Brief Summary – 8th GFBR meeting

27-29 June 2007
VILNIUS , LITHUANIA

The theme of this forum was "Fostering Research Ethics Infrastructure in the Developing World/Transition Societies". It is agreed globally that Research Ethics Committees (REC) or Institutional Review Boards (IRB) are essential to protect the rights and interests of human participants in research. However, with the increasing amount of research carried out in developing nations, concerns have risen as to the effectiveness of ethical oversight in host countries.

In the keynote presentation, Ruth Macklin and Florencia Luna laid out the challenges in establishing an effective ethical review system, i.e., a lack of effective regulations, a lack of adequate support to ensure meaningful ethical review, REC members lacking of appropriate expertise in reviewing due to no or insufficient training received, and the inadequacy of informed consent. The presenters also proposed action to counter these challenges, called for harmonization of international guidelines and a halt on the production of new ones, increased support for RECs and sustainable training for research ethics.

Panel discussions of regional perspectives on the keynote challenges were presented by Douglas Wassenaar - Africa, Rodrigo A. Salinas -Latin America, Xiaomei Zhai - China , Eugenijus Gefenas - Europe, Rosamond Rhodes - North America . All noted the current conditions and challenges in research ethics infrastructure and training at both the regional at the country level.

Challenges in establishing research ethics infrastructure

Discussions centered on four issues.

- To establish RECs, it is necessary to realize that different types of regulation and RECs are needed, the "consulting country" could be taken as a reference. We need to enhance the role of RECs from administrative, academic and policy levels. Participants called for a registry of clinical trials, international cooperation and accreditation of RECs;
- To enhance the work of RECs, the independence of RECs should be improved, minimizing conflict of interest is important, it is necessary to build networking between RECs and civil society, awareness of participant's protection should be fostered;
- Communication amongst RECs should be promoted;
- To improve overall research governance, the relationship between RECs and other bodies needs to be clarified, especially decision-making in terms of authority of review and order of review, i.e. ethical review following grant approval, or ethical review prior to grant application.

Challenges in scope and competencies of research ethics review

For the purpose of ethical review, the scope of research should cover studies on healthy and sick volunteers, clinical audits, social science, and student research; however, expedited review should be adopted for minimal risk research. In order to ensure continuous ethical oversight, RECs need to be assured that safety monitoring plans are in place and RECs should carry out self-monitoring if necessary. Training REC members, asking outside experts when it is required, developing clear standard operating procedures (SOPs), and establishing REC accreditation systems all contribute to competence and specialised technical expertise in RECs. Regarding conflicts of interest, it is agreed that there are different forms, from paying RECs for review, to bonuses paid to researchers for recruiting subjects. Conflict of interest can often not be avoided, but can be controlled by increasing transparency of research.

Models for research ethics training

Four reporters from different regions, i.e., Africa, Asia, Central/Eastern Europe, Latin America , presented research ethics training programs and their experiences in them. Lessons varied from region to region, research ethics training is diverse in terms of training strategies, format, and programmes. Through this session, challenges in health research ethics were identified as follow:

- The infrastructure for ethical research needs to be developed;
- A variety of training courses are needed to meet different needs of researchers, Research Ethics Committee members, high level trainees;
- More trainers should be trained;
- Post-training follow-up and sustainable programmes contribute to successful training.

Two sub-sessions were held afterwards. In sub-session one, seventeen training programmes were presented in the market place to share best practices and innovations in training modules, training techniques and pedagogies. In sub-session two, four trainees presented their experiences of attending research training programmes from the student perspective, they stated the benefits of the programmes and made recommendations. Advantages included achieving experience and competence in bioethics at both the theoretical and practical level; benefiting from invited outsider faculties and trainees of multidisciplinary background; good administrative staff support; provision of scholarships. Recommendations included ensuring the relevance of the course with the prevalent study types at the local area, setting aside more time for reflection during training program, continued technical support and networking after completion of the program.

Mental health research

During the presentation, Rodrigo Salinas gave a plenary address on problems with mental health research sponsored by pharmaceutical companies, he argued that many researchers in this area tend to favour the drug company through bias in publication and carefully constructed research. He highlighted the phenomena of "disease mongering" which turned normal conditions into psychiatric illnesses. Therefore, he advocated for strict oversight by RECs.

Discussion following the plenary presentation focused on the following issues:

• Differences between mental health research and other health research. The major differences lie with the difficulty in defining mental illness, the difficulty in diagnosing mental illness because of a lack of biomedical markers, stigma, vulnerability, incapacity to consent, and insufficient expertise in ethical review;

• Capacity of participants to consent, patients' capacity to consent varies with time, means patients of mental illness may have the capacity to consent when disease improves, while people with psychiatric problems may lose the capacity to consent if they deteriorate, so, delegates alleged that independent assessment of capacity might be necessary, delegates also raised the concern of how to protect participants with mental problems properly without depriving them from research which might benefit them;

• Special protection and precautions for the protection of mental health research participants: Must tailor informed consent to different conditions, proxy consent is needed, RECs should scrutinize the protocols to ensure the "best interest" of the participants, ongoing monitoring and inspection is necessary, exclusion of the most vulnerable participants;

• Special issues related to mental health research in developing nations include undue inducement, a lack of resources for standard care, and the cultural factors of mental illness might be ignored.

Conclusion

- Issues faced by research ethics committees can no longer be divided into those of the 'developed' and 'developing' worlds. The specific needs of transition societies should also be considered.
- Research Ethics Committees need to evolve from being established to being optimized in their work.
- More precise data on research ethics capacity is needed for countries to determine areas that need development.
- Communication needs to be improved - among Research Ethics Committees and between all stakeholders of research in society.
- At the same time, all countries share some common issues, such as: the need for review capacity in specific areas (e.g. mental health research).