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 contexts. 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

Biomedical research in South Asia

Research MAY WELL BE CARRIED OUT in populations rendered vulnerable because of the low levels of ethical, legal and political autonomy, which are a legacy of a history of global control. 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; Lavery et al 2007). They are also an essential pre-requisite when it comes to attracting and hosting future collaborations, whether these are commercially sponsored, refining 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; Lavery et al 2007). They are also an essential pre-requisite when it comes to attracting and hosting future collaborations, whether these are commercially sponsored, refining 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; Lavery et al 2007).

The way to prevent ‘unethical’ process and outcome in research is not through superficial adherence to social norms and resources. However, it was clear from the discussions on the part of subjects and where negligence, corruption and exploitation are made possible by paternalistic and poorly regulated medical systems.

Where external audiences are concerned, there is anxiety that such charges might be indexed to estimations of national development and scientific credibility. Apart from feeding unwelcome national 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 sponsor-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, unreasonable protectors 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 standing point?

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 investigators and the appropriateness of informed consent procedures. Furthermore, the list is expanding as ethics committees strive to discharge their duties responsibly and embrace new dimensions of what 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 documentation, insurance and compensation arrangements and the complex entanglement of values that the researcher runs through questions of payment to research participants. The waters were further muddied as participants grappled with ‘social benefit’ or assessing the extent that certain kinds of research might result in ‘ethical disarray’. There was little evidence that the participants were in anyway shying away from the challenges that engaging with this agenda carries despite the considerable investment needed in terms of knowledge and resources. However, it was clear from the discussion on the particular occasion that those who are most centrally involved in conducting ethics review are carrying enormous and, on occasion, impossible responsibilities and expectations. The task of making appear stable and authoritative that which is constantly evolving is a significant one. For these reasons, the emergence and consolidation of ethical review in developing world contexts is an increasingly important site in which to study the transactions in knowledge, resources and finance that currently constitute international collaboration in biomedical research.

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Notes

1. The International Science and Bioethics Collaboration is funded by the UK’s Economic and Social Research Council [RES 062.23.0215] and is a collaboration between the Universities of Durham, Cambridge and Sussex.

2. The workshop took place in March 2009 in Colombo and was co-organised by three researchers from Durham University alongside staff of the University of Colombo (specifically the Human Genetics Unit and the Faculty’s Ethics Review Committee). The theme for the day was the ethics of international collaboration. Case studies of international collaboration were presented by Prof. Harun Ar Rashid (Director, Bangladesh Medical Research Council), Dr. Vasantha Muthuswamy (MD, DGO. Former Deputy Director General, Indian Council for Medical Research), Dr. Shin Krishna Giri (Secretary, Nepal Health Research Council), Prof. Hemantha Senanayake (Chair of the Ethics Review Committee, Faculty of Medicine, University of Colombo, Sri Lanka), Dr. Cristina Torres (Co-ordinator, Forum for Ethical Review Committees in the Asia Pacific Region) gave an overview of the challenges faced in developing ethical review capacity in the region. The audience consisted mostly of local academics, doctors and clinical researchers.

References


Durham, Cambridge and Sussex.
