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# A 'good' ethical review: audit and professionalism in research ethics

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How does one conduct, measure and record a 'good' ethical review of biomedical research? To what extent do ethics committees invoke professionalism in researchers and in themselves, and to what extent do they see competence as adherence to a set of standard operating procedures for ethical review? Drawing on ethnographic fieldwork with the Forum of Ethics Review Committees of Asia and the Pacific (FERCAP), a capacity-building NGO that runs ethics committee trainings and reviews in the Asia Pacific region, I develop an analysis of ethical review and its effects. I focus on a 'second-order audit' run by FERCAP, which recognises committees according to a set of standards that are designed to render 'local' committees internationally legible. The article adds to a growing comparative literature that expands studies of audit-like measuring and disciplining activities beyond western contexts and enriches readings of 'ethics'. I begin and end with a reflection on the ethical effects of a measurement practice that takes ethics itself as its object.

**Key words** research ethics, audit, professions, Asia, transnational

## Introduction

[53] <sup>1</sup>What are the ethical effects of a measurement practice that takes ethics as its object? To address this question I explore the assessment of biomedical research ethics committees conduct in five Asian countries by a regional NGO.<sup>1</sup> I pay particular attention to the relationship between audit processes and the idea of being a ‘good professional’ (Pels 2000; Exworthy and Halford 1999). This was a central question to members of the organisation I worked with: how does one conduct, measure and record a ‘good’ ethical review of biomedical research? If one is seeking to foster ethical behaviour, they ask, should one look to audit-based practices, or attempt to shape people’s sensibilities and actions?

These questions circulated during 2009–10, as the Forum of Ethics Review Committees of Asia and the Pacific (FERCAP) was working to train and evaluate ethics review committees.<sup>2</sup> My ethnographic work with FERCAP explored how practices of ethical review are being taken up in government and private hospitals and universities across the region. Working with over 100 institutions and 300 individual members, including doctors, academics and research administrators, FERCAP was the most successful of five arms of the Strategic Initiative in Developing Capacity in Ethical Review (SIDCER), funded in part by the World Health Organization’s Tropical Disease Research section. Operating from a two-person office based at Thammasat University, Bangkok, FERCAP’s main activities involve travel across the region to conduct training, [54] and their key activity of surveying and recognising (not auditing or accrediting) ethics review committees in Asia and the Pacific region. Through this surveying work, they bring standards to bear on what constitutes a ‘good ethical review’ and, alongside a process-oriented definition of doing ethics, give attention to the possibilities for an ethics of individual reform. But how they carry out their auditing work has characteristics that set it apart from the well-known effects and tactics of audit (Strathern 2000). It is their approach that interests me here, since it imbues the measurement of ‘ethics’ [ethical review] with certain ethics of practice [reviewing ethical review].

Building on Power’s 1994 work and essays collected in *Audit cultures* (Strathern 2000), scholars have traced how, as audit-based mechanisms shift ‘domains’, they re-work relationships, responsibilities, accountabilities and forms of governance (Strathern 1992). Two recent examples demonstrate these technologies of governance and our theorising about them. Merry (2011) has examined indicators as a mode of ‘measuring the world’, characteristic of the ‘dissemination of the corporate form of thinking and governance into broader social spheres’ and the need for critical analysis ‘in the contest over who counts

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<sup>1</sup> Page numbers in square brackets indicate published page numbers. They are inserted where the new page *begins*. Other notes in this text are *endnotes* and can their associated content be found at the end of the text.

and what information counts' (S83, S85). In a similar way, STS scholars Jensen and Winthereik (2013) have used their study of Danish aid auditors to advance understandings of how audit regimes 'loop' in upon and come to apply to those who administer them: auditors, too, are now subject to audit (cf. Power 1994: 7–8).

This article adds to these debates by exploring how ethics operates as a form of governance: it sketches the relationship between the measurement mechanisms of FERCAP's activities and the way committee members talk about their roles. However, if ethical review of biomedical research is a kind of first-order audit, FERCAP's work in reviewing and 'recognising' ethics committees' activities is a second-order audit. It fulfils Power's prediction that the logic of audit may be to 'replace the monitoring of quality [ethical review] with the monitoring of systems to monitor quality [the recognition program]' (1994: 6). FERCAP's activities at the intersection between ethics and audit constitute a form of 'mutual reference point' (Strathern 2000: 282), whereby a codified ethics 'could be thought of as an enlarged or magnified version of audit: it specifically relates 'good practice' to individual conduct' (Strathern 2000: 292). Here, however, the conduct is that of the collective, the committee, whose biomedical members collapse a distinction between a community whose individual conduct is being checked (biomedical researchers) and those who do the checking (committee members). Furthermore, their 'good practice' becomes a question of doing ethics ethically, a topic explored in Peter Pels' work (1999, 2000). In his interrogation of the specific interface of ethics and anthropology, he traces in broad strokes a common history for a romantic ethics and a utilitarian economics, identifying as the outcomes the poles of audit and professionalism between which a 'liberal pendulum' swings (2000: 148). Using Campbell's (1987) revision of Weber's Protestant ethic, Pels identifies at one pole of his 'liberal pendulum' a romantic ethic tied to feeling and liberated by the imagination. At the other pole is a utilitarian and productivity-oriented ethic, in which economic calculation demonstrates moral excellence (Pels 2000: 147–8). In what follows, I attempt to divorce Pels' rich argument from its investment in the anthropological profession and turn it in on the governance of biomedicine through ethical review. FERCAP's work exists because of ethical review processes, a (utilitarian) mode of governing biomedical research rooted in distrust of the medical professional [55] (romantic). This tension he identifies between these utilitarian and romantic poles is evident in the question FERCAP asks itself: where should one look for governance of biomedical research – professional sensibilities or measurable processes? That it has become such a question is indicative of the generation of an intriguing dichotomy. If Pels' liberal pendulum is suspended, in this case, between a romantic professionalism and utilitarian audit, what are the different meanings of 'ethics' in effecting these different strategies of governance?

Pels's groundwork allows me to situate the work of FERCAP in a context

where 'ethics' has moved from being in the custody of the medical profession, to being something that is done 'to' medical professionals, through institutions such as the ethics committee. It is furthermore something researchers can 'get', or receive. The first section of the following attends briefly to the way in which bioethical histories of the USA are told in FERCAP's Asian trainings, demonstrating how sites of biomedical research are linked now not only by experimental practices, but also by particular forms of 'ethics practice'. I build here on the work of the UK historian Duncan Wilson, whose research showed how ethics review committees separated ethics from professions during the burgeoning era of audit. The second section examines the contemporary effects of that shift through FERCAP's activities, showing how their work across Asia operates as a second-order audit, reviewing and 'recognising' committees' practices of review. In training and reviewing ethics review practices, we see the ordering and auditing work of governance techniques beyond the nation state. The third section returns ethnographically to the relationship between the audited and the professionalised self, to describe ethics as a technology of governance that simultaneously engages with, and matures out of, the limits and disappointments of ethical review as a pre-emptive audit. I suggest that in FERCAP's practices we find not only new calculations of audit practices, but also configurations of familiar states of responsabilisation.

## **Profession to audit**

Collectively, the papers assembled here observe that audit regimes increasingly operate beyond the nation state (Shore and Wright, this issue). FERCAP's work is transnational, and my own fieldwork as an observer and trainee surveyor took place in five of the ten Asian countries in which they work: Sri Lanka, Thailand, Taiwan, the Philippines and mainland China. In this section, I introduce the landscape of transnational research ethics as described to me by two women who coordinate FERCAP's work across these different settings. Their accounts illustrate the take up of Euro-American histories of bioethics, as well as practices of research ethics. My argument draws additionally on material gathered from attending workshops and trainings on Good Clinical Practice and Human Subject Research Protection, and participant observation in the review of ethics committee work – The Survey – in each of my five fieldwork countries. While nations, climates and legislation changed between sites, the core review team remained constant: committees of around 10 people, formally required to be of equal gender and prescribed profession. FERCAP's activities are partly a response to the growth of clinical trials through the 1990s and 2000s, especially those that run the same trial protocol in several places at once. The spread of standardised biomedical research infrastructure and techniques [56] (Rosemann 2012; Petryna 2009; Sariola and Simpson 2012) has also brought demands that research protocols be reviewed 'locally'. When FERCAP presents its programme of 'recognition' to prospective committees, it describes a world in which trials are composed from research done in different

parts of the world. 'The same trial being done in Asia, we see it 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, towards the end of my research, I listened as a FERCAP surveyor 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, one protocol done in different countries all at the same time.

This expansion of multi-sited research has led to multi-sited review processes. Just as the scientific data of multi-sited trials has now become integrated into what it means to produce 'good' science (Douglas-Jones 2012a), so too has ethical review. 'Good science' is based on both reliable and ethical data.<sup>3</sup> For more than a decade, international collaborative trials have meant that capacity-building activities in ethical review have been going on all over the world (Eckstein 2004). They aim at establishing and training committees to perform an ethical review of a research proposal. More recent documents produced by the European Medical Association put the need for 'local' ethics committees more strongly, insisting that a local ethics committee is a prerequisite to a clinical trial taking place at all (EMA 2012). But what drives these demands? The practices of ethical review remain a concern of clinical trial sponsors, for whom the ethics committee 'is an entity over which sponsor auditors have no jurisdiction', meaning that 'what is beyond the documentation ... is a complete unknown for the sponsor and their auditors' (Hamadian and Johansen 2010: 17). FERCAP's activities offer a thorough measure of competence for external or distant parties relying on the committee's review (cf. Espeland and Sauder 2009).

Those involved in FERCAP's activities make their own arguments for local capacity building in ethical review: Juntra Karbwang, a UK-trained Thai researcher and at that point WHO employee – one of my key interlocutors – is 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, a process that, in good audit tradition, entails 'helping (monitoring) people help (monitor) themselves' (Strathern 2000: 4). Speaking about the initiative and its intended effects, Juntra commented that 'review has to come from within the country. Rather than use England ... or Geneva, why not harness capacity?' She leverages her position as an experienced Thai researcher against her job and colleagues in the WHO when speaking about the inadequacy of inequalities in review capacity: 'Why use Geneva [as a reviewer]?', she asks; 'the power stays with them'. At meetings with the WHO in Geneva she questions the assumption that other countries 'don't know how to do review' and asserts that they do. The 'review of review' process she has been instrumental in establishing provides the evidence she needs for this claim.

[57] Part of my work in understanding FERCAP's activities has been to trace conceptual and national legacies in the ideas being discussed and practices being taught: techniques of accountability achieve efficacy in different ways, they gain different purchases when employed in new places (Kipnis 2008), and they carry parts of their histories with them. One story regularly told in trainings I attended on Human Subject Protection was of the infamous Tuskegee syphilis study in the USA (Reverby 2009). The New York Times first broke this particular story on 29 July 1972, to huge uproar. It revealed that even though an effective cure for syphilis – penicillin – was discovered during the course of the 40-year-long study, researchers did not treat the participating patients. In the aftermath of Tuskegee it was clear to the American public that 'fundamental questions needed to be asked about the nature of authority assigned to physicians' (Wilson 2011: 199). Wilson highlights the comments of Yale-based lawyer Jay Katz, who used Tuskegee to claim that 'doctors possessed no unique expertise that justified making them the sole arbiters of medical ethics'; his suggested remedy was '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 suggests, led to a profound shift in the locus of governance over biomedical research: ethics review committees, regarded as external to the research, were seen as better placed to assess the ethics of research than doctors. This 'profound shift' had been building for decades (Stark 2012; Wilson 2012), not least since the Nuremberg Trials after World War II, but a new 'exteriority', to use Wilson's language, marked the burgeoning audits of the 1980s. External review of biomedical research has today taken deep root alongside other audit-based activities that began to flourish in that decade. Sociologist Laura Stark argues that, in the USA, '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' (2012: 7).

These 'procedures' are the focus of FERCAP's work, although what they do is not based in state policies, as in Stark's work, and is not contained by national borders. Their focus is on building 'capacity' in ethical review across the Asian region. The organisation's coordinator, Cristina, commented that her approach:

has made it possible to operationalize the basic ethical 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 committee members in reviewing protocols, consent forms, and related documents. (Torres 2011: 49, emphasis added)

While FERCAP's trainings are peppered with bioethics stories – a litany of historical examples I became familiar with over the course of research – the trainings also observe and police a distinction between bioethics and research ethics. Members of FERCAP described their encounters with bioethics as 'philosophical' and 'discussion based' and they did not count bioethics classes in 'moral dilemmas' as 'skills', since resolutions were not the priority. This

contrasted with an emphasis on procedures in FERCAP's approach to research ethics. 'We focus on a system', explained Cristina, 'for us, the guidelines are there and what is more important is to be able to operationalise those guidelines'. Through the enrolment of quality control models and standard operating procedures, ethical review can be described, assessed and evidenced. This activity, in the language of FERCAP, is referred to as The Survey.

[58] Checking and measuring ethical review processes, The Survey focuses on and continues the 'profound shift' of ethics as a form of audit, as distinct from an ethics rooted in the professional.

### **Auditing the audit**

The Survey, as conducted by volunteer members of FERCAP, measures the work of ethical review committees against standards drawn up by a working group of SIDCER, who met in Olympia, Washington in September 2005 to create what is now known as the Recognition Program (SIDCER 2005). FERCAP's Survey implements these standards, marshalling logics of audit to answer the problem perceived by clinical trial sponsors and capacity builders alike: how do you know that an ethics review committee conducts a 'good' review?

The SIDCER Recognition Program is accompanied by a statement that its standards provide the international community with 'a way to measure and provide accountability regarding the quality and effectiveness of ethical review worldwide' (Karbwan Laothavorn 2011: 11). As Jacob and Riles note, '[o]ne of the interesting features of modern ethics is that it must continually be demonstrated – it must be bureaucratically evidenced, revealed, documented, enacted, performed' (2007: 181). The authors of the SIDCER standards included directors of quality assurance, internal auditors, quality assurance analysts, directors of regulatory affairs, and though the majority were from the USA, the group included members from eight different countries. The standards were designed without reference to specific national laws or guidelines, in order to be internationally applicable. FERCAP is therefore able to use them across the ten countries where it works to assess how ethics committees operate, what their assessment criteria are, and how they document and follow-up proposals. However, as Merry remarks, such devices reveal 'a slippage between the political and the technical', as measures are always 'rooted in particular conceptions of problems and theories of responsibility' (2011: S88). Hence, the theory of responsibility that shifted the governance of medical research from the professions to external review gives rise to a new problem: how to govern the resulting ethics committees?

The Survey is where the theories of responsibility (and accountability) built into this mode of governing are reinterpreted. While the activities that FERCAP surveys would be recognisable to a biomedical or clinical auditor, the way they are carried out might not be. During research, I took part in these

activities as an observer-trainee, learning the ropes of surveying in three countries, and discussing future or recent surveys in two more. A committee initiates the recognition process by conducting a Self-Assessment, measuring their committee against a checklist of requirements. The survey that follows this is a three-day event, during which a survey team of four to six members, plus up to 10 local trainees, reviews the reviews made by the committee under study. The survey team selects cases, scrutinises the files and minutes, and examines the continuing review practices of the committee. Survey team members interview committee members, and observe a meeting at which the committee reviews a protocol. The amount of work is vast, but the tone is one of (sometimes strained) conviviality. Unlike an audit process, which might position itself 'as an increasingly private and invisible expert activity' (Power 1994: 26), FERCAP's work is conducted at a point where hospitality meets audit (Douglas-Jones 2012a). The enterprise is founded on a [59] principle of mutual investment: the surveyed may become surveyors in turn, and all surveyors have themselves at some point been surveyed. The standards surveyors hold others to are standards they are held to themselves. Survey days are long, often lasting 12 hours or more. Vast amounts of (excellent) food are eaten. There will be time taken for meals out together, and for seeing sights: historic buildings, parks, museums and palaces. Surveyors are drawn from other parts of the network: international surveyors lend 'objectivity' to the review (Hamadian and Johansen 2010; Douglas-Jones 2012a), while local surveyors provide knowledge of national laws, and sometimes translation. The team are invited – as guests – by the committee under review, and emphasise that they come 'as friends', to learn and to improve both the committee and themselves. Surveyors receive no remuneration for their work and participants – surveyors and surveyed – are often actually friends, spending long hours together poring over documents, training others, receiving and giving tours of offices, making presentations with suggestions for improvements. Doing criticism well is difficult, even if one is an invited guest, and the model developed by FERCAP poses questions about the extent to which this is governing-at-a-distance, and about the strange bedfellows made by collaboration and competition (Douglas-Jones 2012a). FERCAP's Survey practices are thus a fusion of a monitoring gaze and a mutualistic, developmental ethos. This begs the question: where is the 'relationship of power between scrutinizer and observed' (Foucault 1977: 200) on which assessment and judgement appear to live? Rather than submitting to being 'objects of information', surveyed committees remain subjects in communication (1977: 200), part subject to, and part conversation partners in the mutual establishment and maintenance of SIDCER standards. Through these standards, FERCAP measures how well a committee conforms, and recognises those which do, awarding them a certificate and a cut-glass trophy at the annual November conference. The rapidly growing Recognition Program has assessed more than 120 committees.

One might ask: why has the Recognition Program been so successful? Since

the process is entirely voluntary, why do committees submit themselves to evaluation? Are there alternatives? When FERCAP presents its program of 'recognition' to prospective member committees, it begins by describing an international research arena in which ensuring the quality of research is paramount. The idea of 'harmonisation' of research protocols, standards and formats across regulatory regimes, which assisted the uptake of Good Clinical Practice (International Conference on Harmonisation 2010; Holden and Demeritt 2008), is extended from protocols and mechanisms of data reporting to ethical review procedures: their alignment ensures trial results are acceptable to regulatory bodies such as the United States Food and Drug Administration (USFDA). Participation in the Recognition Program may help committees to attract international research in the future: their name will be listed on the FERCAP website, and the ethics committee may display FERCAP's logo on its own website. Sponsors of research are invoked: 'sponsors', committees are told, 'would like to have assurance that the Ethics Committee is compliant with Good Clinical Practice (GCP). If it is not, it becomes GCP deviation, a violation', which can threaten the acceptability of trial data for regulators. While 'local' ethics committees are necessary for sponsors, their members also desire the research that a recognised ethics committee might bring. Adopting an internationally recognised form of governance, even though it is not a regulatory requirement, is suddenly appealing to committees and their institutes for the potential ticket it offers to a global marketplace of trials. As Kipnis would put it, 'seeing like a governing agent in a complex industrial society makes audit an attractive tool' [60] (2008: 286). This statement also applies to committees as governed agents themselves. The responsibility for compliance has shifted 'to the monitored organisation, corporation or country itself' (Merry 2011: S88).

As FERCAP and its activities have grown over the last decade, questions of its legitimacy have been raised. If it aims to perform 'rituals of verification' (Power 1997: 1, quoting Douglas 1992), then what rituals count, and whose truth comes to matter? These questions fit with the broader contestation over epistemic authority seen in this issue: who should set standards, and how do global rankers gain their positions? In what ways does the growth of non-governmental organisations intersect with the growth of ranking and indicators beyond the nation state (Shore and Wright, this issue; Keck and Sikkink 1998; Irwin 2008; Merry 2011)? During my research, researchers, committee members and representatives of Departments of Health across the region asked FERCAP about whether its activities could amount to 'accreditation', felt by many to be an activity that only a state had the authority to bestow. The organisation responded by emphasising that its project was one of 'recognition', not 'accreditation', the former involving supportive capacity building and a developmental, voluntary agenda. The number of committees voluntarily submitting themselves to the process, they argued, was evidence enough of the need for its supportive and constructive work.

In both its friendliness and seriousness, the Survey rests in the shadowy anticipation that European and American drug regulatory authorities will sometimes begin an ‘actual’ audit of sites in Asia for ‘compliance’, opening a space of ethical review perceived as out of reach to trial sponsor auditors and national drug regulators (Hamadian and Johansen 2010). During my research, an American organisation AAHRPP (the Association for the Accreditation of Human Research Protection Programs Inc.), which explicitly ‘accredits’ ethics review committees, was beginning to make inroads into what they viewed as the ‘Asian market’, accrediting a committee in Singapore, as well as committees in China, India, Taiwan and South Korea. In their own language, ‘AAHRPP’s accreditation standards are becoming the standards of choice around the globe’, and for the US-based company, international accreditations serve as ‘a reminder that we truly can have one standard for research protections worldwide’ (AAHRPP 2012). Leaving aside the universalising ambitions of the form (rather than content) of this mode of doing ethics, what does the presence of AAHRPP make visible?

Since FERCAP describes its work as ‘grassroots’ and ‘bottom up’, the contrast its members make with AAHRPP’s accreditation process is helpful. While discussing his committee’s recognition by FERCAP, Bill, a researcher who served on an ethics committee in Taiwan, commented that FERCAP was a foundation project, that its intention was to ‘build capacity, help build up from ground zero’, whereas AAHRPP was ‘already at the top floor of that skyscraper, the sign of the qualified’. Speaking of his experiences in Taiwan, he commented that ‘now that almost all the committees in Taiwan have been recognised by FERCAP, some are trying to shift to AAHRPP. Now that has become the gold standard’. Bill felt that if one committee got AAHRPP accreditation, others felt pressure to get it:

We like competition. If you were independent, and I have AAHRPP or FERCAP and you don’t have, people will think your Ethics Committee not good enough, so that’s the reason why we have to get more and more. [61] Bill’s statement reflects a logic that I saw repeatedly in my interviews, which I tried to unpick with the question ‘good enough for what?’ Bill’s reply was, ‘For our thinking, we can say “I’ve got an international recognition, you know I’m an international level.”’ And why was this important, I asked? ‘For fame!’ he exclaimed. It was not just the opinion of others driving committees and their members. Bill himself felt a strong sense of pride. ‘I know how it feels’, he said. The prospect of acquiring AAHRPP’s ‘gold seal’ was also appealing to recognised committees for reasons of ‘continuing improvement’. As one secretary, whose committee was on its way to six years of recognition, put it: ‘In my way, I think our committee is just beginning, it is not yet mature.’ Similarly, in Pune, India, at the Jehangir Clinical Development Centre, CEO Pathik Divate said of his committee’s recent AAHRPP accreditation:

We viewed [it] 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)

The Survey appears to be set up along utilitarian lines, affirming the need for ethical review to audit biomedical research, and relying on standards to produce a second order audit that reviews the review process. However, its mutualistic, capacity-building orientation distinguishes it from AAHRPP, as do the claims it makes on ethics committee members' professionalism, as I explore below.

## **Audit to professionals**

FERCAP is clearly a measuring organisation, and one of the outcomes of its 'capacity building' is that committees become known to themselves, to one another and to external others such as sponsors of clinical trials. While FERCAP has no ranked classes of recognition, or 'top 10' committees, it is itself ranked by some of its members as secondary to the US-based AAHRPP. It also provides a measure by which countries can pit themselves against one another by comparing the number of committees recognised: Bhutan has 1, China 44; Taiwan has 23, South Korean 28, and informal competitions arise as a result of recognition as enumeration. But what kinds of subjects is FERCAP geared towards producing? How do people navigate 'interrelations among [its] written plans, official pronouncements, off the record comments and observed social practice' (Kipnis 2008: 285)? One might imagine that alongside this structured audit-like recognition of committees, individual exam-based qualifications would also be available, contributing to an ongoing growth in credentialing and accreditation (Brown and Bills 2011). Indeed, credentialing of individuals is a large and lucrative industry for ethical review in the USA through the CIP, the Certified IRB Professional program. Developed by the Boston-based Public Responsibility in Medicine and Research (PRIM&R) in 1999, this credentialing of individuals to sit on ethics committees (known in the USA as Institutional Review Boards, or IRBs) was something FERCAP attempted to emulate in 2008 with their 'Certification for Ethics in Research Proficiency', or CERP. Cheaper, available in local languages, and not based solely on US documents, policies and legislation, it was intended to be a way to support and mark out the new ethics professionals. It was not at all successful: as one interviewee [62] recounted for a preliminary meeting in Taipei, Taiwan, 'nobody wanted to take it ... there were more speakers than audience!' This low uptake was repeated across the different sites where FERCAP works. I suggest it reveals a different relationship between the bundle of techniques of governance known as audit, and the idea of the professional. There are 'IRB professionals' in certain parts of the world, most prominently the USA, for whom reviewing proposals and running review is their job. For most of FERCAP's members across Asia, however, these roles are voluntary, on top of existing duties as practising clinicians, lawyers and researchers. This makes the invocation of 'the professions' both more interesting and more complicated.

While FERCAP's survey work is a network of nascent ethics professionals supporting one another in building committees and writing standard operation procedures, it is also a network of biomedical researchers, since many ethics committee members are practising clinicians themselves. Thus the kind of recommendations for how committee members should be and behave was not aimed at carving out a separate profession. There was something far more interesting going on.

With their understanding of how committees 'work' across the region, FERCAP's project with ethics committees began to specify, implicitly, the kinds of skills and attitudes deemed part of building 'capacity' in ethical review. At a pre-conference training I attended in Chiang Mai, Thailand in 2009, held in a side room of the Imperial Mae Ping Hotel, about 60 people from across the region had convened. They were there to discuss the qualities and responsibilities of the two parties most directly implicated in the management of ethical review committees: Secretaries and Chairpersons. The format focused on the presentation of personal experiences, and drew out qualities of 'integrity and moral rectitude' in the committee members beyond their formal 'role' on the committee. During this session, for example, a Chairperson was described as someone who 'cannot tell people to be ethical if he or she is not ethical'; a Chairperson 'cannot be having an affair. If you are unfaithful to your wife, how can you be faithful to the review process?'

This commensurability between personal and professional ethics is not the professionalisation of 'best practice, training standards and public responsibilities' described by medical anthropologist Kleinman (2010) in contemporary China. Nor is it a 'loop through which professionals demonstrate (to other professionals) their adherence to standards' (Strathern 2000: 292). FERCAP's professional is also not immediately recognisable as the 'self managing individual' who 'renders themselves auditable' (Shore and Wright 2000: 57). It is perhaps not even best described as 'professionalism' in the classic Weberian sense of separating the institutional role from the self. Rather than developing a fully-fledged persona as ethics professionals, FERCAP members are encouraged to understand ethics through a personal transformation. In this they resemble perhaps more closely the 'romantic' rather than the 'utilitarian' ethic of Pels's argument (2000). They were supported in taking up a 'duty'-based ethics that is compatible, in the words of FERCAP's coordinator, with '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).

I also observed counter narratives to regulation through ethical review in stories that narrated committee members' own attitudinal shifts. One member told me that her involvement with ethical review began when she volunteered. 'It was in me already', she said, 'being involved in IRBs just made it come out stronger.' Similarly, during a Good Clinical Practice session in Bangkok, I had been discussing with a Thai [63] committee member, Cathy, the difficulties

her committee had experienced in implementing ‘standardisation’. Cathy pointed out something she thought I hadn’t quite grasped, as I struggled to reconcile the priorities presented in the training. ‘No rule can write it all’, she said simply. ‘Regulators cannot do what integrity and the culture of a faculty can do.’ She hoped people would first recognise that rules exist, and then attend courses to learn more about doing research well, but ethics would only be effective, she thought, when people ‘become ethical not just in their rules but in their life and mind’, in a dialogical engagement beyond individualism (Laidlaw 2013). Such an attitude fits poorly with calculation, even if it resonates clearly with self-management and responsabilisation. Since those who run ethical review committees are themselves biomedical researchers, FERCAP hopes they will in turn convey these transformed attitudes to their colleagues and fellow researchers at their institutions.

The mismatch between regulation and ‘integrity’ that Cathy pointed to highlights a tension that surfaced at the organisation’s annual conferences in 2010 and 2011 (Douglas-Jones 2012b). Medical and institutional frustrations with proceduralised ethics have, in the USA, given rise to a renaissance of the idea of the professional, despite ongoing reference in trainings to the failures of professional ethics and the back-drop of research scandals from which ‘external’ ethical review draws its legitimacy (Taylor 2007). In 2004, medical researchers in Canada drew on William Sullivan’s research 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 Cruess et al. 2002). This statement emerged from decades of experimentation with ethical review and associated accreditation in North America, where complaints are raised 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). At the FERCAP annual conferences, the absence of ‘evidence’ for the effectiveness of ethical review actually brings something else to the fore:

[W]e simply have to say, ‘All right, we’re really talking about integrity, integrity is what we’re falling back on in hope that that’s what is actually going to protect human subjects’ [...] Not a committee, not regulations. (Koski 2011: np)

The intersection of interest in ‘integrity’ between members of FERCAP and American medical researchers is, I suggest, not coincidental, but care must be taken in reading the significance and implications of the overlap.

## **Conclusion**

Building on Pels’ arguments for the status of ethics in anthropology, I suggest that what FERCAP struggles to hold steady is the relationship between a romantic ethic, in which people act on principles, and a utilitarian ethic, now

bundled into review processes, procedures and second-order audits that come to operate as rankings. Within this latter utilitarian framework, which FERCAP advances and supports, something that resembles Pels' romantic ethic seems to re-emerge in the face of dissatisfaction with [64] ethics-as-audit. North American advocacy for a return to governance through the professions and professionalism is reaching FERCAP's conferences (Douglas-Jones 2012b), yet these conferences themselves exist because of review, a practice that emerges from the assumption that locating ethics in the professions was not enough (Wilson 2011). When FERCAP members articulate their interest in personal and professional integrity, when they take their involvement with ethics as a way of living and reject the figure of the credentialised IRB professional, they nonetheless still do so within the framework of a desire for recognition, and of regional competition for clinical trials. The ethical professional selves they invoke may reference familiar ideals of legibility or self-management, but also other disciplined and cultivated characteristics such as duty, filiality or faithfulness (see also Kipnis 2011). This is not therefore a story of inevitability, or of a 'global' form (such as ethical review) assimilating 'local' environments of research practice and governance (Collier and Ong 2005: 11).

Mechanisms of research ethics are a historically specific response to the kinds of public scandals that left the idea of professional integrity empty and inadequate as a moderator of medical research. Ethics committees themselves developed out of crises in the contract between biomedicine and the state (Hedgecoe 2009; Wilson 2011 for the UK; Stark 2012 for the USA), emerging at a time when mechanisms of accountability looked like audit processes. This article demonstrates how the legacies of such forms of governance, which have been worked into the operation of the clinical trials industry, are evident in the expansion of clinical trial infrastructure into Asia. With biomedical research come ethics committees, and with ethics committees come FERCAP's second-order reviews. As an anticipatory mode of governance, such review makes its assessments prior to anything taking place (Strathern 2000: 295; Amit 1996). One might also say that the establishment of ethics committees in some of FERCAP's participating countries is itself anticipatory. Many committees that participate in FERCAP's Recognition Program are intensely proud of what they see as their initiative, having neither been forced into being by public scandals or government pressure, nor otherwise obligated to seek FERCAP's recognition or AAHRPP's accreditation. This voluntarism itself has effects: the measure and recognition of FERCAP does not function as a national indicator, and is not in the hands of any government, even if it functions as an indicator that committee members themselves use to compare nations. The (often hard won) cut glass trophies that sit in ethics committee offices across Asia, denoting Survey recognition, represent prestige within a growing economy of accreditation for ethical review. I have therefore sought to make visible this tussle over what counts as ethics, a topic of increasing concern to anthropologically inclined minds (Lambek 2010; Laidlaw 2013). In

this paper, the question plays out through the simultaneous desire of my interviewees for utilitarian accreditation and romantic professionals with integrity. FERCAP's work challenges what it means to do a 'good' ethical review, and how this current form of doing ethics in biomedical research is itself to be recognised as ethical.

1 Research ethics committee or just ethics committee (EC) is the shorthand used most frequently in FERCAP's presentations; IRB is used more by American commentators and countries that orient their ethics review procedures towards the American model. In this text, I refer to ethics committees.

2 ESRC Grant Number RES-062-23-0215.

3 This argument nods to Stark's acute observation that ethics committees, or in her US context, IRBs, 'are consequential because they affect how researchers go about creating knowledge – and, as a result, the kinds of things that are knowable' (2011: 234).

## References

Amit, V. 1996. 'The insidiousness of bureaucratic banalities: some implications for anthropological fieldwork', Paper presented to IV EASA Workshop 1996.

Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) 2012. 'Two more earn AAHRPP Accreditation: Major Clinical Research Center in India and CRO in U.S.', AAHRPP Web Document Library (<http://www.aahrpp.org/apply/web-document-library/major-clinical-research-center-in-india-and-cro-in-u-s->) Accessed 14 October 2014.

Brown, D. and D. Bills 2011. 'An overture for the sociology of credentialing: empirical, theoretical and moral considerations', *Research in Social Stratification and Mobility* 29: 133–8.

Campbell, C. 1987. *The romantic ethic and the spirit of modern consumerism*. Oxford: Blackwell.

Collier, S. J. and A. Ong 2005. Global assemblages, anthropological problems, in A. Ong and S. J. Collier (eds.), *Global assemblages: technology, politics, and ethics as anthropological problems*, 3–21. Malden, MA: Blackwell.

Cruess, S. R., S. Johnston and R. L. Cruess 2002. 'Professionalism for medicine: opportunities and obligations', *The Medical Journal of Australia* 177: 208–11. Douglas, M. 1992. *Risk and blame: essays in cultural theory*. London: Routledge.

Douglas-Jones, R. 2012a. *Locating ethics. Capacity building, ethics review and research governance across Asia*. PhD thesis, Durham University, UK.

Douglas-Jones, R. 2012b. 'A single broken thread: integrity, trust and accountability in Asian

ethics review committees', *Durham Anthropology Journal* 18: 13–27.

Eckstein, S. 2004. 'Efforts to build capacity in research ethics: an overview', *Science and Development Network Policy Briefs, Middle East and North Africa* (<http://www.scidev.net/en/middle-east-and-north-africa/policy-briefs/efforts-to-build-capacity-in-research-ethics-an-ov.html>) Accessed 1 September 2014.

EMA (European Medicines Agency) 2012. Reflection Paper on Ethical and GCP aspects of clinical trials of medicinal products for human use conducted outside of the EU/EEA and submitted in marketing authorisation applications to the EU Regulatory Authorities. EMA/121340/2011.

Espeland, W. N. and M. Sauder 2009. "'Rankings and diversity": tight coupling and organizational change', *American Sociological Review* 74(1): 63–82.

Exworthy, M. and S. Halford (eds.) 1999. *Professionals and the new managerialism in the public sector*. Buckingham: Open University Press.

Foucault, M. 1977. *Discipline and punish*. London: Penguin.

Hamadian, L. and A. K. Johansen 2010. 'Reviewing the ethical reviewers: the SIDCER/FERCAP experience', in *FERCAP @10*. FERCAP: Bangkok.

Hedgecoe, A. 2009. "'A form of practical machinery": the origins of research ethics committees in the UK, 1967–1972', *Medical History* 53: 331–50.

Holden, K. and D. Demeritt 2008. 'Democratising science? The politics of promoting biomedicine in Singapore's developmental state', *Environment and Planning D: Society and Space* 26: 68–86.

International Conference on Harmonisation 2010. *ICH 20th Anniversary Value Benefits of ICH to Drug Regulatory Authorities – Advancing Harmonization for Better Health*. Geneva: ICH Secretariat ([http://www.ich.org/fileadmin/Public\\_Web\\_Site/News\\_room/C\\_Publications/ICH\\_20\\_anniversary\\_Value\\_Benefits\\_of\\_ICH\\_for\\_Regulators.pdf](http://www.ich.org/fileadmin/Public_Web_Site/News_room/C_Publications/ICH_20_anniversary_Value_Benefits_of_ICH_for_Regulators.pdf)) Accessed 10 September 2014.

Irwin, A. 2008. STS perspectives on scientific governance, in E. J. Hackett, O. Amsterdamska, M. Lynch and J. Wajcman (eds.), *Handbook of science and technology studies*, 3rd edn, 583–609. Cambridge, MA: MIT Press.

Jacob, M. A. and A. Riles 2007. 'The new bureaucracies of virtue: Introduction', *PoLAR: Political and Legal Anthropology Review* 30: 181–91.

Jensen, C. B. and B. R. Winthereik 2013. *Monitoring movements in development aid: recursive partnerships and infrastructures*. Boston, MA: MIT Press.

Karbwang-Laothavorn, J. 2011. *SIDCER @ 10*, in C. E. Torres and A. M. Navarro (eds.),

*FERCAP@10: In commemoration of a decade of capacity building in ethical health research in the Asia-Pacific Region*, 11–16. Pathumthani: Forum for Ethics Review Committees in the Asian and Western Pacific Region.

Katz, J. 1972a. 'Who is to keep guard over the guardians themselves?', *Fertility and Sterility* 23: 604–9.

Katz, J. 1972b. *Experiments with human beings*. New York: Russell Sage Foundation. Keck, M. E. and K. Sikkink 1998. *Activists beyond borders: advocacy networks in international politics*. Ithaca, NY: Cornell University Press.

Kipnis, A. B. 2008. 'Audit cultures: neoliberal governmentality, socialist legacy, or technologies of governing?', *American Ethnologist* 35: 275–89.

Kleinman, A. 2010. 'Remaking the moral person in China: implications for health', *The Lancet* 375(9720): 1074–5.

Koski, G. 2011. Human research subject protection: a time of reflection, renewal and reform? No – It's time to redesign! Oral webinar presentation for Institutional Review Board Services, Saskatchewan (<http://xtalks.com/xto451irbervices.ashx>) Accessed 10 September 2014.

Laidlaw, J. 2013. *The subject of virtue: an anthropology of ethics and freedom*. Cambridge: Cambridge University Press.

Lambek, M. 2010. *Ordinary ethics: anthropology, language and action*. New York: Fordham University Press.

Merry, S. E. 2011. 'Measuring the world: indicators, human rights and global governance: with a comment by John M Conley', *Current Anthropology* 52: S83–S95.

Pels, P. 1999. 'Professions of duplicity: a prehistory of ethical codes in anthropology', *Current Anthropology* 40: 101–36.

Pels, P. 2000. 'The trickster's dilemma: ethics and the technologies of the anthropological self', in M. Strathern (ed.), *Audit cultures: anthropological studies in accountability, ethics and the academy*, 135–72. London: Routledge.

Petryna, A. 2009. *When experiments travel: clinical trials and the global search for human subjects*. Princeton, NJ: Princeton University Press.

Power, M. 1994. *The audit explosion*. London: Demos.

Power, M. 1997. *The audit society: rituals of verification*. Oxford: Oxford University Press.

Reverby, S. M. 2009. *Examining Tuskegee: the infamous syphilis study and its legacy*. Chapel Hill: University of North Carolina Press.

Rosemann, A. 2012. *Multi-polar technoscience: clinical science collaborations in a changing world system*. PhD thesis, University of Sussex.

Sariola, S. and B. Simpson 2012. 'Blinding authority: randomized clinical trials and the production of global scientific knowledge in contemporary Sri Lanka', *Science, Technology & Human Values* 37: 555–75.

Shore, C. and S. Wright 2000. Coercive accountability: the rise of audit culture in higher education, in M. Strathern (ed.), *Audit cultures: anthropological studies in accountability, ethics and the academy*, 57–90. London: Routledge.

Stark, L. 2011. Meetings by the minute(s): how documents create decisions for Institutional Review Boards, in C. Camic, N. Gross and M. Lamont (eds.), *Social knowledge in the making*, 233–56. Chicago, IL: Chicago University Press.

Stark, L. 2012. *Behind closed doors: IRBs and the making of ethical research*. Chicago, IL: University of Chicago Press.

Strategic Initiative in Developing Capacity in Ethical Review (SIDCER) 2005. SIDCER Recognition Program. UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR).

Strathern, M. 1992. *After nature: English kinship in the late twentieth century*. Cambridge: Cambridge University Press.

Strathern, M. 2000. *Audit cultures: anthropological studies in accountability, ethics and the academy*. London: Routledge.

Sullivan, W. 1995. *Work and integrity: the crisis and promise of professionalism in North America*. New York: Harper Collins.

Taylor, H. A. 2007. 'Moving beyond compliance: measuring ethical quality to enhance the oversight of human subjects research', *IRB: Ethics and Human Research* 29: 9–14.

Torres, C. E. 2011. Reflections on the FERCAP experience: moving forward with partnerships and networks, in C. E. Torres and A. M. Navarro (eds.), *FERCAP@10: In commemoration of a decade of capacity building in ethical health research in the Asia-Pacific Region*, 43–53. Pathumthani: Forum for Ethics Review Committees in the Asian and Western Pacific Region.

Wilson, D. 2011. 'What can history do for bioethics?', *Bioethics* (Online First): 1–9. doi: 10.1111/j.1467- 8519.2011.01933.x Accessed 20 September 2014.

Wilson, D. 2012. 'Who guards the guardians? Ian Kennedy, bioethics and the "ideology of accountability" in British medicine', *Social History of Medicine* 25: 193–211.