

Ethics Committee in Asia

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What I want to do is share with you an experience that we have had in an organization for research ethics review in Asia that we call FERCAP. FERCAP stands for Forum for Ethics Review Committees in Asia and the Pacific. In addition, I am going to present to you an issue that we have had to deal with in collaborating with the pharmaceutical industry to achieve our objectives.

The Forum for Ethics Review Committees in Asia and the Pacific, as its name indicates, is a forum dedicated to the improvement of health research ethics review. Its membership comes from countries covered by the World Health Organization's Western Pacific Regional Office and South East Asian Regional Office.

The people who originally proposed the organization of a regional network in the region about three years ago thought that the initiative was necessary because many countries needed to improve their capacity to conduct a thorough review of health research proposals. There were countries that lacked the capacity altogether. Many institutions engaged in research activities without submitting their protocols to ethics review at all.

The organizers of FERCAP thought that the problems they wanted to address were best viewed from a regional perspective that allows a manageable degree of networking and discussion. As it is, the organizational set-up draws on resources from the region and focuses on issues that characterize regional experiences and needs. Nonetheless, help has come from outside the region. Even before FERCAP's birth, it was fortunate to be able to count on help coming from the World Health Organization-Tropical Disease Research (WHO-TDR), the European Forum for Good Clinical Practice (EFGCP), the University of Bergen and the government of Norway, the European Community's Regional Malaria Control Programme (EC-RMCP), as well as from the pharmaceutical industry. The nature of FERCAP's initiatives has also made inter-regional networking indispensable.

FERCAP was established to (1) support capacity-building for research ethics review in the region, (2) help gain access to resources for such initiatives, (3) provide a forum for the exchange of information and ideas regarding research ethics review and serve as a conduit for the dissemination, examination and discussion of guidelines, declarations and other documents intended to provide guidance for ethics review. Through its Internet listserv, FERCAP also serves as an electronic forum for consultations on topics pertaining to research ethics.

The members of FERCAP have initiated capacity building through training

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programs at the international, national and local levels. Perhaps the most prominent among these training programs is an International Course on Research Ethics that has been offered in collaboration with Thammasat University in Bangkok and Norway's University of Bergen for the past two years. On a smaller scale, similar programs have been conducted in the Philippines, India, Indonesia, Malaysia, Pakistan and a few other countries. An international course will be held in Manila on October 22 to 25.

A National Training Programme was held last month in the Lao People's Democratic Republic with the financial support of the European Community's Regional Malaria Control Programme. The activity had the additional objective of laying the groundwork for the organization of a National Ethics Committee. Around 50 participants took part in the programme held in Vientianne on August 28 to 30, 2001. There were representatives from all hospitals, provinces and concerned government agencies in the workshop that dealt with various aspects of research ethics. In preparation for the workshop, the organizers held meetings with key government offices in order to ensure that their needs were taken into account, and to generate support for the objectives. The training materials, including PowerPoint presentations, were translated into the local language. Case studies were selected on the basis of their significance for the region. The response to the workshop was very positive and Draft National Guidelines for Research Ethics Review have now been drawn up. The Lao National Institute of Public Health is now waiting for its national government to act on its proposal for the institution of a National Ethics Committee to review health research involving human subjects.

Following on the success of the exercise in the Lao People's Democratic Republic, similar training programmes will be held in Cambodia and Vietnam in the first quarter of 2002.

What I have not yet mentioned about FERCAP is that it accepts membership not only of research ethics committees but also of pharmaceutical company representatives. In one forum, I referred to the practice as making a pact (or making an agreement) with the devil.

Indeed, we may be making an agreement with the devil. The economic situation in many countries is such that there are hardly any better options. But the question I have been debating in my mind, and I present it to you now, is: Is it necessarily devilish to play with the devil?

Let me give you a further background with respect to my own country. I have been working with the National Ethics Committee that is responsible for the ethical conduct of health research since 1992. For a while, we had the resources to conduct training programmes throughout the country. We have had funding support for such activities sporadically in the last few years. More recently, we have been getting none at all. The National Ethics Committee still thinks that it will compromise its integrity and independence if it accepts assistance from the industry. In fact, it has refused to accept fees for conducting an ethics review of research proposals. In the meantime, many institutional committees have had to proceed without having their members go through training.

As it happened, pharmaceutical companies and other research agencies were

getting frustrated because of the very slow processing of their proposals and their inability to propose research in many institutions that did not have the capacity for review. Some members of ethics review committees got together with representatives of pharmaceutical companies and hesitantly agreed to see how their interests could be served. The situation was:

- the pharmaceutical companies wanted to ensure that training was conducted so they could submit proposals and have them acted on promptly;
- ethics review committees needed capacity-building so they could deal with proposals properly;
- FERCAP had the expertise to conduct training.

The situation indicated a convergence of interests, and the parties have since formed a working alliance. Is it an unholy alliance? To be sure, some of us who have been involved are bothered. Have we compromised our integrity?

From the beginning, we have been very transparent in our operations. We have made public our motivation for accepting help from industry. We tell the public that we have accepted such help and that they should tell us if they think there is something we are doing that compromises ethical standards in research. So far, we have been able to sleep soundly at night. I hope we can continue to do so even if we continue to play with the devil.