## **REPORT 1**

## Introduction

On 14-15 October 2000 the Second Meeting of the Global Forum on Bioethics in Research was held in Bangkok, Thailand. Representatives from national research sponsoring agencies, intergovernmental organizations, research organisations, NGOs interested in biomedical research, and industry representatives attended the meeting. The programme focused on 'responsibility to the community' and 'capacity-building'.

## Background

The Global Forum on Bioethics in Research originated from a meeting organised by the Fogarty International Center (FIC) of the National Institutes of Health (USA) on 21-22 June 1999.

At the end of the June 1999 meeting, the participants agreed to the establishment of a Global Bioethics Forum that would be an ongoing forum dedicated to the promotion of ethics in biomedical research around the world. The idea would be to develop a long-term mechanism that enjoyed multiple institutional support without being 'owned' by any one or several institutions. The Global Bioethics Forum would work on rotating responsibilities and would be established in a rotating geographic location. The Forum was based on the following considerations:

The background principles guiding biomedical research are largely the same and widely agreed on;

- The workshop had identified issues and problems for patients, subjects, and communities, as well as for researchers and institutions;
- The current level of adequacy of existing mechanisms for guaranteeing a high level of ethics in international biomedical research are suboptimal [referring to existing guidelines as well as current informed consent and ethical review mechanisms];
- Significant differences of various kinds in the approach to bioethics exist around the world .

The Global Bioethics Forum was subsequently renamed the Global Forum on Bioethics in Research and it held its first meeting on 7-10 November 1999 in Bethesda, Maryland. The meeting was attended by approximately 120 delegates from 34 countries. The programme focused on developing partnerships between research sponsors, investigators, and research participants and their communities. This meeting concluded that the Forum should be seen as 'an opportunity to exchange views in an environment that fosters mutual learning'.

This meeting was subsequently followed by a Planning Committee Meeting for the Second Global Forum on Bioethics in Research held at the FIC on 21 March 2000, preceded by a meeting on draft OPRR Procedures to Obtain Assurance for International Research on 20 March 2000 at the FIC. The Planning Committee Meeting discussed the issues to be addressed at the Bangkok meeting.

## The Content of the Meeting

The purpose of the meeting was to examine two issues in international research:

- 1. Responsibility to the Community,
- 2. Capacity-building.

The first day of the meeting focused on Responsibility to the Community. The meeting was opened by Natth Bh. of the Centre for Vaccine Development at Mahidol University, Thailand. He spoke of the need to link health research to national development and community benefit. The experience of Thailand in the development of HIV vaccine trials demonstrated the need to establish health research as a fundamental vehicle for contributing to the development of health resources at the national and community level. This presentation was followed by two presentations on the responsibility of researchers to communities, one from a developing country perspective and one from a developed country perspective. M. Makgoba of the Medical Research Council in South Africa stressed the importance for developing countries in maintaining and developing their own research agenda's to meet their own health needs.

Three case studies illustrating the responsibility of researchers to communities were presented. Vichai Ch. of the Thai Ministry of Public Health presented on the importance VaxGen phase III trial in Thailand. J. Karbwang and H. Engers of the WHO discussed the TDR mandate in capacity-building and provided two examples of how TDR had developed negotiations on drug prices between industry, WHO, and local communities. G. Solarsh of the Africa Centre for Population and Reproductive Health Research in South Africa presented a video presentation developed by M. Bennish of Tufts University on questions that arise when a research centre enters a developing community. These case studies were followed by group discussions focused on examining how communities might contribute to designing and enhancing research for health. The groups reached no conclusions. Finally, eight short presentations were made on community benefit agreements.

The second day of the meeting focused on Capacity-building. Z. Bhutta of Pakistan discussed his involvement with the Aga Khan University ethical review committee and emphasized the need to support ethical review in developing countries. This was followed by a session in which the project of the Forum for Ethical Review Committees in Asia and the Western Pacific (FERCAP) was presented. The history of FERCAP since the beginning of the TDR WHO activities in August 1999 was presented alongside the development of the Operational Guidelines for Ethics Committees That Review Biomedical Research. Members of FERCAP presented the various workshops and activities of FERCAP. The FERCAP initiative demonstrated that capacity-building is most effective as a grass roots initiative. L. De Castro, Vice-President of FERCAP (University of the Philippines), emphasised the connection between FERCAP and the other TDR regional initiatives for developing capacity in ethical review. This was followed by a presentation by D. Picou of the Caribbean Health Research Council in Trinidad and Tobago on a strong background to research ethics already prepared in the Caribbean and an initiative being started within the same framework as FERCAP. K. Hofman of the FIC then discussed the FIC awards for education programmes in international research ethics. Members of the audience also presented a wide range of other capacity-building initiatives.

The presentations were followed by a general discussion on capacity-building. The members of the audience stressed the diversity of capacity-building initiatives and the need for the variations in approaches.

S. Gallagher of CIOMS then presented on the plans for the ongoing revision of the CIOMS Guideline, and expressed the intention to deliver the revised version of the Guideline at a meeting prior to next year's meeting of the Global Forum. J. Idäpään-Heikkila of CIOMS gave a short presentation on the major changes to the newly revised Declaration of Helsinki.

At the close of the meeting, I. Evans of the MRC in the United Kingdom presented the plans for the next meeting (3rd meeting) of the Global Forum on Bioethics in Research to be held in The Gambia on 7-8 November 2001.