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In recent decades, research in the biomedical sciences has been increasingly located in settings outside of the global north (Petryna 2009). Much of this research arises out of transnational collaborations made up of sponsors in richer countries (pharmaceutical industries, aid agencies, charitable trusts) and researchers and research subjects in poorer ones. A recent workshop on the ethics of international collaboration, held in Sri Lanka, confirmed that in addition to the usual concerns about the protection of human subjects in biomedical research, these engagements raise a host of new ones.

Robert Simpson

### RESEARCH MAY WELL BE CARRIED OUT in populations rendered vulnerable because of the low level of education, the lack of political or economic resources. The protections that medical and research ethics offer in these contexts tend to be modelled on a western tradition in which individual, informed consent is paramount and, furthermore, is couched in legal and technical requirements. When science travels, so does its ethics. Yet, when cast against a wider backdrop of global health, economic inequalities and cultural diversity, such models often prove limited in effect and inadequate in their scope (Benatar 2002, Bhutta 2002). Attempts to address both of these concerns have generated a wide range of ‘capacity-building’ initiatives in bioethics in developing and transitional countries. Organisations such as the Global Forum for Bioethics in Research, the Forum for Ethical Review Committees in the Asia Pacific Region and the World Health Organisation have sought to improve oversight of research projects, refine regulation and guidance, address cultural variation, educate publics about research and strengthen ethical review committee structures according to internationally acknowledged benchmarks (see for example, Emanuel et al 2004; Lawry et al 2007). They are also an essential pre-requisite when it comes to attracting and hosting future collaborations, whether these are commercially sponsored, charitable trusts) and researchers and researchers and research subjects in poorer ones.

Bioethical capacity building

As part of a larger study of the ethics of international collaborations in biomedical research, our own work is focused on the ways in which a heightened preoccupation with the ethics of research is playing out in contemporary Sri Lanka. Our aim is to map and to understand both the spread of international collaborative research as well as the intellectual, bureaucratic and political activity that is stimulated in the name of bioethics capacity building. However, in studying collaboration, we ourselves are also drawn into collaborations of various kinds. In this article we report on an event which was held to facilitate dialogue between ourselves and regional stakeholders in our research. The event focused on the ethics of international collaboration and provided an important context for reflection on the current state of play and an opportunity to air some of the issues that are faced when it comes to national and regional engagement with global science and experimentation.

At one level, the workshop provided an opportunity for participants to show the considerable progress made in responding to the ethical challenges posed by the growing traffic in international collaboration and particularly where these concern the outsourcing of phase II and III clinical trials. Significantly, many of the discussions gravitated towards ethical review committees; their constitution, operation, remit and effectiveness. In conformity with the Declaration of Helsinki, such advisory committees are seen as crucial when it comes to anticipating the costs and benefits to both subjects and the public of research to the region, be this researcher-led research or sponsored research (funded by pharmaceutical companies). Where internal audiences are looking on, a different set of anxieties present themselves. Discussion of contentious issues suggested that the committees find themselves walking a fine line. On the one hand, they may be perceived as too restrictive, that is, unreasonably protective of human subjects and their interests and therefore impeding scientific and economic development. On the other hand, the expectation that ethics committees will operate as a kind of bulwark against moral and scientific imperialism might bring charges of excessive permissiveness, that is, they are not nearly protective enough of subjects and therefore are complicit in abuse, injustice or exploitation in research. Members can easily find themselves vilified from all sides. In this regard, an important question that emerged from the discussions is what happens when things go wrong following positive approval by an ethics committee and how to manage the professional and, possibly, legal ruptures that this brings.

Ethical vanishing points?

The way to prevent ‘unethical’ process and outcome in the ethical review of research that was professed by many of the participants was further resort to ‘capacity-building’. Yet, it was hard to see that this strategy would not result in a remorseless game of catch-up into which all are drawn in the quest for some kind of ethical vanishing point. Indeed, as the discussions progressed, the load that ethical review was taking on seemed to get heavier and heavier, and, as a consequence, focus fell more on operating procedures and the way that these might be tightened up to ensure effective regulation of research. The momentum appeared to be moving firmly in the direction of greater procedural elaboration, more formulaic approaches to evaluation and a consequent consolidation of power in the process of ethical review, as national ethics cultures expand to fill the ambiguous moral spaces that international research increasingly opens up.

On the evidence of the collaborative workshop, the list of competencies and responsibilities that ethics committees active in the field of international collaboration might be expected to have is a long one. They must cover relevance of the trial design, its scientific validity, the balance of risks and benefits, the suitability of the investigators and the appropriate-ness of informed consent procedures. Furthermore, the list is expanding as ethics committees strive to discharge their duties responsibly and embrace new dimensions of what it is to be ‘ethical’. Here committees must, perform, move into complex cultural territories for which there is little in the way of guidance. Examples alluded to included information sheets, the technicities of translating informed consent documenta- tion, insurance and compensation arrangements and the complex entanglement of voluntariness with the desire to be ‘incompetent’. Such anxieties are greatly exacerbated when operating in settings where inequalities of risk are high, for example, because of poor education and literacy on the part of subjects and where negligence, corruption and exploitation are made possible by paternalistic and poorly regulated medical systems.

When external authorities are concerned, there is anxiety that such charges might be indexed to estimations of national development and scientific credibility. Apart from feeding unwelcome stereotypes, appearing inadequate when it comes to the conduct of ethical review could have real consequences when it comes to the ability to attract research to the region, be this researcher-led research (funded by universities, charities, NGOs or governments) or sponsored-led research (funded by pharmaceutical companies). Where internal audiences are looking on, a different set of anxieties present themselves. Discussion of contentious issues suggested that the committees find themselves walking a fine line. On the one hand, they may be perceived as too restrictive, that is, unreasonably protective of human subjects and their interests and therefore impeding scientific and economic development. On the other hand, the expectation that ethics committees will operate as a kind of bulwark against moral and scientific imperialism might bring charges of excessive permissiveness, that is, they are not nearly protective enough of subjects and therefore are complicit in abuse, injustice or exploitation in research. Members can easily find themselves vilified from all sides. In this regard, an important question that emerged from the discussions is what happens when things go wrong following positive approval by an ethics committee and how to manage the professional and, possibly, legal ruptures that this brings.

Ethical permissiveness?.....