Making Room for Ethics: Spaces, Surveys and Standards in the Asia-Pacific Region

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Abstract

This article examines the work that goes in to 'making room' for ethics, literally and figuratively. It follows the activities of a capacity building Asia-Pacific NGO in training and recognising ethics review committees, using multi-sited field materials collected over 12 months between 2009 and 2010. Two queries drive this article: first, how are spaces made for ethical review –politically, infrastructurally, materially – as committee members campaign for attention to ethics and access to offices in which to conduct their meetings? Second, how are the limits of 'local circumstance' negotiated during a review of the committee's work: what does the implementation of standards in the area of ethics look like? I then discuss what standards of ethics practice mean for more fraught questions of the universal in bioethics. Rather than regarding ethics systems as backgrounds to global health projects, this article's STS and ethnographic approach reveals ethical review as a site of contested standardisation.

Keywords: Asia-Pacific, ethics review, standards

Introduction

This article examines the geographic expansion of ethical review as what the editors of this special issue call a 'silent backdrop' to, or 'mundane infrastructure' of, global health projects. Based on multi-sited fieldwork with an ethics capacity building NGO in five South and East Asian countries during 2009 and 2010, the two lines of argument examine efforts to "make space"—literally and figuratively—for ethical review. While the histories and evolution of ethical review have become objects of vigorous attention across the medical and social sciences (Dingwall, 2007; Taylor, 2007; Stark, 2011b; Schrag, 2011; Hedgecoe, 2016), the practicalities of expanding ethics review practices into novel sites and spaces are less frequently examined. Rather than exploring the ethics *of* global health projects (Crump et al., 2010), or the particular challenges that global health projects present for research ethics (Stephen and Daibes, 2010), I use an STS focus here to consider ethical review as a material practice with increasing international presence, taking place in meeting rooms and offices around the world. I am particularly interested in the making of physical spaces dedicated to ethical deliberation, which I consider along two axes.

The first explores material arrangements as signs of hard won political, infrastructural and institutional support for the work of ethics review committees. Rather than focusing on or evaluating

the specific content of committee decisions—a well elaborated theme—I am interested here in the framing of ethical review as a set of practices that mark out space both in terms of claiming "real estate" for ethics in university and hospital premises, and in the political landscape of how questions of ethics come to matter in the administration of research. The second argument explores the rooms of ethics as sites where international standards for conducting review are negotiated and met (SIDCER, 2005; WHO, 2000, 2002). Global health research is often oriented towards standardised solutions (Engel, Van Hoyweghen and Krumeich, 2014: 5), and in the last twenty years the language of standards has also emerged in ethical review. Committee rooms and offices are sites where committees are assessed according to such standards, but are they best viewed as "artifacts? Practices? A mode of governance?" (Dunn, 2009: 118). What are the challenges to the 'universal' forms designed to universally accommodate 'local' content? (Riles, 2002) And what happens when we bring together the universalising ambitions of standards into the domain of ethics, where the idea of universals has a fraught history? Through these two foci, I seek in this article to illuminate tensions around what counts as the limits of local circumstance, as a growing number of ethics committees across the Asian region materialise 'global' standards in their rooms for ethics.

My analysis builds on 12 months of ethnographic research and interviews with an organization aiming to foreground standards in ethical review: the Forum of Ethics Review Committees of Asia and the Pacific (FERCAP hereafter). The Forum was first proposed in 1999, during a World Health Organisation Special Program for Research and Training in Tropical Diseases (TDR hereafter) seminar on the *Ethical Review of Clinical Research in Asian and Western Pacific Countries* held in Chiang Mai, Thailand (Chokevivat, 2011: 6). At the seminar, the group noted the comparative absence of ethical review committees (and lack of standard operating procedures for those that did exist) at a time when multi-sited clinical trials were rapidly growing in the region. The international group of researchers and committee members agreed to start building regional capacity in ethical review themselves. They could have chosen to pursue an occasional workshop, the capacity building initiatives that were beginning to arise with global health discourses and funding (Eckstein, 2004; Brada, 2011), or trainings that came with (often unequal) international research projects (Crane, 2014; Hyder et al., 2004). Instead, the researchers at this early meeting defined their intentions as "grass roots", and committed to improving standards within the region, providing "home grown protection" from potentially unethical or predatory research for the region's human subjects. Rather than, as one researcher I spoke to put it, "allowing the power to remain with ethics review committees in Geneva", FERCAP's work became based in Asia-Pacific researchers who knew the region and its institutions. It was a time of international movement in the field. In November 1999, the draft of the WHO/TDR *Operational Guidelines for Ethics Committees Reviewing Biomedical Research*–a document jointly proposed by the WHO and the Council for International Organization of Medical Sciences (CIOMS) and foundational for FERCAP's subsequent work–was discussed and finalized in Bethseda, Maryland (USA). By early 2000, instead of attempting to work through governmental bureaucracies to try and establish national systems of quality assurance for ethics committees, the participants of the Chiang Mai meeting were busy establishing FERCAP (Chokevivat, 2011: 7). The founders, many of whom were also involved in the establishment of the TDR based Strategic Initiative in Developing Capacity in Ethical Review (SIDCER hereafter), recognised that "no one model will work for all ethics committee around the world" (Karbwang-Laothavorn, 2011: 12). "Nevertheless" wrote Karbwang, a founding member and leader of the SIDCER initiative, "ethics committees have an obligation to raise their standards and improve their practices by working more closely with one another and those who carry out the research" (Karbwang-Laothavorn, 2011: 12; see also Petryna, 2005).

The location of ethics was a pressing question for those setting up and running ethics committees across Asia in the early 2000s. They asked one another "Where can and where should we have our discussions?" Tied up with this material question was another, more figurative sense of

making space: "how can we make others see ethics as important?" As Brada writes in discussion of medical pedagogy's role in the making and doing 'global health[1]' in Botswana, "[s]paces and subjects emerge in relation to one another" (Brada, 2011: 306; see also Margolis et al., 2002). Finding and making these spaces and subjects was work that FERCAP set itself, and its snowballing growth, which coincided with my field study, meant that making space for ethics—both in terms of importance and physical location—was a matter of high concern. Following ethics approval from ethics committees in the UK at the universities of Cambridge and Durham, as well as committees in two fieldwork sites, Colombo and Manila, I traveled in my necessarily multi-sited fieldwork. I moved between the hospitals, universities and offices where FERCAP conducted its work, observing training sessions. Initially a welcome outsider, studying the ambitious, growing network, I met with committee chairpersons, secretaries, laypersons and lawyers at conferences and recognition activities. Following and observing activities taking place in Thailand, the Philippines, Taiwan, mainland China and Sri Lanka, I interviewed more than 30 members of ethics review committees in the network. As time went by, I trained alongside these committee members, attending workshops in basic and advanced ethical review, Standard Operating Procedures, Conflict of Interest, and in techniques for assessing, or surveying, an ethics committee. These experiences became the foundation for my analysis, which began during fieldwork and continued throughout 2011-12. Analysis work took a variety of forms, including typing up extensive field-notes, transcribing recorded interviews, supplementing understandings of organisations with document searches, drawing diagrams of connections between people, ideas, and projects, and conducting further historical desk work as I explored the 'unlooked-for' (Strathern, 1998: 3), working to produce descriptions not only of the work of the NGO but their conceptualization of their work within a field.

An additional form of observation gave the study a further reflexive dimension. Towards the end of this period of fieldwork in 2010, I became part of FERCAP's extensive transnational network of ethics committee volunteers who form Survey teams, leading groups looking at the rooms of ethics committees, the documentation of committee decisions, and follow-up practices with investigators. I thus briefly participated in implementing the SIDCER 'Recognition Program' (known colloquially as the Survey), an initiative that began in 2005 to assess and recognise ethics committees for adherence to a set of standards oriented at 'quality and effectiveness' (SIDCER, 2005). At the time of my fieldwork in 2009-2010, FERCAP had recognised the work of around 50 committees. Today that figure stands at over 200—across 10 different countries across the Asia-Pacific Region (FERCAP 2015)[2]. Coordinated by just two full time employees, members of the network—ethics committee members and administrative staff—volunteer to "Survey" or review one another's committees according to the SIDCER standards. These standards were derived in 2005 from three key documents: the *WHO Operational Guidelines for Ethics Committees that Review Biomedical Research* (2000), the WHO complementary guideline *Surveying and Evaluating Ethical Review Practices* (2002) and the ICH-GCP *Harmonised Tripartite Guideline for GCP E6/R1* (1996) (SIDCER, 2005). Surveyors conduct this assessment in English, which is the network's operating language, and in order to not raise barriers to entry to the recognition program, FERCAP do not require full translation of all documentation at their assessments, just the presence of a local translator. Research thus took place predominantly in English, though occasionally committee members would assist with real-time translation of live ethics committee meetings, or of documents in Thai or Mandarin.

Having a designated room is a precondition for participating in the sought-after SIDCER Recognition Program and in this way; it also comes to serve as a symbol of the commitments of an institution or its faculty to the process of ethical review. Committees know, and can leverage the knowledge, that if their ethics committee loses its room, it will also lose its recognition status. Furthermore, during the Survey, committee offices themselves become a site of contestation, within which local and international participants negotiate compliance with SIDCER standards over

what counts as a 'recognition ready' committee—and by implication a 'good' ethical review (Douglas-Jones, 2015). As we see in the second two sections of this article, the Survey prompts committees to make their "inner workings" (Dunn, 2009: 121) visible[3], and—through the possibility of withholding recognition—the Survey has the power to compel changes in future behaviour. In this way, we can read the rooms of ethics as participants in, and tools through which, the standardisation of space becomes part of disciplining practices (Foucault, 1983).

Framing global health and ethical review through STS

The pairing of 'global' with 'health' to form 'global health' begets a world of practitioners and funds, economies and spaces, even if there is no common definition of global health research, nor agreement on how such research should be governed or evaluated (Stephen and Daibes, 2010; Buse, Hein and Drager, 2009; McInnes et al., 2012; Neufeld et al., 2014). Where ethical review meets global health, it is easy to read global health projects as providing simply a new dimension to existing ethical debates – with some scholars taking the meta-ethical position that global health projects are ethical in themselves, and others seeing global health research as posing new and challenging questions of inequality for research ethics (Crump et al., 2010; Stapleton et al., 2014; Lairumbi et al., 2011; Yassi et al., 2013). Within research ethics, the emphasis in recent years has been placed on the need for 'local' review of 'global research' (EMA, 2012) as a way of dealing with ethical questions around the origin of data. Like the phrase global health, such a statement about 'local' review of 'global' research appears self-explanatory.

From the viewpoint of STS and anthropologies of science however, the terminology of global health invites critical distance. As Donna Haraway (1995: xix) argued more than twenty years ago, "[t]he global and the universal are not pre-existing empirical qualities; they are deeply fraught, dangerous, and inescapable inventions". Yet the 'global' often "summons no further exemplification: it is a macrocosm, a complete image, and requires no theoretical underpinning" (Strathern, 1995: 169). In the same way, the local of 'local ethical 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, 1995: 167). When we turn, with these observations in mind, towards the push for global health, we begin to recognise the way in which the label 'global health' choreographs particular kinds of imaginaries. As Brada (2011: 286) argues, perhaps what makes "global health" "global" is more to do with configurations of space and time, and the claims to expertise and moral stances these configurations make possible. Discussing pedagogical training in Botswana, she points out that the category of the 'international' structures medical practice (Brada, 2011: 296). Yet the stakes are high in taking on this language using the critical vocabularies of STS and anthropology: ""Global health" is shaping practices, subjectivities, and power relations […] changing the way policymakers as well as medical practitioners […] see the world (Erikson, 2008)". Following Brada's lead, I contend that we must pay close attention to the language used in describing these worlds and the way it brings them into being. In my case, the attention extends to the organising effects of calling parts of ethics committees practices 'local' and others 'global' (Latour and Callon, 1981; Kearney, 1995; Strathern, 1995; Jensen, 2007), the role of 'international' guidelines in forming standards, and the effects these standards have for the spaces in which the idea of ethical review is cultivated.

A critical STS approach also positions a capacity-building NGO such as FERCAP within the broader frames of changes in the financing and policy environments of global health (Erikson, 2008) and statecraft (Jasanoff, 2004). FERCAP's capacity building orientation derives from its founding aims and its links with WHO-TDR, an organisation that has for a long time been committed to building capacity for health research (Langsan and Dennis, 2004; TDR, 2008). As former TDR director Robert Ridley wrote in a 2010 WHO newsletter, "the role of TDR and other international research-funding agencies is less and less to bring external research to developing countries but rather to

foster and help build on the research capacity already within them and to assist countries in addressing their own needs and priorities" (Ridley, 2010: 2). As well as contextualising the role of NGOs in carrying standards, in work elsewhere, I have sought to highlight the self-evident nature of capacity building, an increasingly globalised practice in itself (Douglas-Jones and Shaffer, 2017), enmeshed with the worldwide growth of NGOs (Mertz and Timmer, 2010; Delise et al., 2005; Higgins and Tamm, Hallström 2007). NGO capacity building is seen as a central feature of global health projects (Stephen and Daibes, 2010) along with social justice, community engagement and partnership, "often underpinned by a principle of solidarity" (Benatar and Singer, 2010). FERCAP is paradigmatic of this NGO-based capacity building, yet arises from within the region. It states a clear ambition "to develop […] capacity building for ethical review practice across the continents to address the fundamental ethical gaps and challenges encountered in global health research" (SIDCER, 2005). The organisation itself, as much as its activities, can be seen as part of the wider global health apparatus, assembling a 'mundane infrastructure' for research ethics in tandem with research projects (Garrett, 2007; Brown et al., 2006).

In the opening two sections of this article, I examine more closely this backgrounded work: the less noticed infrastructural (Star, 1999; Carse, 2012; Furlong, 2010). In contrast with the sensitivity and controversy of ethics universalization debates in the 1990s, the standardisation of ethics *processes* is more easily regarded as 'mundane' and routine, desirable for reasons of committee reliability or from the point of view of work process management. Increasingly required by institutions, funding bodies and publishers alike, ethical review now constitutes a passage point through which projects falling under the 'global health' umbrella must pass, both at home and abroad (EMA, 2012; Dingwall, 2007). Yet from the analytical standpoint of STS, we know that such 'infrastructural backgrounds' only appear as background from certain, usually privileged, positions (Star, 1990). Making them visible requires attention, or 'infrastructural inversion' (Bowker, 1994). Within the domain of biomedical infrastructure for example, Street's (2012) analysis of the affective and colonial materiality of Madang Hospital, Papua New Guinea demonstrates one such making-visible, as she brings forward the tie between buildings and nation-building: spaces as "purveyors…of power relationships" (Street, 2012: 54; see also Street, 2014). Other recent work in the burgeoning infrastructure studies genre, crossing between anthropology and STS, has extended the term from the built and resource environment (Harvey and Knox, 2012; Anand, 2011) towards the 'poetic', the environmental and the digital (Larkin, 2013; Harvey, Jensen and Morita 2017). The accounts and presentations of ethics committee members in this article demonstrate how convincing institutions and colleagues to 'make space' for ethics is the work of everyday politics, rooms and offices becoming what Larkin (2013: 336) terms a "metapragmatic object, [...] deployed in particular circulatory regimes to establish sets of effects". As I show, holding ethical review practices to international standards is part of a 'circulatory regime' within the Asia-Pacific region, generative of such effects as aspiration and collegiality, as well as compliance and recognition. Establishing ethical review as a form of research infrastructure is neither mundane nor background for those striving to create or improve practices and processes. As such, an STS reading of the building of ethics capacity foregrounds the ways in which global health projects are often premised on the presence of existing material and social arrangements of ethical review, or local capacities for the practicalities of internationally auditable research itself (Simpson and Sariola, 2012: 563-564).

In the second two sections of the article, I explore the relationships between standards and standardisation within research ethics. Standardisation—its consequences and politics—has been an important area of STS-informed research for more than two decades, particularly in the domain of health technologies and 'solutions' (Hogle, 1995; Bowker and Star, 2000; Dunn, 2005; Engel and Zeiss, 2013; Timmermans and Berg, 2003; Timmermans and Epstein, 2010; Busch, 2011). Scholars have been critical of solutions "framed in universalized terms- applicable anywhere, anytime" (Engel, van Hoyweghen and Krumeich, 2014: 5). STS researchers have also been adept at

producing critiques of implicit universalization in technology design, or in expectations of adoption. Indeed, as Timmermans and Berg (1997: 273, 297-298) wrote twenty years ago, "[u]niversality through standardisation is at the heart of medical and scientific practice" yet, as they showed, such universality is always local.

The overlap in discursive arenas—universalisation and standardisation—is important, and forms the basis of my discussion about the place of standards in ethical review. Moving on from debates of ethical imperialism (Angell, 1988), wranglings about the universality of ethics principles (Macklin, 1999; Benatar, 1998) and discussions of the local in ethical decision-making (Benatar and Singer, 2000; Nuffield, 2002) the researchers involved in developing both SIDCER and FERCAP have prioritised training committees with the capacity to conduct ethical reviews themselves, and raising their standards of review. As I show here and in my broader work (Douglas-Jones, 2013, 2015), in doing so they found themselves standardising not ethics principles (a universalising move), but ethics processes and practices. To make claims about universal ethics principles would go against the commitment of FERCAP's founders to 'institutional and national health research governance that should take into consideration the local culture and traditions' (Torres, 2011: 44). Encapsulated in this commitment is the tension Kleinman pointed to in 1999: the need for both "a method for accounting for local moral experience *and* a means of applying ethical deliberation" (Kleinman, 1999: 73, emphasis added). While many across the Asia-Pacific region feel that biomedical research projects are important for ensuring global health outcomes, and agree that the protection of human subjects is best sought through adopting ethical review, there is concern that "differences in the standards and practices of ethical review in different institutions have contributed to inhibiting progress in health research" (Karbwang-Laothavorn, 2011: 11). Committees took enthusiastically to the pursuit of recognition and standards, and FERCAP gained rapid success with its training schemes and the SIDCER Recognition Program. Yet at the same time as committees sought recognition for their practices, the *content* of their decisions—into which debates about the universality of ethics principles would fall—was considered out of the scope of the Recognition Program (Christakis, 1992). Indeed, as Star and Lampland (2009: 8) point out, "[t]o standardize an action process or thing means, at some level, to screen out unlimited diversity". Thus, the challenge of setting standards for an ethics committee and its review while, at the same time, showing "consideration of local culture and traditions" (Torres, 2011: 44) translated into attempts to maintain a separation between principles (not always universal) and practices (standardisable). So where and how are process and content separated? Does a focus on the standards of committee practice successfully evade the ethical content of committee decisions?

To develop these questions and two lines of argument, I have divided the remainder of the article into four empirically driven sections. The first two, *Making space for ethics* and *Making rooms,* develop the earlier infrastructure point, using ethnographic material, interviews and observations from Colombo and Shanghai to show struggles in making both figurative and literal space for ethics in sites of research. In the third and fourth sections, *Standards for rooms* and *Global health, global ethics?* I use a vignette from a FERCAP Recognition Survey in Manila, Philippines to illustrate how the offices of a committee become a site of standardising negotiation. I use this account as a means to return to the discussion I have begun here about of the relationship between standards, universals and standardisation initiatives in the domain of research ethics.

Making space for ethics

Since their early meetings in 1999 and 2000, FERCAP has grown into a network of over 300 members, hosting an annual regional conference which brings together committee members from over ten countries engaged in its work. It has been highly successful in recruiting and galvanising committed volunteers to convene workshops, host seminars, encourage capacity building and undertake Survey assessments. Yet at the annual FERCAP conferences I attended in 2009 and 2010 - in Chiang Mai, Thailand and Shanghai, China respectively - participants still grumbled that their institutions paid little attention to ethical review. Coming together in increasing numbers every

year, conference delegates themselves evidenced the growing interest of ethics review for researchers across the region, but lunchtime conversations and formal presentations revealed anxieties about being taken seriously by managers, bosses and institutions. At the 2010 conference in Shanghai, Da —a Chinese volunteer working with committees through FERCAP—told me that it had taken a long time to draw the attention of both researchers and institutions. "In the early times", he commented, "most [committee members] said 'We don't have support from the institution, nobody notice[s] we are there.' Year after year, at conferences and trainings, he heard how investigators dismissed newly formed committees or showed 'no respect': "Could you just stamp this letter?"", they were asked. It is telling that being asked for a stamp, rather than for deliberation, was insulting to committees who were invested in protecting participants in clinical trials. Committees who engaged with FERCAP's activities were not those at whom the international academic community had levelled critiques of "rubber stamping" (Kass et al., 2007; Jafarey et al., 2012). Across the literature, scholars pay little attention to the often substantial efforts required by committee members and researchers in their own institutions to change the conversation about research ethics—indeed, even to begin it. In what follows, I bring these efforts to the fore.

During the 2010 conference in Shanghai I came to appreciate how challenging it was for some researchers to begin conversations about research ethics within their institution. While numerous informal conversations had implied as much, this insight took its most memorable form as a conference presentation by Hyeon, a delegate from a fast growing medical centre in Daegu, South Korea. Her animated slide show outlined the great efforts to which she and her colleague had gone to persuade members of their institution that research ethics mattered. In South Korea, the name IRB, or Institutional Review Board is used for committees that convene to deliberate the ethics of biomedical research proposals, as it is in the United States.[4] She illustrated their achievements through an animation (figure 1) she had set to the theme music from *My Neighbor Totoro,* a popular Japanese anime. As the presentation played, Hyeon narrated the images on the screen:

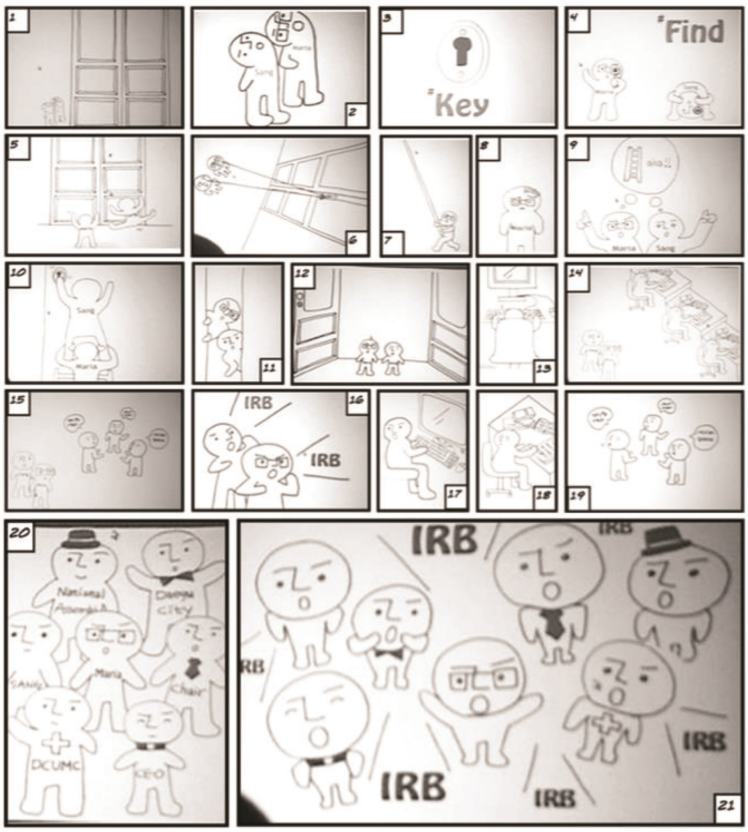

Figure 1. A series of stills compiled by the author from a recording of Hyeon's animation.

> 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] It's difficult. We have to find the key: the key is the main solution to 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 the key[hole]? We try over and over again [7, 8]. We are cooperating together, but we get a ladder and the key to 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 are 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 impossible to make them understand why human projection 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.

Hyeon and Sang's story conveyed—with indirect criticism—how, after a long time, they had successfully brought the need for ethical review to the attention of new actors. These new actors—with their clerical neckbands, bow ties, glasses and top hats—gave authority to the endeavour. Told as an animated adventure, the negotiations and case making were made explicit: a struggle for legitimacy in the face of turned backs and rows of computer-locked workers. Making figurative space for ethics, leading to (for example) funds for trainings, conferences, invited speakers or committee formation, was not always an easy thing to champion, as I now go on to show.

Making room(s)

This challenge—of clearing conceptual and institutional space for ethics—was an oft-repeated lament; not all committees succeeded in the manner depicted in the Korean animation. For many, regardless of their institution or country, a turning point was persuading their organization to dedicate permanent physical space to ethics committee activities. A dedicated room became vital when it was made a formal precondition for participating in the SIDCER Survey, or recognition program in 2005 under the standard on the structure and composition of the committee: "1.4 EC/IRB Office: The EC/IRB should have an office space with necessary equipment and staff for good functioning" (SIDCER, 2005).

Equipment, staff and office space were not always easy to come by. In April 2010 I took part in the Survey of an ethics review committee in Manila, in the Philippines. The committee had invited FERCAP to their city and to their offices, in order to undergo the four-day review of their committee and its activities. The tone at the opening event was welcoming, supportive, in line with the organisation's emphasis on building capacity. As usual, the opening remarks by the lead trainer emphasised the ethos of the FERCAP review process:

> FERCAP exists for the improvement of IRBs, this is not a pass or fail [situation]. 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 still encourage. There is still room for improvement. For example, if you do not have a separate room, you cannot be… [trails off]

Cannot be what? The trainer left his sentence hanging, communicating into the silence a sense of unspecified lack. 'Recognised' is the straightforward answer; the requirement for a dedicated physical room marks another mode of (literally) "making space for ethics". To illustrate some of the intricacies of this "cannot be…", I turn to an incident from the beginning of my fieldwork.

The first committee I encountered in the field did not have a room of its own. Soon after I arrived in Sri Lanka, in early 2009, I had become a regular

visitor to the Medical Faculty in the University of Colombo, setting up practicalities and making new connections. Late one afternoon, 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. The monsoon rains were pouring down the windows, drowning out the low discussion of the meeting happening at a table opposite. As we crossed the common room, we looked at the group's table, piled high with paperwork, around which a dozen or so people were sitting. "Looks like an ethics committee," I joked to her quietly. 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. She had started research in the country over a year beforehand, and recognised people 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 the manner it was now reviewing another proposal, just a few meters away. Not only had my plans for research been discussed by this group of people, but I would also, I hoped, soon be interviewing them about their committee. Deeply conscious of the research ethics of my (even unintentional) presence, my colleague and I quietly left.

That the committee was meeting in a common room—a room that, 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 the idea of 'capacity building' that was part of my project's title, that the first hints of a link between the 'where' of ethics—its physical institutionalisation—and its social robustness began to emerge. I was interviewing Dr Suraj, a chair in the Psychiatry department at the same medical faculty. He had been involved in establishing the field of 'ethics' within the University: as we talked about 'research ethics capacity', he emphasised the need for local capacity, and a willingness to build up institutions through training others. He drew his examples from histories of his own department, Psychiatry, as well as reaching for Sri Lanka's histories as a colony, to explain how he had gone about introducing research ethics to the medical faculty where he worked:

> Psychiatry was not a department in the 1970s [when I graduated]. 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, [here in Sri Lanka] 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.

These descriptions of growth in the discipline of Psychiatry acted as a parallel for our discussion on how research ethics, as a set of knowledges, was being introduced:

> Something happens in the UK or the US, someone comes [here], gives a lecture, 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' this knowledge base both in people and in the institutions that he had supported, particularly through the institutionalisation of Psychiatry within the physical buildings of the university:

> Dr. 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, [but] 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?

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

Dr. Suraj's thorough critique of the brief 'capacity building' initiatives led by international visitors in both colonial and more recent times had produced both his commitment to developing ethics expertise as 'local knowledge' and an intention to physically ground that expertise in material artifacts- the books, computers, resources and a room. Leaving the offices where Dr. Suraj and I had talked, I stopped by the room he had mentioned. In the one of the high ceilinged colonial buildings of Colombo's Medical School, the tall wooden door bore a small printed sheet reading "Ethics Committee Room". 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 this room, I was told that progress on turning it into the ethics committee offices 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, with dedication it would happen, commented those locally engaged in pursuing recognition, indeed, it had to happen in order for the committee there in Colombo to invite FERCAP for the Survey.

By the time I returned to Sri Lanka, just over six months later, this dusty room had been transformed. The space, on the ground floor of the Colombo Faculty of Medicine's Pathology building, had been cleared, freshly painted and a new floor laid. It was filled with new furniture and equipment, chosen with the FERCAP Survey in mind. On arrival, I went to find Thilini, one of the ethics committee secretaries I knew, only to be redirected to her new committee office. The overhead fans were whirring, and brand new, locked filing cabinets were lined up behind her desk. A second secretary had been recruited to join her, and we talked about their experiences of the (then) recent FERCAP survey. I moved to take a look at the adjoining committee meeting room through wooden slatted swing doors, to which Thilini had just delivered some snacks from the canteen. As I did so, she blocked me with her body and a smile. "Confidential meeting," she said.

In this transformation of both room and staff, steps had been taken to institutionalise ethical review in a way that materially laid new hopes for home grown ethical compliance over dusty floors and colonial pasts (Stoler, 2008; Street, 2012). For Suraj, the room was a change in the status and permanence of ethics in the institution. Unlike the visitors who had previously come and gone, carrying knowledge of ethics literature and practices, the room and its filing cabinets, reference books and computer systems were evidence both of 'institutional buy in' and of a new 'persistence to behaviour patterns' (Gieryn, 2002: 36). As both material marker and site for the conduct of ethical review, this new office had paved the way for the committee to invite a FERCAP Survey team, since they now fulfilled the self-assessment criteria. In this way, spaces themselves are made into a means of doing ethics—and this is both the focus of a FERCAP Survey team visit, and of the following section.

Standards for rooms

So far I have focused on the rooms and offices of ethical review that result from the efforts of staff at universities and hospitals across the Asian region. Small and large acts had to come together for committee members to persuade their hospitals or institutions of their importance: keys for an office to be dedicated to ethics committee work, renovation works, timeslots in meeting rooms for deliberation, budgets for administrative secretaries, funds for new filing cabinets that could be locked. Far from a background concern for global health projects, the material infrastructure that supports ethical review activities is in itself the culmination of years of political negotiation with colleagues and administrations. But once the room has been acquired, and committees thereby granted access to the recognition process, FERCAP can be invited to conduct the Survey for the SIDCER recognition program. I now move my discussion to the way in which committee rooms become the sites of negotiation over how the five standards set by SIDCER would be seen to be met.

When FERCAP surveys a committee, it takes the five standards of its parent body, SIDCER, as its reference point. These standards, as I noted above, were based on international documents, and agreed by delegates from FERCAP, the WHO and American IRBs in 2005. The SIDCER standards inform what the surveyor groups look at, and structure the final presentation made by Surveyors on the committee's performance. There is therefore a great deal that must be looked at and assessed during the four days of review. To overview briefly what surveyors are looking at, I list the five core SIDCER standards here. The first is concerned with the structure and composition of the ethics committee: are the staff and their skills "appropriate to the amount and nature of research reviewed"? The second examines adherence to policies: are there operational procedures in place "for optimal and systematic conduct of ethical review"? The third explores the completeness of a committees' review: are documents reviewed in a timely manner, according to an established procedure? The fourth concerns communication: what is the nature of the correspondence between investigators and the committee? The final standard addresses documentation and archiving: is it systematic and are documents stored for an appropriate length of time? It is these standards, suggest members of FERCAP, that make ethics 'operationalizable' (Torres, 2011: 49), a term indicating the "putting into action" of abstract principles. Operationalization is one of the terms that helps FERCAP and its surveyors avoid evaluating the content of ethical decisions committees make, and focus instead on improving *how* those decisions are made, under what conditions. However, as I will argue, this operationalization, which takes the form of holding committees to the SIDCER standards, is a negotiation (Douglas-Jones, 2015; Engel and Zeiss, 2013; Hogle, 1995). By the time I joined the 2010 Survey in Manila, I was aware of the significance of 'a room' and its role in legitimating and securing the activities of an ethics review committee. Curious about how the Surveyors—the majority from countries other than the Philippies—would read and assess the

Figure 2. The sign outside the committee's office in Manila.

space, I joined each of the three Survey groups on their trips into the Manila Ethics Committee office. Each group received instructions from the Survey Leader, Cristina, 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 was guided by a checklist of questions and visual examination. We shuffled through our Survey packs to find the appropriate sheets of paper. The Ethics Committee office in this Manila Institute was along a main corridor, and clearly labelled with a sign that hung proudly out into the hall perpendicular to the wall. 'Institutional Review Board,' it read.

As we entered, we checked off the first box: "Is the location appropriate"? Appropriateness here was confirmed by its accessibility and obviousness—the proud sign was an indicator that the location was indeed acceptable.

While the room had its own lockable door, it was partitioned off from a larger room with a five foot wall. In this partition there was another door. Both this second door and the partition caused comment from the Surveyors:

> 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!

With the invocation of the space as 'confidential', the partition wall became discussion point at the end of day summary meeting. Assembled in the conference room the committee used for their own meetings, the Surveyors argued back and forth about its relative significance. 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 [the secretary] has to go out and round. We say [in the recommendations] "limit the access to IRB office from other staff"". This direction was aimed at Daniella, a trainee member of the Survey team, who was diligently noting the recommendations in a template powerpoint slide. She in turn paused on the bullet beneath, which to follow the layout, needed to be filled in with a reason for the recommendation. Daniella looked up expectantly, and conversation continued. "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 Daniella, he instructed her to write: "Partition should be higher." At this point the secretary of the committee being Surveyed called out, as she was in the room delivering documents to the usually closed end-of-day meeting. Having overheard the recommendation, she said in dismay: "But we only have one air-con! If you make [the partition] higher, cool air won't get through!" The possibility of someone "reaching" over the wall then turned into "jumping", as a way of maintaining the recommendation : "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 disagreement hanging about who could access what, and how, the meeting closed for the evening.

On the second night of the Survey, the partition came up again. Group B had spoken to the secretaries likely to be affected, who felt it would be difficult for the committee to comply with a raised partition or a wall because one boss was responsible for all the workers in the conjoined space: "The boss needs to see if they're sleeping!" Raising the partition might be possible, they said, on the condition that the new, higher section was transparent. The following exchange then took place:

> A: I say close the [partition] door permanently. They can go out the real door. The entrance to the ERC should be separate.
>
> B: How can they close [the partition door] permanently?
>
> A: 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 partition wall—I will ask for a picture that they made it higher.

On the final day of the Survey, the lead surveyor presented the results. He had included the recommendation that the partition should be raised by *ten inches*. During questions, the ethics committee members asked the surveyors to explain the 'rationale' behind this *ten inch* change to their partition wall, to which the lead surveyor replied:

> It is better to have [an] isolated, secluded space where no other irrelevant people can have access. Now you have two doors so the other side's office has access [to you]. It depends on the composition of people in the other room. The partition is to restrict access, so there should only be one door [into the committee room]. 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.

These criteria—"isolated", "secluded", "irrelevant people" bespeak the lead surveyor's concerns about the confidentiality of the *room*. People feature in the estimation (and enforcement) of 'confidentiality' through their ability to overhear, but the interventions proposed are upon the partition wall itself. The committee worried about how to comply, with the chairperson stating:

> 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 over. 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.

Photographs of this (physical) leak—a fallen-in ceiling, a rainbow of buckets collecting drips on a crackled floor— had been shown in the Powerpoint slides, as recognition by the Surveyors that the committee was doing what it could, under challenging circumstances. Nonetheless, the surveyors replied that it was not space in square meters, but the security of that space which concerned them:

> 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.

Why is the height of this wall so problematic for the Survey team, and what does it have to do with making the physical space meet SIDCER standards? As the team tried to encourage modification of the ethics office, the local committee members raised practical problems: they didn't have space in the hospital to give over to ethics alone; there wasn't an AC in the "ethics part" of the room; how would their boss see if they were sleeping? What the surveyors' recommendation reveals is a concern with both the physical and symbolic segregation of ethics. This is not merely securing space in the sense of claiming it (for the storage of ethics related documentation, technologies and processes): what is at stake here is the achievement of *closing* space. Throughout the account, the desire for a *confidential* space drives anxieties about the room divider, and ultimately the recommendation for a ten inch addition. Here, the space is being evaluated for the kinds of behaviour it can ensure or invoke. Modifying the height of the wall may not close the space entirely – there is no full wall after all– but the ten inches are a negotiated compromise that leans both towards making a space confidential through inaccessibility, and recognising the 'local circumstances' of immoveable A/C units, and watchful bosses. We might also observe the way that the Surveyors' desire for the committee office to be a 'confidential space' replicates ideals held by committee members for the trials they review. Since the Belmont Report in the USA (National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, 1979) identified confidentiality as falling under the principle of "respect for persons", ethics

committees have been charged with examining how the confidentiality of information collected during research will be maintained (CIOMS, 2002: 75; WMA, 2013). Here, in the Survey, confidentiality also became a quality that the committee and its space needed to exhibit, even though the ethics committee would hold its meetings to deliberate in a meeting room elsewhere. So while a separated office room was preferable, where space simply wasn't available, Surveyors accepted the limitations on committees and—as in the account above—negotiated over how this standard would be implemented[5]. The limits of local circumstance–of leaks, A/C and labour transparency–met compromise in a ten-inch partition raise.

This account of disagreement during the Survey in Manila illustrates the ongoing negotiation of expectations. The SIDCER assessment has formalised a set of standards to which committees are assessed during the recognition program, "aim[ing] at making actions comparable over time and space" (Timmermans and Berg, 1997: 273). These requirements for comparability and reproducibility of rooms of ethical review become inscribed both in Surveyor's checklists and in the weight of its assessors arguments during the course of the four day visit, with standards showing themselves as "simultaneously overdetermined and incomplete" (Timmermans and Epstein, 2010: 81). As STS scholars have long since observed, negotiation is part of what a standard is when it is put into practice (Star, 1995; Lampland and Star, 2009; Engel and Ziess, 2013). I now move to reflect on the distinction between form and content when considering ethics standards during the SIDCER recognition program, by returning to the question I posed about the relationship in ethical review between standards (here, targeted at practices) and universals (a project of principles).

Global health, global ethics?

Efforts to produce standards for ethical review are active parts of current research discussions across Europe (SATORI, 2015), and arise within growing certification and accreditation programs targeted at committees and ethics professionals worldwide (Rodrigues, 2015; Ghooi, 2015). In their review article, Timmermans and Epstein drew on the literary theorist Raymond Williams to note that while standards connote authority and achievement, standardisation – while functional for industry, "connotes a dull sameness" (Timmermans and Epstein, 2010: 70-71). It therefore matters that it is the sphere of ethics where standards are being brought into use, since 'sameness' has long been a contentious matter in ethics discussions. Throughout the 1990s, philosophers debated the possibility of global ethical principles, spawning branches of bioethics concerned with international, then global health (Macklin, 1999; Benatar, 1998). Troubling anthropology with a what seemed to be a "dangerous break with local moral worlds" (Kleinman, 1999), the universalization debates about ethics in biomedicine have tended to foster controversy, bounded by disciplinary language, professions and institutions (Marshall, 1992). In contrast, standardisation is a more familiar language for biomedical researchers and clinicians themselves, part of the professional worlds of people who sit on the ethics review committees, and often regarded as a neutral inherent good through which diverse settings and systems can become 'interoperable'. Indeed, one committee member in my study memorably lamented to me that there was no International Organization for Standardization (ISO) standard for ethics, as there was for his haematology laboratory. These distinct genealogies for universalization in ethics and standardisation in biomedicine mean that they carry opposing moral valences, which play into distinctions between standards for ethical review and 'universals' of ethics drawn by members of FERCAP. By "not doing bioethics" members of FERCAP stated they were deliberately not delving into the "philosophical debates" about universal or "Asian bioethics" which many felt were unresolvable, and a way of avoiding concrete action to improve standards (Douglas-Jones, 2013: 35). Instead, by working with the SIDCER Recognition Program, they were staying focused on operationalised standards, set according to ethical principles laid down by others, elsewhere, in international guidelines.

So what might it mean that, instead of "doing bioethics", standardisation language is being applied to ethical review? Introducing this

paper, I asked whether a focus on the standards of committee *practice* successfully evades the issue of universality in committee *decisions*. By providing insight into the priorities of committees participating in this standards oriented NGO recognition program, I have shown that a separation between the form of ethical review and the ethical content of decisions cannot be entirely clean. Concerns about how ethical *research* is done inform concerns about how ethical *review* is done. If I have emphasised in this article how the *form* of doing ethics is at stake here, in the rooms of ethics and the material standards to which they will be held, then attending to where bifurcation between standards and universals takes place becomes a methodological question. In 2005, the year FERCAP launched their implementation of the SIDCER Recognition Program, Petryna (2005: 187) wrote that the debate between ethical imperialism and ethical relativism "as it stands, is unresolved". I would suggest that the recognition program, tied in to global accreditation regimes and increasing attention to standards of review, is one formulation of resolution. When tied to the *content* of ethics, standards were highly contentious. By revising the genre and language, by focusing instead on standards of *practice*, the Recognition Program deftly shifts the terrain. It enters the realm of sought after accreditation, the sense of participating in a "global" economy of achievement, reputation and forward momentum. In principle, it leaves committees free to exercise discretion for the ethical content of their review while they work hard at achieving the standards for the *form* by which decisions are taken.

However, to return to Brada's (2011) attention to the creation of subject positions that linguistically and affectively generate spaces of global health, I would argue that the power of the 'international' standards brought into play in this account re-locates what will count as the limits of local circumstance. As she puts it, labelling something international "marks a rational, standardizing, and benevolent, if also distant, zone of transition between the unmarked setting, resources, and guidelines" (Brada, 2011: 296). FERCAP implementation of the SIDCER recognition program, by requiring a room for ethical review, recognises that the form taken by review practices has consequences for the content of it. In the requested ten inches of material change, we see an effort to standardise local ethical review, meet international standards and produce global comparability, while sidestepping the fraught questions of universal principles for ethics. It is precisely this innocuous terrain shift that gives me analytical pause: does standardisation of form also sidestep a discussion of the ethics committee as one of many potential ways of pursuing ethical deliberation, its suitability in a given setting, or other ways in which communities might wish to deliberate and decide upon which research projects they invite, and which they refuse?

Conclusion

Making space—literally and figuratively—for ethical review is bound up in the shifting priorities and pressures of biomedical research. An STS focus on an NGO operating to build capacity in ethical review in the Asia-Pacific region allows us to examine more closely the relationships and processes that go into making the 'mundane' infrastructures of global health projects. Opening this article, I made the case that it was important to look at how ethical processes and ethics committees are gaining and making spaces as part of regional collaborations to address "challenges encountered in global health research" (SIDCER, 2005). Inspired by Brada's (2011: 286) argument that what makes "global health" "global" is to do with configurations of space and time, the first part of my argument has ethnographically examined the spaces made and claimed for ethical review. FERCAP members challenge existing social and infrastructural arrangements, and use their rooms as a symbolic achievement that qualifies the committee for assessment by FERCAP under the SIDCER Recognition Program. This analysis adds to STS further illustrations of the social and infrastructural implications of the expansion of biomedical sciences around the world, and to use Street's phrase, encourages us to attend to spaces as "purveyors…of power relationships" (Street, 2012: 54). It also opens up the scope for critical debate on the purchase, relevance and of STS analytics in sites beyond Euro-America, through which the 'global' of global health is made and

understood, and ethics is given meaning in practices. Just as the tension between a desire to implement standards while "tak[ing] into consideration the local culture and traditions" (Torres, 2011: 44) plays out in these spatial negotiations of local circumstance, this same ethnographic material prompts reflexivity about STS's own conceptual apparatus, and where *its* limits might be (Law and Lin, 2017). In this article I have also asked what, in the tension between a desire to standardise processes while continuing to respect differences in approaches to ethics, would count as the limits of local circumstance in ethical review? I have shown that the rooms of ethics become sites where, during recognition, the degree of compliance with or deviation from the SIDCER standards must be negotiated, and that this may entail a ten-inch addition to a room partition, or the way the gaze of a boss intersects with the flow of an air conditioner, as 'confidentiality' escapes its bounds of lock and key to be instantiated in room partitions too high to climb over. While STS has long carefully attended to standardisation, here at the intersection of ethics, audit and biomedicine, we find both practical manifestations of standards for the conduct of ethical review, and also their capacity to redirect focus to form, potentially evacuating from ethics the indeterminacy that stymied its crystallization into a universal settlement. Ethical review thus emerges as a site of ongoing attention and negotiation, standard making and aspiration, a site through which STS scholars are challenged to examine the question of universals, not only in scientific research but also in its governance. In the observations of this article, STS researchers might therefore find the familiar sense of making spaces for the otherwise, in conversations, material infrastructures, and even standards themselves.

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NOTES

1 Like Brada (2011: 287), I do not wish to take the conceptual terrain of 'global health'as somehow 'outside' my analysis. Indeed, the construction of global health as a category, and as a form of classification, is what (in my reading) brings the editors to read STS and global health alongside one another in this special issue.

2 To draw up the standards by which the Recognition Program would be implemented, American and international volunteers trained in ethical review as well as Quality Assurance, auditing, and Regulatory Affairs met in Olympia, Washington in 2005.

3 And yet - arguably - not more open to public view, as the gaze to which a committee is opened is that of the Surveyors alone. The public dimension of ethical review is contested internationally, particularly in the USA. Stark (2011a) notes that some committees are considering holding meetings with public access, while others continue to closely guard their anonymised committee minutes. The principles of the debate fueling this desire for committee transparency were not present in the countries I conducted fieldwork in during 2009-10.

4 I acknowledge and agree with Hedgecoe's point (2012) that elisions between the different terms used to describe evaluative ethics bodies can lead to weakened analysis. However, in this case, I am reproducing the division that held in the field, which was largely between committees in countries where there was a history of American presence (e.g. the Philippines) or contemporary collaboration (South Korea) and countries that looked more towards Europe, Geneva and the WHO for guidance. The former called themselves IRBs, the latter Ethics Committees or ECs.

5 In a different instance I observed in a Chinese pre-survey, a Survey coordinator announced to a hospital considering seeking recognition that they did need "something that *separates*, a door you can enter." The reasoning was that, according to the Surveyors, 'science' and 'ethics' could not be found together: a 'marked division' in space was necessary.