Brief Summary – Third GFBR meeting
21-23 February 2002
CAPETOWN , SOUTH AFRICA

- The theme of this forum was "Bioethics and public health research, including ethical guidelines related to post-trial access to drugs". During the conference, developing countries had significant input on key issues in international collaborative research, some of which are listed below:
- **1. Whether current ethical guidelines constrain or promote post-trial access to drugs, devices, or vaccines**
- Differences in interpretation and difficulties in translating research principles into realities must be both urgently and amicably resolved with respect to post-trial access to drugs, devices, or vaccines. Conducting research scientifically is already a challenge, it is even more difficult to conduct it both scientifically and ethically. A researcher must be well-prepared both in the scientific design of the research and in safeguarding the well-being of the community, by carefully setting stopping rules and properly arranging post-trial treatment. Sponsors of the study must pay attention to building the infrastructure of the community in which the study is conducted, and ensure there are adequate pilot studies.
- **2. The difficulties in creating ethical guidelines and establishing ethical review process in developing countries**
- Initially, there was discussion about the scramble for Africa , as the continent presented the biggest and most attractive laboratory for Western researchers. Participants highlighted the lack of regulation of the ethical review of research, and the unavoidable conflict of interest that existed in some African countries, and the difficulties those countries encountered in creating rigorous ethical review processes. Participants called for the establishment of strong regional and national regulatory frameworks.
- The issue of informed consent was one of the many concerns for participants. Participants raised the need to recognise the legitimacy of different levels of "permission" and highlighted that community permission can never replace genuine individual consent. Furthermore, participants raised concerns about the consent of rural women in HIV vaccine trials in developing countries after a comprehensive picture of the research was displayed. Delegates questioned whether those women were fully informed and voluntarily participated. Current ethical guidelines regarding vulnerable populations are often simply articles of faith and are sometimes more concerned with legal indemnity. A process supporting informed voluntary decision-making is needed.
- **3. The standard of care to be provided during trials**
- In general, a new therapy should be tested against the best current therapeutic methods, but if the best current therapy is not accessible in the developing country in which the trial is taking place, how is the principle be applied? Should the best current therapeutic method be the control? Perhaps the reasonable control might be the currently affordable standard of care. The ethical principle guiding new interventions should be judged in the context where the study is conducted.
- Discussions were further extended to the area of research on traditional medicine and genomics research. Regional experience shows that in terms of research on traditional medicine, the developed world might learn from the developing world. Genomics may impose more inequities than already exist in current global health, therefore, bioethical reflection and timely and decisive regulations are needed to improve equity in global research.
- In summary, we need to move from discussion on the content of ethical guidelines to how to apply them into practice to solve real world problems.