwan an alternative to ethics committees was offered, tied closely to the education of doctors, changing not only their training but also their formation as physicians. The interviewee began by

lamenting the quality of research that was being done, suggesting that the doctors were 'well intentioned', but quite 'thoughtless' when it came to patient comfort and safety. 'Some day we will produce better doctors, our Silent Mentor program will help with that.' I asked some follow up questions about this program, mostly pursuing my interest in the relationship between ethics review and how researchers were regarded. I learned that in the early 1990s, Taiwan faced a massive shortage in cadavers for medical training purposes. Students were struggling to learn gross basic anatomy. Then, in 1995, a person who 'felt she had received a lot from society,' donated her body. This act did not go unnoticed by the hospital's Buddhist founder, Master Chen Yen, who, according to my interviewee said

> If we could utilise a program as interface to bring out the best of medical students and inspire face to teach students best and use the program to educate people in society that every phenomenon has meaning: getting born, getting sick and getting death has meaning.

When Edith, observing the interview, saw my interest in the Silent Mentors program, she arranged for me to visit the unit and have meetings with several of the program coordinators. The visit took place the following day. I was greeted by representatives sharply dressed in navy blue and white. The tone was professional — I was a welcome international guest, who had come to find out about the innovative cadaver donation program. The corridors on the perimeter of the second floor were bright and airy. A kind of mummification process meant that cadavers could be kept in a central temperature controlled room, which my guide revealed by drawing a curtain. I was given a view of the darkened space in which embalmed bodies, wrapped in white, rested on narrow metal shelves. There was an extended moment of reverent silence as we gazed in, and Sam closed the curtains again. In a low voice, Sam told me that students come here, and in a tone indicating surprise said, 'They even talk to them.' We walked the perimeter, looking at the posters and poems, statements by donors and letters from students. Su Chen was one of the Silent Mentors whose extraordinary life caught my eye.

> Teacher was sold by her step-father to a Taiwanese opera group. Since then, she had been making living by performing at the temples and theaters. Her graceful movement and beautiful voice won her the leading role. At the age of 17, she was forced to give up her career and become the mistress of a Taiwanese Mafia Boss. Unfortunately she needed to bear the financial responsibility to support her husband's luxury lifestyle. Working diligently, she gradually expanded her green onion stall into a market with 600 stalls. After her friends and husband took over her business forcefully, she indulged herself in excessive drinking. Since becoming a Tzu Chi volunteer, she had found the new meaning of life and wished to encourage the frustrated people by her story. She determined to be a silent mentor and to keep on helping others.

Why had the students found out about Su Chen's life in this detail? Why were the walls lined with photographs of donors, and the stories of their lives? Why did the organisation insist on non-anonymous donors?

Students are required, in the summer before the course, to learn about donors' lives through home visits to the families. Then a memorial blessing ceremony is held, where the four medical students stand opposite the family members, around the anatomy table where the body is placed (Lin et al. 2009), Buddhist nuns lead the ceremony with chants. 'The body is open so that the family can take last look', Sam told me 'You hear the crying and mourning. At the time, students face great pressure'. During the dissection classes, the stories and pictures that the students have gathered are projected on screens and classes begin with 'students respectfully and humbly greeting the cadaver.' They are encouraged to think of the cadaver as a teacher, and some students address the body directly. Writing in the British Medical Journal, Lin et al. describe the program:

> The actual dissection course lets students connect their 'teachers' to their biographical profile, which rests at the dissection table to serve as a constant reminder of the underlying human story. This custom also promotes mindfulness of the teacher's life experience that may manifest physically. Meeting donors and learning about their lives fosters humanistic values in students, such as gratitude and respect in light of the donors' selfless giving (2009:1439).

At the end of the corridor in Hualien, I was shown into the Great Body Teacher Memorial Hall. The lights came on as the doors opened, illuminating rows of small crystal boxes, crafted in the shape of the Hall of Still Thoughts by a master Taiwanese craftsman. 'The ashes of Silent Mentors are placed here. Students sometimes come and visit them', Sam told me. 'They come to visit the silent mentors and thank them, some tell me that they confide their difficulties and feel that the silent mentor will continue to look over their shoulder as they work.

In an interview following my tour, the clinical director of the Silent Mentors program, who had taken the English name Ben explained some of the reasoning behind the Program to me in this way:

> There are two parts to being a doctor, one part is a healer, the other is being a professional. Its based on a social contract, between medical society and the whole society, that is medical professionalism....the base of medical professionalism has three points. To practice with skill, knowledge and with morality to service others. However, morality and service are becoming weaker and weaker. How do you design a curriculum to help students learn morality and service to others?

He, and other members involved in ethics review repeatedly told me about a change in doctor-patient relationships. Barbara, the lay member on the committee from Chapter 5, considered it

part of her role on the IRB to 'change the atmosphere between medical people and patients. 'Because right now,' she said 'the relationship sounds like more commercialized — I pay you, you use me. It used to be friends, family doctor [...] So have to change relation — doctor, nurse, patient, family. They should be friends, like family.' Barbara thought this change in attitude had been in part inspired by research practices. 'They think it should be more cold blood, more science style, more powerful.' Part of George's solution to designing a course to 'help students learn morality' was the Silent Mentors program, which he described as containing a 'hidden curriculum': 'We need more good doctors, not more famous or fame making doctors. So we want to train the student to respect, not just by lecture or television, but by this kind of role model'. The role model was the Silent Mentors themselves.

Towards the end of an interview with one of the program coordinators me this back to the reason I was in Hualien at all: Ethics Committees. He had been using a powerpoint presentation designed for an international audience to help me understand how he saw the relation between silent mentors program, spirituality and modern medicine. As he explained to me:

> To study medicine is a kind of spiritual practice. So physicians have to reflect how to contribute to society. If every physician can learn this, there is no need for the IRB. I'd like to use the surgical department, I'd really wish we can, by this foundation, train more and more good surgeons and serve the society and make IRBs unnecessary.

The link between training and the obsolescence of the committee illustrates a different place of hope for the future of ethical research, which falls not in audit but another kind of watching. By transferring the ethics to the researchers, the committee would write itself out of existence. George hopes to replaces a committee with a person, through a process which renders the external cadaver internal, intended to govern and censure reactions. It anticipates a future, invisible patient who will be the recipient of the trainee doctor's care. What comes to the fore is the question of what an ethical subject is, and what regulation becomes in such a regime. I am reminded of Riles' discussion of the introduction of the Real Time Gross Settlement (RTGS) system in Japan, during which, she tells us, debates raged over the correct involvement of the state in financial markets. Deregulation, in her story, was 'framed as putting an end to state interference in the market', but, she says,

> [i]n practice it entailed not so much an end to state intervention as a transformation of the role of the state, from a visible quotidian force to a less visible but arguably far more consequential role of shaping the very nature, preferences and objectives of the private actors who populated the market. This is deregulation as transformation rather than disappearance (Riles 2011:186).

What Sam's dream reveals in his dream is a version of ethics which, like Sato's hope for more rational actors, is directed at altering those who practice, so that through them changes come about. In the comment by the Silent Mentors trainer, he is innovating towards making ethics committees obsolete.

In Chapter 1, ethics review had been detected as a weakness in the system, through a view of the system as an 'integrated and objectified whole' (Douglas and Wildavsky 1983, Riles 2000, Stinchcombe 2001) The 'integrated and objectified whole' looks rather different from George's point of view, starting with not the relationship between investigators or sponsors and ethics committees but, as he does, with that between doctors and patients. I have argued that at the same time as FERCAP is pushing for legal regulation and the systematisation of ethics, it is also, inspired by the turn towards professionalism in the West, encouraging the creation of an ethos of responsibility. George has a very similar objective, only that he is not orienting the responsibility toward bureaucracy but toward the cultivation of that responsibility in the student. The final dream is the closest we have come in this study of ethics to the patient: the Silent Mentor becomes the archetypal patient; all patients. We might ask does this 'really work?' Does it actually change the attitudes, and more importantly, the behaviour of students as they go on to become doctors? While these would be good questions for further research, they are also revealing in themselves. What is interesting to me about the Silent Mentors example was that it *suspended* the monitoring of people, and moved the site of that monitoring into their professional personas, through their training. That the dream *existed* was the point.

Concluding Remarks

The Ethics Committee is, as I have established, a recognisable form of governance, standing 'outside' and 'above' the actions which it is supposed to regulate (Strathern 1985). But the versions of 'ethics' presented in this thesis target actions differently. In the stories of this chapter there are very varied versions of utopian futures for biomedical research, ranging from all seeing computers to ISO standards under which all committees would give the same result. Each of the views on the future of ethics above reveals in its answer to the problem of governance an answer to the question of what people are thought to be. Cathy and Sam see regulation as secondary to the desire of a researcher to be good, to behave well. A question posed by Scott (1998) is what utopian dreams leave out, eliminate, mangle. In Chapter 6, I employed Riles' analysis of Alternative

Dispute Resolution (ADR) to suggest that by *not* attending to the cultural specificities, by putting difference in the 'gap,' FERCAP's region-wide operations became possible. Scott would argue that:

> the lack of context and particularity is not an oversight; it is the necessary first premise of any large-scale planning exercise. To the degree that the subjects can be treated as standardised units, the power of resolution in the planning exercise is enhanced. Questions posed within these strict confines can have definitive, quantitative answers. The same logic applies to the transformation of the natural world (1998:346).

Dr Shar's dream of an ISO ethics — made vivid through his analogy with the standardisation of laboratory procedures for blood sampling techniques — offers this kind of 'natural world' planning for ethics. The search for definitive answers is a feature not only of the biomedical research enterprise as it spans the globe, but also of our time:

> A recurrent theme of Western philosophy and science, including social science, has been the attempt to reformulate systems of knowledge in order to bracket uncertainty and thereby permit the kind of logical deductive rigour possessed by Euclidean geometry (Scott 1998: 321).

Scott writes that '[t]he aim of Jeremy Bentham and the utilitarians was [...] to reduce the study of ethics to a pure natural science' (1998:321), citing Bentham's hope of:

> every circumstance by which an individual can be influenced, being remarked and inventoried, nothing...left to chance, caprice, or unguided discretion, everything being surveyed and set down in dimension, number, weight and measure' (Bentham, in Scott 1998:321)

Dr Shar and Dr Koski's dreams show the perils of running ethics so close to science; they demonstrate the ease by which modelling — whether of ISO standards or aircraft protocols — attaches to and becomes a model for thinking about ethics. Crucially, the spread of 'evidence based' rhetoric goes beyond the evidence desired in FERCAP Surveys, in anticipation of audit, and even beyond the 'evidence based ethics' (Sugarman 2004, Emanuel et al. 2004) which hopes to prove the efficacy (or not) of ethical review on Human Subject Protection. In medicine, the linkage of 'good evidence' with 'efficient data management and swift retrieval' (Ecks 2008: S80) has led to projects such as the Cochrane Library (Lambert 2006a: 2613) through which 'short texts try to give quick answers to quick clinical questions [...] To bring this information into everyday practice, EBM supporters lobby for the use of computers that can be taken along on ward rounds' (Ecks 2008: S80). It is a model being replicated for ethics, oriented towards answers, with online resources designed at 'building capacity' of committees in developing countries. During the last FERCAP conference I attended in 2010, a presenter promoted a collaborative project promising 'quick and reliable access to information,' an ethics version of the Cochrane

collaboration. Such projects give fuel to Molyneux and Geissler's cautions (2008) about ethics guidelines. They express concern that on the one hand, 'rather than fostering genuinely ethical research, there is a risk that detailed rules and requirements may prevent ethical thinking' and on the other, 'rules and regulations may enable researchers, funders and institutions to side-step the more fundamental ethical issues of the politics of poverty and inequality, which should be at the core of the public health agenda' (2008: 692). For them, '[w]ell functioning ethics review boards should not be blindly applying principles and guidelines but should rather be drawing on them in a scholarly skillful way to ensure a *balanced* approach in considering each study' (2008: 692, emphasis added). Whether the mode of medical 'answers' will work with the different pushes towards 'evidence based ethics' remains to be seen, but the ethics committee as a form, though it is designed for decisions, it is not designed for answers. As Scott writes:

> An oral dialogue[...]is alive and responsive to the mutuality of the participants, reaching a destination that cannot be specified in advance. A written text, even if it takes the form of a philosophical dialogue, is a cut-and-dried set of codified rules (1998: 323).

This is the challenge faced by FERCAP as it seeks to 'operationalize' and support committees in their use for the (written) principles and guidelines set out by the WHO, CIOMS, Nuffield and Helsinki. As those who seek to demonstrate FERCAP's efficacy know only too well, '[f]ormulas of efficiency, production functions and rational action are specifiable only when the ends sought are simple, sharply defined and hence measurable' (Scott 1998:322).

The standardisation verging on automation in the realm of ethics is evident, but it bears asking why it is desired. Miyazaki (forthcoming) recounts the dream of Tada, a derivatives trading team manager, for an 'automatic trading machine' which, once programmed with 'one or two hundred variables' would be able to outperform his entire trading team. All it needed was traders to share their strategies, so patterns could be found. To Miyazaki, Tada was 'assigning traders the task of creating the very means of replacing themselves', the machine accomplishing the task of 'reimagin [ing] the present from the perspective of the end, the moment of the machine' (2012:151). What intrigues me about Tada's dream is that it combines Koski's machinic ambition with Sam's obsolete Ethics Committee. Perhaps, then, what is desirable about Koski's dream above is not the removal of uncertainty of 'temporally linked strategies', leaving the 'machine' as the only agent, the calculations the only act. Ethics with these scientific traits, a scientific ethics, produced and distributed through practices of audit, risks becoming unable to ask questions about 'the theories, knowledges, ethical thought and principles' (Overing 1985) of those upon whom research might be conducted. Ethics, as an late-modern enterprise, assumes the knowledge producing traits

(scientific rationality) (Edwards, Harvey and Wade 2007:4) of the knowledge producing mechanisms (science) which it evaluates.

Conclusions

Within the scope of the International Science and Bioethics Collaborations Project, this research was charged with the analysis of capacity building in mechanisms of governance. Taking ethics as the mode, and committees as the form, this thesis has examined some of the relationships that constitute that governance. I have looked closely at FERCAP's implementation of the SIDCER Recognition Program and the rooms of ethics review committees through the stories of those involved. While much of its subject matter may have seemed dry — standard operating procedures, strategic quality management, committee meetings — I have sought to show why people care so much about this; why they dedicate energy, resources and time to the various forms of 'ethics' that have populated this thesis. The questions that *they* are asking are far from dry, indeed, they are hugely important. In their content and in the way in which they are posed they are also, as Kapferer would point out, products of their times (2010:205). How do you make people good? How do you protect those who participate in clinical trials — whatever their reasons for doing so?

The central argument of this thesis is that an ethics committee is not a neutral device. While commentaries on the 'western' origins of contemporary ethics have focused on its Judaeo-Christian roots, I sought to show just how many assumptions the committee *as a form* carries: about people, discussion, evaluation, even the nature of politics (Latour and Weibel 2005). I have sought to demonstrate that ways of doing ethics in themselves have political histories, legacies and effects. The worlds in which a committee is both required and works have been subjected to anthropological attention, the contextualisations reframed. Let me separate the terms committee and ethics, for that is how this thesis has approached them. In the first three chapters I explored the materiality of the committee, FERCAP's efforts to operationalize 'ethics' through processes over principles. I focused on making ethics real through rooms, photocopiers and standard operating procedures; the co-imbrication of objects and people in monitoring, measurement and standards. I also took up this theme in my examination of the committee as a 'form'; something which arranged space, people and, in so doing, revealed its assumptions about what people and 'society' were. The central chapters of the thesis (Five and Six) investigated the ideal(s) of the committee and how it both exploits and controls 'perspective', opening the question of what it means to 'do' ethics. The varying logics of the committee were explored through laypersons and the 'society' they represent or contain. True to the opening question, I pursued this particularly Durkheimian theme through FERCAP's interest in making people 'believe' in ethics, the use of

duty and hope in 'moral force', deemed necessary in the absence of 'systems'. But this too carried assumptions of what people are, how and what they believe, and how their 'insides' are configured.

The division between internal and external forms of governance does not only echo the debates in the field of ethics, such as those laid out by Noah and Coleman in Chapter 4. It also repeats anthropological and sociological distinctions, revealing their explanatory power. I have asked after the locations of ethics and found — in the framings that the question prompts — the product of a particular way of thinking. The ethics committee is a product of what Euro-Americans think governance should look like. It is outside, and at a 'higher level,' it puts ethics in a realm 'above' medical research. The committee works to be 'objective' and authoritative through its expertise, and through the work of groups like FERCAP, the committee and ethics are measurable. While 'the West' has been a key actor throughout the chapters, a 'gold standard' and site of already–existing systems, this is largely an image of a West which does not exist. The USA, 'are the worst of the lot for consistency [in IRB operation],' commented Frank Wells of the European Forum for Good Clinical Practice[96] in a speech to the FERCAP Conference in 2010: 'How many ethics committees are there, in the States? Actually they don't quite know.' Despite this, I have shown how standards, stories like Leslie's and images such as Dr Koski's cloth weave through the the narratives of FERCAP as both threat and encouragement, showing that the concerns which that environment produces also travel.

I suggest that the formulation of an answer to the question of the 'where' of ethics repeats internal and external divisions, again revealing the:

> intransigence of pre-existing social forms that get in the way of, or alternately, encourage certain kinds of social/sociological understanding. They reside in how as practitioners we already think (Strathern 1999a:272).

There is a component vital to European and American debates which seems absent from the material presented in this thesis. It occasionally enters FERCAP discussions through the presentations of international guests: 'the public.' While 'the public' has not played the same role in this research as it does in Euro-American discussions of science and ethics, or "Mode 2 Science" (Nowotny et al. 2001), Latour reminds us, in his conversations with students, that apparently invisible entities always leave a trace:

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[96] A not-for-profit organisation based in Brussels, established for and by those with a professional involvement in the conduct of biomedical research. Membership includes universities, pharmaceutical companies, pharmacists, doctors and regulators.

> If they act, they leave some trace. And then you will have some information, then you can talk about them. [...] Invisible things are invisible. Period. If they make other things move, and you can document those moves, then they are visible (Latour 2005: 151).

While 'the public' leaves few traces in the Asian parts of this material, I believe the most compelling trace lies in fears expressed about the potential, the *possibility*, of scandal. When stories such as the Coast close-down circulate (Chapter 1), they lead committees to feel they are operating in the shadow of a scandal to come, to seek ways of avoiding it. As a Taiwanese committee member lamented wearily,

> The problems are never ending, but goal can't be sacrificed. You cannot say 'Don't do any more human subjects research.' We need IRB in the system but IRB is just a Review Board. Research scandals, like the scandal in Korea? We're working to prevent that. We must push it, [keep it] moving.

The latent publics of Asian bioscience 'make other things move' (Latour 2005:151); what is seen is a reaction in preventative anticipation, the effect of a home grown scandal. 'The public,' arising in the stories and imaginaries of American and European commentators, is not invoked as a *reason* for IRBs in Asian narratives. No Tuskegee stands for injustice, crimes of World War Two never led to East Asian Nuremberg Trials (Kleinman 2010:1075). Koski's opening image of a broken thread revealed the vulnerability of "science" to scandal, as did Coleman's opening concern with the suspicions of the American public about research. It is not coincidental that both commentators are American. I suggest that concerns about 'the public' arise not only in their images and descriptions but also in the form of the committee. To merge the discussions of Chapters 3 and 4, I suggest that the committee as it operates in the countries where FERCAP works is a model hewn from Mode 2 science (Gibbons et al. 1994, Nowotny et al. 2001, 2003), but running largely in the absence of public debate, sometimes in the absence of legislation and even governmental interest. This slide from Dr Dissanayake, the Sri Lankan delegate at the 2008 FERCAP Conference makes the point (Figure 33): there has been *no demand from the public or the government* for the 'action' his presentation has detailed — the establishment of the Forum of Ethics Review Committees in Sri Lanka (FERCSL), the creation of National Guidelines for Ethics Review Committees, Workshops and Courses on GCP and SOP development, and the establishment of the Sri Lankan Clinical Trials Registry.

Like the ethics committee's assessment itself, ethical review of research in Asia is largely anticipatory. 'Public trust' is not conceived as lost because it is not (always) deemed necessary. More than this, it is absent because of different political histories of governance. As Holden and

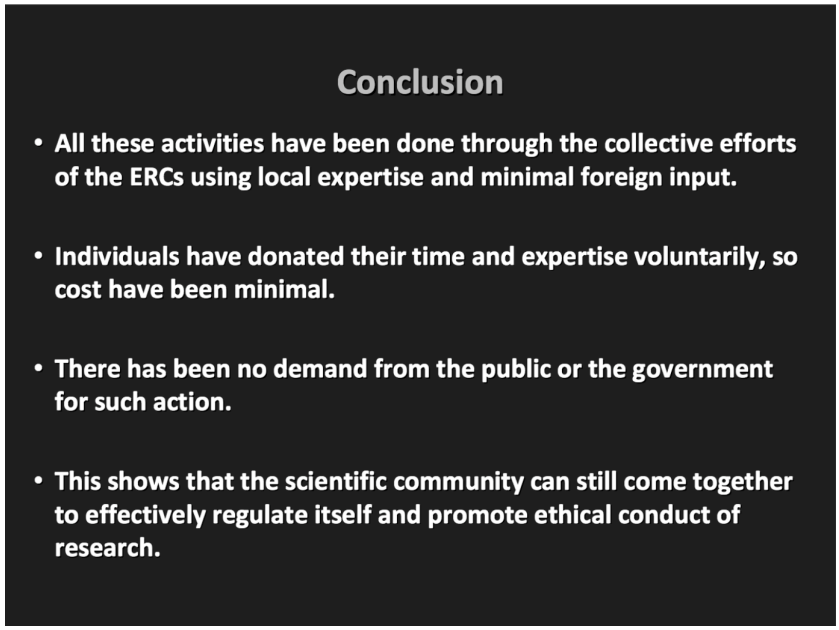

Figure 33: Dr Dissanayake's 2008 Concluding Conference Slide.

Demeritt remark critically of Singapore, public statements on human subject protection in research are aimed at an 'international research community and its investors, rather than to an agitated Singaporean public concerned about the proper and dignified use of their bodies in biomedicine' (2008:81). Committees are not the *result* of scandal (for an American history see Stark 2011b), they anticipate it. I propose to take this present absence of publics a step further. In Chapter 4, I argued that versions of the committee in use invoke 'microcosms'. These rely on a notion of a public for their legitimacy, but the public represented on them is a very select version: Harsha's enactment of the layperson (p.180) shows this most clearly. Staying with my Sri Lankan examples, Colin (p.156) argues that a public debate would not be a 'rational debate.' In the place of national mechanisms of public accountability, in Chapter 2 I demonstrated the way the implementation of the SIDCER Recognition Program through the Survey brings members of the FERCAP network together in reciprocal monitoring. This is regarded not as bias but as strength: the committees depend upon one another to keep standards high. FERCAP, I argue, can be viewed as a mutualistic mechanism through which the network forms its own public.

In my Introduction I pointed to Stark's concern about how committees define what can be known (2011:234). Developing her observation using the material in this thesis on the way committees operate outside the USA I want to suggest that the integration of "ethics" into what makes good science has links to the long tradition of witnessing in knowledge–making. While the

touchstone for the figure of the witness is the Hobbes–Boyle debate over the space and way in which science was 'witnessed,' (Shapin and Schaffer 2011[1985]) there are some important differences to note between it and my allusions towards witnessing in and through the spaces of ethics. I proceed by laying out some of the parallels.

Where Boyle's experimentalists 'insisted upon the public nature of their activity' (Shapin and Schaffer 1985:333), Hobbes's philosophy had to be public in the sense that it must not become the preserve of interested professionals. (Shapin and Schaffer 1985:333) Hobbes' concern was that 'knowledge was dependent on a practice of witnessing by a special community, like that of clerics and lawyers' (Haraway 1996:431). The question of the publicness of Ethics Committees is beginning to be raised, as shown by both Coleman (2004a:14, see also Goldner 2002:109-111) and Stark (2011b), and I addressed concerns about ethics being the 'preserve of interested professionals' in Chapters 4 and 5. When Haraway writes of the air pump, she writes that the 'separation of expert knowledge from mere opinion [...] is the founding gesture of the separation of the technical and the political' (1996:430). Ethics committees, I have argued, are part of the bringing-in of 'society' to science. What my material makes evident is the existing politics of their form, as members of committees across Asia struggle to make their existing social relationships fit with the formulas the committee demands. In showing whose views will count as 'society' (Chapter 5; Strathern 2005b: 476) I have shown different methods of making different voices heard. One of the challenges of the ethics committee, as I have shown, is that it strives to *combine* expert knowledge and 'mere opinion' (qualities deemed separated by the air pump, Haraway 1996:430). As I has shown, however, in the principle 'if it is not scientific, it is not ethical' questions about the scope, methods and questions of research are challenged on the grounds of ethics. The ethics committee is not a direct witness for the object world; it operates at one remove. The nature of that 'remove' came under question in Chapter 5 where the Nuffield Discussion Report (2005) and the experiences of ethics committee members I interviewed showed that committees often review the scientific merit of research at the same time as they review its ethical aspects.

It matters that ethics committees can change what research is done and how. It also matters that the 'social literary and material' technologies which gave air pump 'power to establish matters of fact independent of the endless contentions of politics and religion' (Haraway 1996:430) are now in use by quite a different instrument: the ethics committee. The committee is a material device (Chapter 3) with a literary means (minutes and letters) which employs a social technology of

deliberation (consensus and voting) (Shapin and Schaffer 2011[1985]:25). In their discussions and decisions rests the 'oscillation between the condition of knowing through investigation (research) and the condition of asking what is to be done with that knowledge (management)' (Strathern 2006:195).

I am struck by the similarity between what Haraway describes for the experimental science of Boyle's time — which 'spread as its materialised practice spread,' being 'not a question of ideas, but of the apparatus of production of what could count as knowledge' — and Dingwall's reasoning behind the spread of ethics committees:

> Unless biomedical research has been approved by an IRB-type body, it cannot be published in any major journal. Most leading research countries, and many lesser ones, have installed such systems in order to maintain their access to the international scientific community (Dingwall 2007:788).

Dingwall's description of its spread is another way in which the committee is integrated into the making of 'good' knowledge. Yet part of the challenge faced by ethics committees in the absence of law is persuading investigators to do as they recommend. For this reason, I propose that the ethics committees I worked with are, unlike Stark's declaratory bodies, engaged the work of *attesting,* after Ezrahi's work on visual cultures in science and democracy (1990). I mean this in two senses. First, most ethics committees with whom FERCAP works cannot declare in the way the committees Stark worked with; their decisions are not backed up by law. But their role is (particularly in the case of international multi-sited trials) to bear witness to something being 'ethical.' They attest that they have examined it, and attest it to be so. While I have shown that what is known, how it is known and by whom it is known all matter, I have also shown that the personal function of the witness becomes — in this ethics — the attestive work of the group. While studies of expert and lay knowledge focus on the roles, capacities and characteristics of each, this analysis of these actors in a committee and *as a committee* allows insight into what I am calling its attestive role. Untethered from an individual point of view, the attestive assemblage mobilises combined evidence into the voice of the committee, which 'speaks as one.' Ethics becomes something that can be obtained and proven through stamps and certificates, and it is the voice of the Ethics Committee which both achieves and grants this.

The second sense in which I intend their attestation is that this act of attesting must itself be attested to; evidenced, minuted, documented. Attesting ethics committees are the objects of the very practices they practice, a relationship complicated by the mutuality of FERCAP. In the transference of principles of evidencing from science to ethics via audit, ethics committees

involved with FERCAP become accountable to an evidentiary regime in which attesting to their own operation is as important as attesting to the ethics of proposals. A committee cannot just be the gatekeeper with which we began at the Regional Collaborative Workshop. FERCAP's work of recognition and the changes in practices it provides through Surveys and Trainings mean that committees learn new ways of functioning materially, from their minutes to their decisions to their archives, their work is made valid through its traceability. The audiences of FERCAP's ethics committees are not 'publics' of the Euro-American accountability discourse but at an audience of concerned (medical) professionals, whom the gatherings of FERCAP make visible. No wonder that to the conference presenter from Sri Lanka, it looked like science was 'governing itself.'

I remarked in the introduction that the concept of ethics in current circulation did not come from nowhere. Strathern reminds us that, 'in pushing and pulling language for the sake of argument, people may force new properties onto old concepts' (2005:51). At the opening of the FERCAP conference in Shanghai, with a nod to the interest shown by Chinese hospitals and ethics review committees in 'ethical review systems', the Chair of FERCAP chose to base his opening comments on his study of Chinese philosophy as a child in Japan, one of the countries over which Confucius' work had 'had influence.' In his brief address, he projected four characters, *Jin, Gi, Rei, Chuyou,* linking these four characters with the operation of ethics review committees:

> Love, humanity and kindness. To hate the wrong thing. Honesty. The right thing to do. Standard to behave, believe. No extreme, no deviation. Balance. These are still important. It is not necessary to produce new things. Confucius already established such a system of SOP! FERCAP is original, but also based on… [I'm] very happy to discuss new things based on old things.

He was suggesting continuity between contemporary developments in the governance of biomedicine through 'ethics' and 'old things' in Confucius. Speaking of the New Reproductive Technologies, Strathern observed that it is perhaps:

> this very capacity to think one is perpetuating old ideas, simply doing again what has been done at other times and in other places before, elsewhere, that is itself a profound engine for change (1992b:44, see also discussion in Green 2005:14)

Throughout the thesis, I have detailed moments of slippage, where what ethics is seems to shift. A preoccupation with quality makes it difficult to see the difference between quality and ethics. Awareness of vulnerability can stand as 'ethics', indeed, awareness of other points of view can even seem sufficient (Strathern 1999a:252). As Juntra seeks ways of measuring and quantifying, we see ethics slip into a form in which it can be numerically evaluated. In analyses of the decision-making of committees such as Coleman's, ethics seems to reduce into a risk assessment, a

balancing act of risks and benefits, modeled on cost/benefit equations which, since the 1930s have given form to rational decision-making (Stark 2011b:11). But in these transformations, the ethical can always escape elsewhere. This is, I suggest, part of its success; part of the continuing chase. If it cannot be easily found in 'society', let us look to the individual. If, as Koski asserted in his webinar, monitoring mechanisms such as ethics review committees leave us 'dissatisfied,' then let us turn to responsibility, professionalism, integrity. These were the qualities which were lacking in the first place, when in the 1980s the UK's Ian Kennedy (1980a, 1980b, 1980c 1981) and the vanguard of bioethicists in the USA drew upon ethics to regulate biomedical research, with 'Kennedy's belief that the inequities of the doctor–patient relationship could be redressed by involving outsiders in the development of medical guidelines' (Wilson 2012:207).

While ethics can be used to address certain problems of proximity, through reference to processes and procedures (Chapter 3), it also causes them. Relationships, with rules or without, have been everywhere in the chapters of the thesis. Dr Sams's rendering explicit of the possible perception of military invasion in his 'follow up visit' slide gave him the scope to play on the potential danger of the Survey, and diffuse tensions. Researchers have been approached gently, with committee members likening their approach to counselling. Some were refused face-to-face meetings with committees, in order that paperwork 'speak for itself'. Knowing enough was essential as "sufficient expertise" came under fire; knowing too much was dangerous, *barkadas* might side with one another. Camilla was kicked out of her committee for her approach to ethics and for forcefully speaking her mind. Edith encountered a version of this problem when she attempted to implement the 'raise hand' voting system on her committee.

> Treating [ethics] like an abstract and absolute science that can be easily downloaded into a variety of cultural settings [...] is likely to obscure and distort the way that local responses to biomedical ethics are being formulated in the developing world (Simpson 2004a:8).

In this thesis I suggest that in fact ethics *is* treated as a kind of science, borrowing techniques of objectification, measurement and standardisation for its legitimacy. Indeed, a 'local' response to biomedical ethics may be to *further* the traits it borrows from science, particularly in settings where ethics is used as a way to create space in existing relations.

FERCAP, I have argued, cultivates a proximity to the comprehension of difference through their distance from it: to use Riles' phrase (2002), difference is left in the gaps. Un-formalized, un-addressed, un-programmed it acts as a ground for the standardisation process. In Chapter 6 I developed an approach to the comparative work of the organisation, looking at the dialogues and comparisons which constitute the regional imaginary through which it achieves its aims. Its

continued ability to 'work' is revealed to lie in careful and skillful talk. In such talk — set against a justificatory background of 'cultural difference' within the region — what is foregrounded is commonality, and what is backgrounded is the detail. This exemplifies Strathern's observation (1995:11) about the phrase 'cultural difference': its simultaneous identification of the incommensurable, and the creation of a framework in which to compare it commensurably. Chapter 6 also demonstrated the way in which influence is made. By not taking for granted the correlation between size and importance, and instead subjecting the creation of that 'size' to rhetorical examination, the thesis demonstrates the utility of Jensen's (2008) suggestions to focus on where power emerges, and how.

Unable to find ethics that are universal, as a method of dealing with difference, form has taken precedence over content. Standards not principles, GCP not Helsinki. Integral to this precedence is measurement: discussion must look like discussion. The layperson must speak, though we do not know what s/he says. Perhaps, in arriving at the ultimate form, the hope is that the environment has been achieved in which something that looks like ethics can be done. Is ethics in the answers or the process? In 'not doing bioethics,' in refusing the endless deliberation towards answers it sees in moral philosophy, in insisting that ethics committees must make a decision, FERCAP chooses process. Unable to watch over every discussion, knowing the infinite permutations of research projects, it has chosen form. It is the pursuit of a sonnet, a form of 14 lines in whose perfect shape poets make play with words. SOPs are far from sonnets, and wordplay would render them the opposite of their intent, but the comparison allows us to see another dimension of the tool: it is a form with sufficient flexibility. Standard operating procedures can always be changed. 1.2.1.2.2 can, without difficulty, become 1.2.1.2.2.1. What more can be said of this apparently technocratic reduction?

Now able to reflect back on the chapters together, I want to point to the the repeated instances, replications of almost-but-not-quite self-similarity across scales and contexts (Green 2005:14; Strathern 2004[1991]: xx). There have been many moments in the chapters where I have pointed to the 'same' arguments being used, the 'same' images repeated or the 'same' patterns of thought present. I return now to a few instances of that 'seriality' (Hornborg 1998:168) to show how not only that scaling matters, but attention to scalar principles does too. The elephant is an obvious example, used in Chapter 2 by the FERCAP Survey to explain how teams worked together, and used by Cristina in Chapter 5 as an example for how a committee might ideally approach a protocol. At times, these moments of replication caused difficulty in analysis, as in in Chapter 3

where I pointed to confidentiality slipping between authors of texts and reviewers of them, between what a protocol must demonstrate and what a committee must maintain (for an example of one pattern of thought being found inside another see Godelier and Strathern 1991). This was equally true of the idea of police, with both surveyors and committees refusing the name. In Chapter 5 I explored the committee as a device of transparency and accountability, principles (and techniques) called for again in the desire to see the spread of clinical trials databases: as an Indian commentator remarks,

> if every piece of research conducted in India were available on a publicly searchable database somewhere, one would know what issues are being addressed, and if they are relevant to the population in which the research is being conducted (Chatterjee 2008:581).

But what to do with this observation of social self-similarity? Perhaps the best course of action is to pay attention to what these replications achieve. To that end, I want to conclude with a final replication: the measurement of balance.

In research, collaboration and its associated multi-part imagery is, as those at the Regional Collaborative Workshop with whom I began remarked, as much an answer to these fears of injustice as a balance of existing inequalities (Volmink 2005; London 2005; Wagner et al. 2001; Emanuel et al 2000, 2004; although see Okwaro and Geissler 2011). In research ethics, dual-ended review seems like a way of weighting against decisions made elsewhere; weighing the detail of the specific will weigh against expertise in 'Geneva' (p.22).

Speaking of biomedical clinical trials, Simpson and Sariola observe that '[b]ased on principles of evidence, and reinforcing those principles [...] knowledge and un-knowledge are balanced in the blinding of a trial' (n.d). Informed consent is one area in which this has been particularly evident. In balancing the information between doctor and patient, or changing that balance, information is given power. Sariola and Simpson show that the information of informed consent can be given an inverse weighting — the *more* information, the *less* credible. 'They will think this doctor does not know what he is doing' (Sariola and Simpson 2011:518).

When in Chapter 7 the South Korean Expert Secretary General described to trainees the work of a committee, she highlighted 'balancing.' 'The IRB is actually a compromise activity in terms of ethics', she said, '[i]f you have high abstract standard you can't approve any proposal.' The Belmont Report was also interested in balances, balancing between maximising possible benefits and minimizing possible harms, and the distribution of the benefits and burdens of research (HHS 1979). Stark writes (2011b:11) that there was no inevitability in the way cost-benefit analysis

became naturalized as the 'dominant logic of government' in America (Espeland and Vannebo 2007:24, see also Centeno 1993). Nonetheless, balance oriented cost-benefit mechanisms came to inform the risk analysis that Coleman (2004a) sought to rationalize, permeating the discussion of Juries and Ethics Committees I took up from Coleman (2004a, 2004b) and Noah's (2004) debate in Chapter 4.

A focus on balance — deliberate or not — *makes* things that can be balanced: fractally generated it looks recursive, organising and producing the 'same-but-different' (Green 2005:14) concern at different scales. Corsín Jiménez (2012:227) observes that 'ours is a society of balances. Of equilibriums and resting points. The macro is balanced by the micro; the local by the global; the self by the other.' In this thesis I have paid attention to the way biomedical research talks of the 'local' and 'global' in clinical trials (Chapters 1 and 4), I have critically examined the poles of the micro and the macro (Chapter 6) and I have considered the balancing done by ethics committees to ensure that participants in trials are protected. In this, I suggest that the repeated instances of balancing in this thesis be seen less as repeated principle than coordinating technique: they are achievements which bring things together in such a way that they seem stable, even if only temporarily. Furthermore, this fractal generativity has other uses. Riles writes that Callon's (1998) work on markets illustrates how the a market as a

> field of knowledge and exchange [...] depends on the possibility of certain forms of equivalence, and hence upon a wide range of techniques for cutting off, excluding, or purifying complexity so as to render values universally calculable (Riles 2011:59).

ICH-GCP, Holden and Demeritt claim, is a 'particularly effective form of standardisation that allows scientific research to travel significant distances and still be relevant to dominant markets of the US and Europe' (2008:83). Ethics when viewed as a part of GCP, and treated in the same way, must also be standardised to ensure that the trial data is valid, that it can be used elsewhere. FERCAP works to create a metric by which Asian ECs can be compared with "Western ECs" in an extension of the way in which trial data from Asian sites can be compared with data from elsewhere in the world. Here I have sought to show how closely political and scientific dreams run together in this standardisaion, and the consequences of this for ethics.

If the replication of balance is a technique, it is one with a long history. Sahlins returns us to biomedicine when he recalls John Adams, 'that famous apostle of the balance of powers' who wrote that

> Some physicians have thought if it were possible to keep the several humors of the body in exact balance it might be immortal; and so perhaps would a political body, if the balance of power could always be exactly even (Adams 1977:99 cited in Sahlins 2007:93).

Sahlins' nod to the history of ideas reminds us that '[b]alancing and proportionality [...] are cultural categories, even if ones deeply entrenched in Euro-American habits of thought' (Corsín Jiménez 2012:228). Similarly, contemplating a global bioethics, Campbell (1999:186) observes that,

> Our idea of 'free, open and reasoned' has been shaped by a particularly western mode of reasoning, one which has been remarkably successful in enabling the emergence of an all-controlling technology, but is by no means the only way, or the even best way, of establishing our ethical signposts. It cannot be accidental that such a way of doing ethics fits neatly into the idea of constant economic progress as an end for humanity.

It may not be the only way to make ethical decisions, but these principles of 'free, open and reasoned' discussion I argue, are found not only in the words of ethics but also the forms of ethics. In this thesis, I have shown how the form of the committee emerges, through FERCAP's work the dissemination, as a device replete — in its physical and social form — with ideas about balance, equality and reason: ethics itself as a device for teaching balancing, to find over and again the location of ethics. In this sense, for all the places I have found for it in this thesis, ethics could be said to lie in the balance.

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