Published in final edited form as:

Lancet. 2002 September 28; 360(9338): 1025–1026. doi:10.1016/S0140-6736(02)11115-9.

How many committees does it take to make a project ethical?

Robert H Gilman, Catherine Anderton, Margaret Kosek, Hector H Garcia, and Carlton A Evans

Johns Hopkins Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD 21205, USA; Asociación Benéfica Prisma, Lima, Perú; Universidad Cayetano Heredia, Lima; and Wellcome Trust Centre for Clinical Tropical Medicine, Imperial College Hammersmith Hospital Campus, London, UK

Sir—Appropriate concern about the protection of research participants in low-income countries has led to changes in the ethics review process that have created a crisis for international medical research. The process of protocol approval may now be deemed an unethical barrier to international health research.

Research projects increasingly benefit from multiple international partners that are frequently required by funding bodies. Internal review boards (IRBs) or ethics committees oversee only their own faculty members and the modifications required by each must be resubmitted to the others. Modifications are frequently required at annual reviews that must again be reconsidered by all.

For example, a 4-year study involving a centre in a low-income country, two in the USA, and two in Europe, would require five initial applications, perhaps two revisions with subsequent resubmissions, and three annual reviews with perhaps two of these requiring modifications resubmitted to all. The result is 15 initial submissions and then, after approval, a further 25 applications in five formats.

This method of review does not facilitate a high ethical standard. Rather, it represents a distortion of ethical review from a cooperative process to ensure high ethical standards into an unwieldy administrative task, which delays and discourages medical research in the areas of greatest need.

We have several proposals that might resolve this crisis. The only effective manner for their enactment would be through the insistence of funding agencies.

First, ethics review of multicentre international studies should be structured so that only one IRB in each participating country reviews the protocol. This should include the IRB at the principal investigator's institution.

Second, the documentation required for protocol review should be standardised, including a uniform format to eliminate needless reformatting.

Finally, the informed consent process is best reviewed locally. Consent forms should be written in simple language to achieve maximum comprehension. However, distinctions between simple and complex terms do not correspond between languages and the local IRB has a better knowledge of the study site and population than does an IRB abroad. The local IRB should, therefore, have sole responsibility for the vocabulary of the consent documents,

whereas the primary international IRB limits its review of the consent forms to issues of content.

As researchers we share responsibility for the predictable consequences of our actions and inactions. Research addressing multidrug resistant tuberculosis, trypanosomiasis, malaria, and other diseases of poverty is needed. We are obliged to advance alternative solutions that ensure the protection of study participants without impeding research targeted at improving health in developing regions. We are not suggesting a process of ethical review that is any less stringent; only one that is less redundant and more appropriate to research in international settings.