Fostering research ethics infrastructure in the developing world and transition societies

GLOBAL FORUM
On Bioethics in Research

Report of the Global Forum on Bioethics in Research
Eighth Annual Meeting

Vilnius, 2007

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Acknowledgements
The GFBR-Secretariat is grateful to: Jacob Leveridge, Carel IJsselmuiden, Catherine Elliott, Douglas Wassenaar, Eugenia Lamas, Eugenijus Gefenas, Florencia Luna, Indra Giraite, Jean Gibbons, Karen Hofman, Marie-Charlotte Bouësseau, Martin Strosberg, Robert Baker and Zulfiqar Bhutta, who all reviewed the earlier and the final version of this report.

ISBN 92-9226-023-5

Keywords
Health research ethics, ethics of mental health research, GFBR, Global Forum on Bioethics in Research, research ethics committees, bioethics, training in research ethics, human participants in research

Published by COHRED on behalf of the GFBR partners: Aga Khan University, Pakistan; Facultad Latinoamericana de Ciencias Sociales (FLACSO), Argentina; Health Research Council of New Zealand (HRC); Institut National de la Santé et de la Recherche Médicale (INSERM), France; Medical Research Council (MRC-UK), United Kingdom; Fogarty International Center of the US National Institutes of Health (FIC-NIH); Vilnius University, Wellcome Trust, United Kingdom; World Health Organisation (WHO), and the Council on Health Research for Development (COHRED), Switzerland-which acts as host for the Secretariat of the GFBR.

Contents

Summary

The eighth annual meeting of the Global Forum on Bioethics in Research (GFBR) was held on 27-29 June 2007 in Vilnius, Lithuania. The three-day meeting was organised by the Medical Faculty of Vilnius University in cooperation with the Union Graduate College Bioethics Program (USA), and the partners of the GFBR [1].

Meeting Objectives

1. To encourage discussion on the major challenges in establishing an effective system of Research Ethics Infrastructure
2. To discuss operational strategies to address these challenges in order to attain the goal of protecting research participants in health research
3. To discuss the ethics of mental health research

The meeting was organised into five sessions (Annex 1,2):

1. Challenges in Operationalizing Research Ethics Review: Establishment, Composition and Organizational Aspects
2. Challenges in Operationalizing Research Ethics Review: Domain and Competencies
3. Models for Training in Research Ethics
4. Ethics of Mental Health Research
5. The Role of International Organisations in Establishing and Supporting Research Ethics Infrastructure and Networking

More than 130 participants from 48 countries attended the meeting, seventy per cent of whom came from developing or transition countries (Annex 3).

Conclusions

- Issues faced by Research Ethics Committees can no longer be divided into those of the 'developed' and 'developing' countries. The specific needs of transition societies should also be considered.
- Research Ethics Committees have been established in most countries. Now their work needs to be optimised.
- 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.
- All countries share some common issues, such as the need for review capacity in specific areas (e.g. mental health research).

1 GFBR Partners: Aga Khan University, Pakistan; Facultad Latinoamericana de Ciencias Sociales (FLACSO), Argentina; Health Research Council of New Zealand (HRC); Institut National de la Santé et de la Recherche Médicale (INSERM), France; Medical Research Council (MRC-UK), United Kingdom; Fogarty International Center of the US National Institutes of Health (FIC-NIH); Vilnius University; Wellcome Trust, United Kingdom; World Health Organisation (WHO), and the Council on Health Research for Development (COHRED), based in Switzerland – which acts as host for the Secretariat of the GFBR.

Welcome and Introductory Remarks

During the opening ceremony of the 8th Global Forum on Bioethics in Research (GFBR), representatives from the Lithuanian Parliament, Lithuanian Ministry of Health, Vilnius University and COHRED delivered welcome speeches, extended their warmest welcomes to the meeting participants, and wished the conference great success!

Dr Antanas Matulas, speaking on behalf of the Lithuanian Parliament, stated that bioethics is important in safeguarding the interests of human participants involved in biomedical research, as well as in promoting the practical application of new techniques in health care, especially in genetics, stem cell science and reproductive medicine. Great efforts and considerable achievements have been made in the last decades in bioethics in Lithuania, including the issuing of the first national law on biomedical research, the main provision of which lays stress on the interests of human beings and individuals being more important than those of science and society. This law also establishes guidelines to a National Bioethics Committee and Regional Research Ethics Committees, both of which are functioning well, and promote academic development in bioethics in universities.

Dr Romalda Baranauskiene, a representative of the Lithuanian Ministry of Health, said that they were happy to host this conference. Biomedical research is very important for the wellbeing of humans, however, research involving human participants and human tissues is a very sensitive issue, therefore ethics committees need to be in place to ensure the ethical governance of that research.

Dr Juozas Vidmantis Vaitkus, representing Vilnius University, introduced the long history and tradition of both the country and Vilnius University. Universities should assume the responsibility of gaining trust from the public when conducting research.

Professor Carel IJsselmuiden, director of the Council on Health Research for Development (COHRED), in the name of the GFBR partners, briefly introduced the history of the GFBR, its partners and the newly established Secretariat, and extended his appreciation to the organisers of the conference and those who attended the meeting. The GFBR-Secretariat host, COHRED, is a non-governmental organisation dedicated to supporting developing countries to strengthen their health research systems.

Keynote Address

KEY ISSUES

- No more international guidelines - key need is instead to harmonise those available
- Institutional support for Research Ethics Committees
- Sustainable ethics training programmes
- Real consultation with research participants and communities

Research ethics infrastructure: Challenges in establishing an effective system

Ruth Macklin and Florencia Luna

In their keynote address, Ruth Macklin (Albert Einstein College of Medicine) and Florencia Luna (Latin American University of Social Sciences (FLACSO)) laid out the challenges they saw in establishing an effective research ethics infrastructure, and proposed actions to meet them.

First, many countries lack laws or regulations governing the ethics of research. International guidelines might be expected to be helpful to Research Ethics Committees (RECs) in these cases. But the arrays of guidelines require considerable interpretation and provide conflicting recommendations on crucial issues (such as the "standard of care"). Macklin and Luna called for the harmonisation of these guidelines and for a halt to the production of new guidelines.

Second, ensuring adequate ethical review is still a challenge. Controversy remains over whether there should be central RECs, or if they should all be local, and over the best way to support RECs while minimizing conflicts of interest. Macklin and Luna recommended that research institutions and government bodies should provide RECs with the needed financial and administrative support to function effectively and independently. Further, they highlighted the importance of prospective registries of trials, and the publication of data from all trials.

Third, ethical research can only be assured if REC members and researchers get appropriate ethics training. However, there is a lack of agreement on what training is sufficient, including whether training needs to be formalized and RECs accredited. They suggested that sustainable training capacity will be achieved only by training people who can then train others in research ethics.

Fourth, there needs to be oversight of RECs, in order to ensure that they are performing adequate reviews of research and complying with the relevant regulations or guidelines. RECs also need to establish monitoring systems, which can oversee on-going research. Such systems are time-consuming and labour-intensive.

Finally, the adequacy of researchers' consultation with participants remains an issue. Informed consent documents from industry are often focused more on avoiding legal liability than conveying information, and the consent process is frequently flawed. Further, though community involvement in research may be enjoined, it is often attempted in the most cursory manner.

Regional Perspectives on Keynote Challenges

Regional Perspectives: Africa

Douglas Wassenaar

Douglas Wassenaar gave a summary of the state of African research ethics training activities and ethics review infrastructure. He noted at the outset that it is impossible to generalise over the whole continent: Africa's "capacity in training and infrastructure varies from the best to amongst the most under-resourced in the world."

Wassenaar listed the current post-graduate training programmes in Africa and the many workshops that have been conducted. These are supported by a wide range of institutions. Surveys of existing RECs showed that about 50% of REC chairs had some research ethics training; this is true of fewer than 40% of REC members. Some problems with short training workshops are that there is no evaluation of the impact of such training and the same people often end up attending them. There are approximately 100 or more RECs in Africa, covering 64% of countries. However, most RECs do not have funding, and many lack office space and administrative support. 80% of surveyed RECs reported no capacity to do post-approval monitoring of trials.

Wassenaar recommended that training, especially workshops, should be needs-driven and more focused. There should be local training by graduates from the Fogarty-sponsored post-graduate programmes, funding should be driven by infrastructure needs, and the effects of training programmes need to be assessed. Francophone and Lusophone West Africa had the greatest research ethics needs; they could be helped by EU-sponsored programmes. Finally, African research ethics scholarship should be developed.

Regional Perspectives: Latin America

Rodrigo A. Salinas

Rodrigo Salinas described the EULABOR project, which is a collaboration between European and Latin American countries to describe and compare the adequacy of these countries' research ethics regulatory systems. He noted the heterogeneous scope and legal status of the various Latin American national regulatory frameworks. For example, only Mexico has a working National Bioethics Commission, and only in Brazil and Chile are RECs responsible for evaluating research protocols. Local translations of international agreements and codes also vary from country to country.

Regional Perspectives: China

Xiaomei Zhai

Xaiomei Zhai identified regulation as the most important factor for establishing an effective research ethics infrastructure in China. She provided an overview of Chinese rules, guidelines and regulations for research with human participants, including the 2007 regulations, which established a national system of ethical review with three levels of ethics committee, each fulfilling a different function. Zhai identified a number of challenges facing the Chinese research ethics infrastructure. These include the lack of a culture of challenging authority, a shortage of qualified personnel, insufficient support for ethics committees, and no monitoring.

Regional Perspectives: Europe

Eugenijus Gefenas

Intra-European differences make it difficult to generalize about the European research ethics infrastructure. Consequently, Gefenas concentrated on the transition societies of Central and Eastern Europe (CEE), and the implementation of European international instruments. He noted some concerns about trials being located in CEE in order to take advantage of poor health care systems and the prestige attached to being a researcher. Gefenas discussed the Council of Europe's Convention on Human Rights and Biomedicine, and the European Union's 2001 Directive on clinical trials on medicinal products for human use. By 2006 the former had been ratified by 19 out of 46 member states, of which 11 were from CEE. Gefenas speculated about why this might be the case. The latter is binding on all 27 EU member states. Gefenas identified problems with divisions of responsibility between RECs and "competent authorities."

Regional Perspectives: North America

Rosamond Rhodes

In her presentation, Rosamond Rhodes focused on problems she perceived with the research ethics status quo. She argued that these problems emerged from two misleading conceptual paradigms. The first arose from the Nuremberg Code, which, she claimed, assimilated doctors to Nazi scientists from whom research participants need protection. The second stems from the Declaration of Helsinki, which views research participants primarily as patients and so leads researchers to conflate their relationship with the doctor-patient relationship. Rhodes argued that the social legitimacy of research needs to be accepted, and that our primary concern should be with the risk of harm through research. Consequently, she suggested, there should be different levels and kinds of review and oversight corresponding to different levels and kinds of risk.

Challenges in Operationalizing Research Ethics Review: Establishment, Composition and Organizational Aspects

KEY ISSUES

- Different types of Research Ethics Committees are needed, which should fit national and local needs
- Enhance role of Research Ethics Committees at administrative, academic and policy levels
- Create conditions under which Research Ethics Committees' independence is maximized
- Promote communication among Research Ethics Committees (RECs) and between RECs and other parties

Moderators Marie-Charlotte Bouësseau, Carel IJsselmuiden, Karen Hofman, Rene Von Schomberg
Rapporteurs Dirceu Greco, Dafna Feinholz-Klip, Jessie M. Orlich

During the feedback from discussion groups to the plenary, it was proposed that in order to build effective RECs, the following should be considered:

1. Establish RECs by:
   - Recognising that there is a need for different types of regulations and different types of REC. Factors such as the kind of project being examined, the level of risk to the participants, the size of the host country, and the number of projects the REC will review should be considered.
   - Mapping what other countries are doing and how they have developed creative solutions to ethical problems, so that the "consultant" country will not make a mistake twice.
   - Advocating for an open registry of clinical trials (See: WHO International Clinical Trials Registry Platform http://www.who.int/ictrp/en/).
   - Enhancing the role of RECs at three levels: the administrative (ensuring fees for administrative activities), the academic (promoting freedom to express ethical concerns), and the policy level (having real support from political authorities).
   - Promoting quality assurance for RECs (accreditation process) to encourage continuing professional training.
   - Increasing cooperation in international research (e.g. networking, accessing the latest research information).

2. Enhance RECs' work by:

- Acknowledging that conflicts of interest are unavoidable in the field of health research; it is necessary to work on minimising or balancing them.
- Creating conditions under which REC independence is maximised.
- Implementing social controls by building stronger networks between RECs and civil society and representatives of NGOs.
- Raising awareness inside the host country about what research is, and what it means to be a volunteer in research.
- Promoting research responsive to local conditions.

3. Promote communication by:

- Informing RECs of the decisions of other RECs (even if this must be limited to whether a study has been approved or not).
- Promptly reporting adverse events and disseminating information about them to the different sites in multi-centre clinical trials.
- Differentiating proprietary information from trade secrets.
- Involving local researchers in multi-centre studies from the early research proposal writing stage, in order to benefit from their contributions.

4. Improve overall research governance by:

- Establishing to which bodies and following which modalities a research protocol should be submitted. For example, whether it should be first submitted to the REC, and, once approved, submitted to the drug regulatory authority, and so on.
- Differentiating the separate areas of responsibility for each body in reviewing a research protocol (for example, may the competent authority reject an application on ethical grounds that the REC has already approved?).
- Clarifying whether REC approval is mandatory and whether its recommendations are legally binding.

Challenges in Operationalizing Research Ethics Review: Domain and Competencies

KEY ISSUES

- Ethical review should cover studies on healthy and sick volunteers, clinical audit, social science, and student research
- Expedited review is needed for minimal risk research
- Ethical oversight is necessary to ensure continuous protection of research participants
- Conflicts of interest are not avoidable, but can be controlled by increasing the transparency in research

Moderators Jacob Leveridge, Catherine Elliott, Eugenia Lamas, Matthias Kaiser
Rapporteurs Andres Soosaar, Ruth Macklin, Carl Coleman

The feedback from discussion groups included a number of recommendations and raised some unresolved problems.

1. The scope of research requiring REC approval

For the purposes of REC review, research should be taken to include studies on healthy and sick volunteers, clinical audit, social science, and student research. There should be expedited review for minimal risk research, with the exception of research on vulnerable populations. A definition of minimal risk is needed that recognizes behavioural and psychological harms. Where different levels of review are possible, there remains the issue of who should decide the level of review.

In student research, there is no difference in the goal to protect human research participants, so the same requirements for review should apply. The distinction on how best to protect research participants involved in health care and social science research was unclear.

2. Challenges and limitations of ethics oversight

The distinction between monitoring, auditing, and inspection is important, but what best describes the oversight role that RECs should prioritise? Is the responsibility of RECs to monitor research, or to ensure that all research has appropriate monitoring plans or quality control measures in place? The concern then is, if all monitoring and auditing measures are adopted and implemented, RECs might not be specifically focused on the ethical issues of research, i.e. informed consent process, benefit-sharing, etc. Yet, without monitoring of research, how can ethical review be achieved?

RECs need to ensure that there is a relevant safety monitoring plan in place to ensure that the interests of research participants are protected. The research protocol should address the issue of reporting of adverse events, the standard used to differentiate the seriousness of adverse events, if they are expected or unexpected, the trial endpoints, and early termination criteria.

3. How and where specialised technical expertise should be obtained

External pressures and a lack of relevant expertise may lead to REC members "rubber-stamping" research projects, which can generate a false sense of protection among research participants. However, there are ways to prevent these pressures, such as: training REC members to deal with difficult cases, asking outside experts when it is required (which does not mean that the expert will then become a REC member), developing clear standard operating procedures (SOPs), and establishing REC accreditation systems. One important expert who is often overlooked is the insurance broker, who is needed to make sure that insurance policies are effective.

4. How to minimise conflicts of interest

There are many different types of conflicts of interests that arise in many different contexts. People may not recognise when they have a conflict of interest. Thus a good definition should be available, and doctors and researchers need to be educated to recognise them.

A patient may regard their doctor as always having their best interests at heart, and consent on this assumption, but the doctor might have other interests when performing as a researcher (they may need participants for a trial, they may be paid for recruiting participants into a trial, and so on). To prevent this, recruitment for trials should ideally be performed by someone other than the physician, and a witness should be present to ascertain the quality of the individual's consent. Alternatively, Community Advisory Boards (CABs) could be called/established. However, it should be borne in mind that recruiters need to be able to answer any questions that the potential trial participant has, witnesses need to be trained, and CABs do not work in a hospital setting when participants are recruited at the bedside.

It was far from clear whether researchers should be paid. Though it seems that payment is fair, paying per participant is more dangerous, since it gives a positive incentive to recruit as many participants as possible and introduces a source of potential bias to the study.

One way to minimise financial conflicts of interest would be to ensure that any money received by researchers from sponsors, in the participant recruitment process, was put into a collective fund for the use of all in the research institution. Regulations in certain countries restrict the receipt of large gifts, but it was also noted that gift giving, holidays etc. were often not well controlled. Increasing the transparency of payments to researchers may be part of the solution, though not all of it.

Where RECs are based in institutions, the applicant can sometimes be identified by the title of the research submitted, even when the application is anonymised. This is one point in favour of moving from the institutional model of REC administration to the regional model. There would then be less chance of a REC reviewing the work of an identified colleague.

Session 3

Models for Training in Research Ethics

KEY ISSUES

- 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

Moderator Martin Strosberg
Rapporteurs Clement Adebamowo, Ren-Zong Qiu, Jiri Simek, Mayra Achio

Plenary Session: Building an Infrastructure through Training – Best Practices and Lessons Learned from Africa, Asia, Central/Eastern Europe, and Latin America

Regional Report: Africa

Clement Adebamowo

Clement Adebamowo noted that mixed efforts are needed for successful training. This includes infrastructure development for ethical research, working synergistically with local authorities and institutions, and offering a variety of training courses and workshops—such as single day training, short courses, degree programs and online training—to meet the different needs of researchers, REC members and high level trainees.

Regional Report: Asia

Ren-Zong Qiu

Ren-Zong Qiu described China as presenting great opportunities, but also challenges for research ethics training. He argued that a successful training programme relies on qualified lecturers, discussion of local issues, appropriate pedagogic methods, post-training follow-up and the sustainability of the programme. He described some co-organized and self-organized workshops and short courses that have been held nationally.

Regional Report: Central/Eastern Europe

Jiri Simek

In Europe, research ethics training differs from country to country. It is currently best in traditional EU countries. In Central and Eastern Europe, fora for ethics committees, international workshops, seminars and summer school courses have been offered. Experience there reveals that more ethics teachers need to be trained, and an institutional background in philosophy, sociology, and psychology needs to be built.

Regional Report: Latin America

Mayra Achio

Mayra Achio discussed the increase in international biomedical studies and clinical trials in Latin America. This has led to the emergence of education and training programmes in research ethics, including masters' programmes and collaborations with developed countries. While accessibility still remains a problem, she urges sponsoring institutions to work with universities instead of with government officials, and to establish regional networks.

Sub-session 3.1

Best practices in training for research ethics: A poster (Laptop) session

The session followed the market-place format, a new type of interactive session, and aimed to share best practices and innovations in training modules, short-courses, certificate programmes, or degree programmes for training in research ethics. Participants were involved with the use of technology (interactive training modules, distance learning, podcasting), innovative teaching techniques (simulations, role-playing, case exercises) and pedagogical improvement (writing and evaluating learning objectives). Presenters gave demonstrations of their programs, projects, or best practices to the Forum audience.

E-Education in Research Ethics: Central and Eastern Europe
(Advanced Certificate Program)

Presenters: Robert Baker, PhD; Zbigniew Szawarski, PhD

Institution: Bioethics Program, Union Graduate College-Mount Sinai School of Medicine

Link: http://www.researchethicseurope.net/apply.asp

Description:

This was a demonstration of the 7-course Advanced Certificate Program (three on-site and four on-line courses) in Research Ethics with particular emphasis on the International Bioethics course. The Advanced Certificate Program is sponsored by Union Graduate College-Mount Sinai School of Medicine Bioethics Program in partnership with the University of Vilnius, with funding from the NIH-Fogarty International Center.

University of the Philippines – Fogarty International Center Bioethics Training Online Support

Presenter: Leonardo D. de Castro, PhD

Institution: University of the Philippines

Link: http://docs.moodle.org/en/Features#Overview

Description:

This is a *Moodle* Online Courseware that provides options for full online instruction in web-based support for conventional classes under the following programs of the University of the Philippines: Master of Science (Bioethics), Diploma in Bioethics, Certificate in Research Ethics, and Intensive Training Course in Research Ethics.

The web-based facility provides flexibility in the conduct and management of instruction in the courses which requires minimal administrative involvement. It allows students to create their own login accounts subject to confirmation by the teacher, and there is a teacher who has full control over all settings for a course.

The Lesson Module is a series of pages that can be presented in a linear fashion, like a slide show, or in a non-linear, branching manner, or a combination of the two. The Resource Module supports display of any electronic content, Word, PowerPoint, Flash, Video, Sounds etc. that are stored locally or remotely. There is a wide array of course activities - Forums, Quizzes, Glossaries, Resources, Choices, Surveys, Assignments, Chats, and Workshops. Activity reports for each student are available with graphs and details about each module (e.g. last access) as well as a detailed "story" of each student's involvement (e.g. postings), teachers can define their own scales to be used for grading forums and assignments. Assignments can be specified with a due date and a maximum grade, and students can upload their assignments to the server. The Choice Module works like a poll and can either be used to vote on something, or to get feedback from every student which enables the teacher to see an intuitive table view of who chooses what. Different types of forums are available, such as teacher-only, course news, open-to-all, and one-thread-per-user.

Including Issues about Global Health in Teaching:
REB 101 (Web-Based Distance Learning)

Presenter: Geneviève Dubois-Flynn, PhD

Institution: Canadian Institutes of Health Research

Description:

The purpose of this presentation was to help people to include ethical issues about global health in teaching. Topics and content, audiences and pedagogical approaches were discussed in detail.

Educational Activities for RECs in the Slovak Republic; Project: Minirepetitorium in Philosophy and Ethics for REC members

Presenter: Katarína Glasová, M.A, PhD

Institution: Institute of Medical Ethics & Bioethics, n.f. Limbová 12, 833 03 Bratislava, Slovak Republic

Link: http://www.imeb.sk

Description:

First there was a presentation of the educational activities available to REC members in the Slovak Republic, focusing on various interdisciplinary audiences.

Secondly, there was a presentation of a new project (since 2007) – Minirepetitorium of Philosophy – that focuses on members and users of Ethics Committees in the Slovak Republic. The main aim of the project is an introduction to the terminology and methodology of philosophy (ethics) to enable an informed discourse among REC members. See web-page: www.imeb.sk (entry: RECs–Education).

A Proposed Course on Bioethics in Public Health Care for the Masters Program in Public Health Management

Presenter: Rodica Gramma, PhD

Institution: Department of Philosophy and Bioethics, State University of Medicine, Republic of Moldova

Description:

The course is directed toward persons who are involved in the Masters Program in Public Health Management within the School of Public Health, State University of Medicine. Students have a clinical background, and are currently (or potentially will be) managers of diverse medical institutions. The main objectives are to familiarise students with the main bioethical issues arising in medical activity, including biomedical research, and to train managers for competent leadership. The course is presented in a module (6 days) and consists of 48 hours of lectures and practical workshops.

Training Program for Research Ethics Committee Members in Brazil

Presenter: Dirce Guilhem, PhD

Institution: University of Brasilia

Link: http://portal.saude.gov.br/portal/arquivos/pdf/volume1ceps.pdf

http://portal.saude.gov.br/portal/arquivos/pdf/volume2ceps.pdf

Description:

The purpose of the Training Course for REC members, sponsored by the Ministry of Health of Brazil in partnership with the University of Brasilia, is to strengthen the research ethics capability in Brazil. The Brazilian System of Research Ethics, the CEP/CONEP System (Research Ethics Committees–National Commission of Research Ethics), currently has about 500 registered committees. The system is linked to the National Council of Health.

The educational material provides information related to ethical analysis, the protection of participants, the functioning of ethics committees, and standardization of the procedures adopted by RECs. The program comprises two modules accompanied by didactic material (including texts, national and international documents, case studies, questions for reflection, and movie scripts).

Module one includes the following concepts: ethics, applied ethics, and bioethics; a theoretical background for ethical evaluation; historical aspects related to research ethics; the CEP/CONEP System; and functional aspects of RECs.

Module two covers: Brazilian politics of science, technology and innovation in health (PNCTI-S); the research process: social implications and community participation; international guidelines; Brazilian legislation and guidelines; free and informed consent; and the ethical evaluation process.

CD Rom Tutorial – Bioethics and Research Ethics: Academic and Extension Programmes

Presenters: Dirce Guilhem, PhD, and Debora Diniz, PhD, University of Brasilia; Fabio Zicker, PhD, Research Capability Strengthening-Coordinator, TDR/WHO

Institution: University of Brasilia, Flaceis-Foro Latinoamericano de Comités de Ética en Investigación en Salud

Link: http://www.who.int/tdr/media/multimedia/default.htm

http://www.flaceis.org

Description:

This Tutorial CD Rom, Bioethics and Research Ethics: Academic and Extension Programs, is a product of a pioneering initiative on research ethics developed by the University of Brasilia, in partnership with the Institute of Bioethics, Human Rights and Gender (Anis) and the Latin American Forum of Research Ethics Committees in Health (FLACEIS). The initiative is supported by the Special Program for Research and Training in Tropical Diseases (TDR/WHO), Ministry of Health of Brazil-Department of Science and Technology (DECIT), and UNESCO. The main objective is to promote to the academic community's principles of justice and equity in the context of social, biomedical and clinical research involving human subjects. Issues related to science and technology development, cultural differences, health care knowledge and practices, and the vulnerability of developing countries' populations involved in externally funded research are highlighted in the documents.

The CD (in Portuguese and Spanish) contains academic programs on research ethics for undergraduate and graduate students. It includes a lecture plan, case studies, questions for discussion, international and Brazilian regulatory documents on research ethics, reference documents, sets of slides, and a 10-year Brazilian bibliography on research ethics. In addition, it includes an educational course for the general population based on the analysis of movies addressing biomedical research.

This material will be distributed freely to educational institutions and Research Ethics Committees with the objective to strengthen the scientific and ethical capacity of researchers, members of ethical committees and the community at large. It is expected that it will strengthen good research ethics practices and the quality of health research in Brazil and Latin America.

On-line Tutorial in Research Ethics & TRREE for Africa

Presenter: Marie Hirtle, LL.B, LL.M.

Institution: Biotika Inc. Recherche & conseil | Research & consulting

Mont-Royal (Québec) Canada

Link: http://ethique.msss.gouv.qc.ca/didacticiel/index.php?lang=en

Description:

This online tutorial was developed specifically for research ethics board (REB) members and support staff who work in the institutions of the Québec health and social services network. While the on-line tutorial deals with numerous pertinent national and international-level issues and texts in the regulation of ethical research, it focuses on those issues and texts that are of particular concern in the Québec context. This programme has been very well received by the target audience (ethics committee members and administrators). The on-line course has several modules each with a similar structure: short explanatory text that is followed by challenging questions that require the application of key concepts. The on-line tutorial is supplemented with face-to-face workshops on ethical deliberation that build on the content of the tutorial.

A second project currently ongoing, TRREE for Africa (www.trree.org), will use a similar approach and bring together bi-directional training material for the research ethics community in African countries. It will provide introductory on-line training in research ethics in both French and English. In addition, TRREE will provide the structure to make resources of African countries available on the website.

Lessons Learned in Implementing and Running an Ethics Review Committee (ERC) in Burkina Faso

Presenter: Bocar Kouyaté, MD, MPH

Institution: National Ethics Committee on Health Research of Burkina Faso

Description:

The Ethics Review Board (ERB) in Burkina Faso was launched in November 2002 with three main objectives: (1) to assess research protocols to be implemented in Burkina Faso, (2) to monitor adherence of research groups to the principles of ethics in health research, (3) to develop a code of ethics in health research.

At its inception, the ERB was a multidisciplinary team with nine members coming from civil society and various government ministries (health, breeding, human rights and research). The background of the members included the following fields: sociology, public health, clinical trials, and law. None were really trained in research ethics, relying rather on the experience they had gained from their work in the field.

The priority of the ERB was to set up guidelines for ethical review of the research proposals submitted by various research institutions as well as individual researchers. One of the main activities was to look for additional resources to develop a code of ethics for health research and train various stakeholders (researchers, members of ERBs, etc.).

The ERB received a three-year grant from the EU to support the development of the code of ethics and the operational costs of the ERB. In the presentation the outcomes of the three years' activities of the ERB under various constraints and challenges were discussed.

Development of the SIDCER IEC/IRB Recognition Program in CIS States

Presenter: Olga Kubar, MD, PhD

Institution: Forum for Ethics Committees, Commonwealth of Independent States

Link: www.feccis.net

Description:

The purpose of the project SIDCER IEC/IRB Recognition Program in countries of the CIS is to implement the highest ethical and scientific standards in the process of ethical review of biomedical research. The project includes the self-assessment of the Ethics Committee (EC), training of EC members and EC survey assessment and future recognition. According to the recognition programme, the education of EC members covers the following modules, including the lectures and working groups.

Module 1 - Human Subject Protection – This module focuses on the preparation of EC members to use universal ethical principles and international and national guidelines in the ethical review process. The program includes questions on research methodologies and ethical issues in various types of health research; privacy and confidentiality of health information; research among vulnerable subjects, and other aspects of the protection of human rights in the process of independent ethical review.

Module 2 - Constructing a Standard Operating Procedure (SOP) – This module includes an overview of SOP preparation and guidelines for Ethics Committees; establishment of an IEC/IRB; review procedures; and other SOPs which contribute to implementing good ethical practice in ethical review and the organisation of an EC's activity.

Module 3 - Inspection and Survey of the Ethics Committee – This module includes a surveyors' training workshop with a series of lectures and self-training activities for the inspection and conduct of actual surveys of the EC.

Initiating Open Discussion with Young People on Bioethical Issues: A Pedagogical Tool for Presenting Topics of Biomedical Research, Organ Donation, Medically-Assisted Procreation, and Genetic Testing

Presenter: Laurence Lwoff, MD

Institution: Legal Affairs, Bioethics Department, Council of Europe

Link: http://www.coe.int/T/E/Legal_affairs/Legal_co-operation/Bioethics/

Description:

The objective of this program is to provide essential information on the scientific, legal, and ethical aspects of a range of topics and propose cases and questions to start discussions with young people. For each topic, the tool is presented as a set of five fact sheets. Three topics have been addressed so far: organ donation, medically assisted procreation and genetic testing. In development are fact sheets on both cloning and biomedical research.

Distance Learning Experience in Research Ethics: An Introductory Level and an Advanced Level Course in Research Ethics

Presenter: Irene Melamed, MD

Institution: Training Program in Research Ethics in the Americas, Latin American Faculty of Social Sciences, FLACSO

Link: http://www.flacso.org/ecuador.php

Description:

This was a demonstration, through interaction with the virtual platform, of the course's purpose, learning objectives, content and structure of the curriculum and evaluation (knowledge, attitudes, and practices). The course is conducted under a grant from the National Institutes of Health–Fogarty International Center.

Podcasting a Lecture

Presenter: Ann Nolte

Institution: Bioethics Program, Union Graduate College-Mount Sinai School of Medicine

Link: http://www.researchethicseurope.net

Description:

This was a demonstration of the podcasting of a lecture on neuroethics (given at the CEE Advanced Certificate Program in Research Ethics at Vilnius University, sponsored by the NIH-Fogarty International Center) using "iTunes University."

Certification and Continuous Education Program for Clinical Research Teams

Presenter: Jessie M. Orlich, MBA, San José

Institution: Universidad de Ciencias Médicas (UCIMED), Costa Rica

Description:

UCIMED has established a program for clinical research teams. Its objective is to increase ethical awareness in clinical research and improve the quality of clinical research in Costa Rica in general and in projects approved by UCIMED's IRB in particular. The program includes four projects: (1) formal registration as UCIMED researcher team members, (2) certification as principal investigators, secondary investigators, clinical coordinators, and other supporting research team members, (3) good clinical practice training (40-hour course) and (4) online continuous education courses (in partnership with Duke University). This program started in 2007 and there have been positive results in projects 3 and 4. Projects 1 and 2 depend on technological issues still to be solved. During the Forum, a description of projects 3 and 4 was presented, with preliminary results, in order that other organisations may take advantage of this experience.

Global Research Ethics Map

Presenters: Sarah Putney (in association with Kelly Safreed-Harmon, Elizabeth Bowie, Caitlin McCormick, Marie-Charlotte Bouësseau)

Institution: Human Subjects Administration, Harvard School of Public Health; World Health Organisation

Link: https://webapps.sph.harvard.edu/live/gremap/index_main.cfm

Description:

An online guide to human subjects regulations and guidelines throughout the world.

Online Course "Research Ethics in Biomedicine"

Presenter: Andres Soosaar, PhD

Institution: Department of Public Health, University of Tartu, Estonia

Link: http://webct6.e-uni.ee/webct/expandPublicCourse.dowebct?courseId=41036001

Description:

This on-line course provides a theoretical overview of basic aspects of modern biomedical research ethics and also imparts a set of practical skills. The course contains 5 sections: (i) ethos of science; (ii) forms of scientific misconduct; (iii) common ethical requirements in biomedical research; (iv) ethics of non-clinical biomedical research; (v) ethics of clinical research. Potential audiences for the course include scholars (students, researchers and physicians) who are doing biomedical research.

Research Ethics Program for PhD Students at the Jagiellonian University Medical College, Krakow, Poland

Presenter: Zbigniew Zalewski, PhD

Institution: Department of Philosophy & Bioethics, Jagiellonian University Medical College

Description:

A course on research ethics for PhD students at the Medical College of the Jagiellonian University, Krakow, Poland. The course contains 15 hours of lectures and 15 hours of seminars. The course utilizes some guest lecturers to present some specific subjects, e.g., moral dilemmas of genetic research and use of biotechnological inventions in modern medicine (professor of medical genetics), research in critical care medicine (professor of anesthesiology), the workings of the REC and its role in maintaining the quality of research (chairman of the university's REC). The rest of the lectures are devoted to the basic principles of research ethics, its history, and main documents (domestic and international, both ethical and legal). Seminars are devoted to detailed discussion of such topics as the use of a placebo in clinical research, moral commitments presumed in scientific methodology, and fakes and mistakes in research. At the end of the course, students take part in public debates on elected topics (in groups of 5-6 participants).

Sub-session 3.2
Student Perspectives on Training programmes

Moderator Barbara Sina
Panelists Dirce Guilhem, Angelica Angeles, Elizabeth Kwagala, Joanna Rozynska

Presentations of student perspectives on bioethics training programmes were given by participants from the programmes of the Latin American Faculty of Social Sciences (FLACSO), the South African Research Ethics Training Initiative (SARETI), and the E-education Advanced Certificate Program in Research Ethics in Central and Eastern Europe. They shared the benefits of attending such programmes, such as achieving experience and competence in bioethics at both the theoretical and practical levels, benefiting from the invitation of outside faculty and trainees of different disciplines, good administrative staff support, and the provision of scholarships. The student recommendations included: taking account of the relevance of the course given the prevalent study types in the local area; setting aside more time for reflection during training programmes; and continued technical support and networking after the programme.

FLACSO Training Programme
Dirce Guilhem and Angelica Angeles

The FLACSO training program involves seven months of tutorial-based training, with three one-week seminar components. Participants must be fluent in Spanish and competent in English. The course subjects cover issues such as euthanasia, feminism, medical anthropology, and clinical research methodology.

Several strengths of this programme were identified by the presenters. These included the high level of competence of the co-coordinators, the ability to participate in actual RECs, and the fact that the course was aimed towards the development of a scientific paper. The presenters made some suggestions for improvement: that the course be broader than the current focus on clinical research, that there needed to be more networking between participants, and that there could be continuing technical support after the close of the course.

SARETI Training Programme
Elizabeth Kwagala

The goal of the SARETI training programme is to build ethical review capacity in bioethics in Africa. Various training methodologies are applied: work with case studies, meetings with trainees and faculties, mentoring of trainees, and attendance at REC meetings. The presenters felt that strengths of this programme lay in its multi-disciplinary content, and the associated multidisciplinary nature of the fellows who attend. Further strengths were the follow-up of fellows by staff, the strong commitment of staff to the course, and the efficiency and ability of the administrative staff. The only weakness mentioned by the presenter was that the course was almost too full to allow reflection; although this statement was qualified with the fact that reflection was possible after the course.

Recommendations made for SARETI were the idea of follow-up refresher workshops after the completion of the programme, further mentoring tailored towards potential publication in ethics journals, and the inclusion of more "how to train trainers" material in the programme, training participants in the skills of being a facilitator.

E-education Training Programme

Joanna Rozynska

The objective of the programme is to provide participants with both knowledge of and capacity in research ethics, thus helping to foster research ethics infrastructure in Central and Eastern Europe. The course attracts students from many different disciplines, and is of sixteen months duration, involving seven courses, three of which are onsite and four of which are online.

Participants in this course saw its advantages as being its international nature, the fact it was taught from the perspective of Central and Eastern European countries, that it was multidisciplinary, that it formed a combination of both theory and practice, and finally that it provided a great deal of flexibility. The availability of scholarships provided an extra incentive for further study.

Session 4

Ethics of Mental Health Research

KEY ISSUES

- Emphasize the social value of research to guard against:
  - Biased studies due to difficulties in defining and diagnosing mental illness
  - "Invented disorders" which could turn normal conditions into psychiatric illnesses
- Scrutinize research protocols for the "best interest" of the participants, especially regarding the issue of capacity to consent
- Special issues arising in mental health research in developing nations include undue inducement, insufficient resources for standard care, and disregard for cultural factors

Moderators Douglas Wassenaar, Dafna Feinholz-Klip, Joseph Millum, Dinesh Singh

Rapporteurs Liz Shaw, Prabha Chandra, Jean Gibbons, Hugh Whittall

Plenary Session:

Ethics of Mental Health Research

Rodrigo A. Salinas

Rodrigo Salinas' plenary address focused on problems with research trials sponsored by pharmaceutical companies. Around two thirds of published trials of psychiatric drugs are industry-sponsored, and of these 90% show results that favour the sponsor's drug. Salinas argued that a combination of publication bias and carefully constructed studies allow researchers studying psycho-active drugs to get the answers they want. For example, studies of drugs sometimes bias results through the careful selection of exclusion criteria for research participants. Not only does this sort of manipulation of trials make the results less meaningful, it also leads to increased risks to patients. In the case of the exclusion criteria, for example, those criteria may not be mentioned when the drug is marketed. Salinas also highlighted the trend towards "disease mongering," whereby conditions once considered normal are turned into psychiatric illnesses. For instance, he cited research which suggested that a million Australians suffered from a novel ailment called "social disorder." He warned of the dangers of moving the boundary between sickness and health. Finally, Salinas suggested that too much research focused on developing "me-too" drugs. He argued that more critical examination of the social value of psychiatric research is needed. This, he said, is a job for RECs.

Break-out Group Instructions: Ethical Issues in Research on Mental Disorders
Session Convener: Douglas Wassenaar

Preamble

Several guidelines exist concerning research on mental disorders. These offer various approaches to some of the specific questions that arise in this area. However, several additional questions arise that are not always explicitly dealt with by such guidelines. These additional questions include ethical issues concerning disorders whose definitions are unclear and which themselves are the subject of ethical debate. There is also ongoing debate about the proper management of some of these disorders with regard to their impact on civil liberties. Some argue that the legal framework surrounding the treatment of mental illness is itself unethical. Furthermore, mental disorders and mental illnesses are the research focus of a wide and often competing range of disciplines ranging from criminology to neurology, employing a range of methodologies from focus groups to neurosurgery.

Some of the key issues addressed in most guidelines relate to ways in which research on mental disorders differs from research on other disorders. The research differences are based on the conceptualisation of ways in which mental disorders differ from other health and social problems. The main difference identified in most guidance relates to differences in competence and capacity to consent. Most of the special guidelines assert that capacity to consent is more likely to be impaired in mental disorders than in other forms of health and social research. Most of these guidelines stipulate or recommend special procedures for researchers and investigators to follow in conducting research on persons with impaired capacity or competence. (In general, capacity is a clinical term referring to ability to understand, retain and use information in decision-making, while competence is a legal term which is much more categorical than the clinical term).

Note: This session of the GFBR was on the whole confined to research with adults, as research with children with mental disorders typically raises a further level of complexity.

Purpose of the session:

The purpose of this session was to revisit and consider some of these ethical issues in the light of existing guidance, and also to determine their relevance to developing country settings.

Acknowledgements:

Several papers, documents and comments from colleagues contributed to this outline; thanks are due to: Benjamin Olley, Anthony Pillay, Werdie van Staden, Cathy Ward, and Tuviah Zabow. Nicole Corbella is thanked for editing the comments from the breakaway groups.

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Summary of Feedback from Break-out Groups on Ethical Issues in Research on Mental Disorders

Each question below refers to one of the questions posed to the Break-out groups.

Question 1

From the point of view of researchers and Research Ethics Committees (RECs), what, if any, are the major ways in which mental illness itself differs from other health problems?

Six ways in which mental illness differs from other health problems were identified.

1. The complexity/difficulty in defining mental illness
   Defining mental illness is problematic. Mental illness covers a huge range of conditions and the terminology used in the definition of mental illness may be vague, broad and/or inconsistent. This has implications for research in that if one is unable to define mental illness or agree on key criteria, it may not be possible to define the research question or target population.
2. Diagnosis is difficult/subjective
   The diagnosis of mental illnesses is difficult as, unlike most other health problems, mental illness can be a social, cultural or political construction. Cultural relevance and social perspectives therefore have to be taken into consideration. There is also a lack of biomedical markers for most forms of mental illness. As such, the diagnosis of some mental illnesses is made on the basis of what the patient says. Furthermore, the diagnosis of mental illness is often complicated by the differing degrees of mental illness and the various scales and criteria for measuring mental health.
3. Stigma associated with mental illness
   In many communities there are negative perceptions of mentally ill or disordered persons, with subsequent low social integration, stigma and ostracism.

4. Increased vulnerability of mentally ill patients
   Mentally ill patients are potentially more vulnerable due to their dependency on others and their reliance on representation by a third party. In some cases, the patients themselves may lack awareness of their own illness and the implications of interventions.
5. Ability to consent is affected
   Mental illness often affects understanding, mental ability, attention, concentration, and cognition, all of which may impair the ability to consent. However, the fact that mental illness does not always correlate with an inability to consent was raised. The question of whether mental illness necessarily implies vulnerability if the patient has capacity to consent was also raised.
6. Different implications for ethics review
   It was questioned whether RECs have the technical knowledge to critique the methodology used in mental health research, whether there is enough expertise on RECs to be able to recognise a well designed research project and whether scientific review should be separated from ethical review in the case of mental health research.
   In mental health research, researchers and RECs should pay careful attention to:
   - The need for clear and justifiable inclusion/exclusion criteria.
   - Informed consent to allow inclusion.
   - Independent procedures to measure capacity.
   - The diagnostic criteria that have been used.
   - Measurement of end-points, which can be very subjective.
   - Justice and evaluation of the social worth of the proposed research.

It was suggested that RECs reviewing mental health research should have competent persons (e.g. a psychiatrist or clinical psychologist) on the committee.

Question 2

What, if any, are the main ethical implications for research, of the problems with capacity and competence that are likely to be associated with mental disorder?

Mentally ill patients are often thought to have impaired capacity, which impacts on their ability to make an informed decision. However, lack of capacity should not be assumed in patients with even severe mental illness. Capacity can be variable and should be assessed independently of the illness. Furthermore, competence and capacity vary over time and can be affected by medication. It was questioned whether changes in patient's competence need to be reassessed throughout the study, especially in medium and long-term studies.

Researchers need a clear understanding of the legal definition of competence and implications for assessing capacity. The question of whether persons declared incompetent by a court can enter a trial/study if the researchers consider them to have the capacity to consent was raised. There needs to be an awareness of the possibility of conflict of interest if researchers are themselves involved in the determination of capacity for research. Such assessment should therefore be independent of the study. Researchers and RECs also need to consider issues of confidentiality in respect of legal representatives. Concerns were raised

regarding how researchers can be confident that the legal representative or proxy knows the wishes or represents the best interests of the patient. It is therefore essential that RECs carefully examine protocols to consider inclusion/exclusion criteria in terms of capacity/competence/representation.

For research to be ethical it has to be directly relevant to the specific population on whom it is being conducted. Therefore research conducted on mentally ill participants should not be possible with persons who do not have the mental health problem in question. Special justification is needed for studies that are not specifically targeted at the mental condition leading to incapacity. This leads to the question of whether incapacitated patients should be excluded from research that could benefit all sectors of the population e.g. research on heart disease with patients with Downs Syndrome. Although it is clear that this group is different from the general population, care should be taken not to 'over-protect' them and exclude them from potentially beneficial research.

Question 3

Should there be special precautions and/or procedures for the ethical conduct of research with mentally disordered persons who have diminished capacity and competence? If so, what should these special precautions and procedures be?

The following special precautions and procedures were suggested:

- Informed consent procedures should be tailored to different levels of capacity.
- Mentally ill participants should have someone who can make proxy decisions for them if they are not able to consent themselves.
- Proxy decision makers should be independent of the researcher and sponsor.
- RECs should examine protocols for how the 'best interests' of the patients will be considered.
- There should be ongoing inspection/audit/monitoring/scrutiny of research with mentally ill patients.
- The most vulnerable subsets of the groups being researched should be excluded from studies.

Question 4

Are there any special issues in research on mental disorder that arise in developing country/under-resourced settings? If so, what are these and what additional measures do they require?

Three special issues in research on mental disorders were thought to arise in developing countries and/or under-resourced settings:

1. Undue inducement

   Special attention needs to be paid to the risk of undue inducement in view of the high levels of poverty in developing countries. Furthermore, in general, the poor quality of local care in developing countries may mean that entry into any trial is seen as a benefit (i.e., it is always in the participant's best interests to enter a trial as they receive a high standard of care and access to facilities not normally available to them).

2. Standard of care/lack of resources
   The relatively sophisticated facilities in the West where people can be treated while in a trial are often not available in developing countries. There are poor health care systems and facilities for mental health care in developing countries and local doctors may have variable psychiatric competence which may, among other things, result in serious adverse events being reported but not acted upon. It is also possible that due to social/cultural differences some medical staff in developing countries may be less sympathetic to mental illness.

   In under-resourced settings, psychiatric hospitals are often understaffed. In such cases, getting legal help and advocacy is difficult, which increases vulnerability. In developing countries, institutional capacity and resources to manage issues are limited, so it is possible that an extra cautionary approach may be taken by RECs as the default, despite the potential risk of exclusion from beneficial research. Research also needs to be monitored and there are often limited resources to do this in both developed and developing countries.
3. Local relevance
   Questions were raised about whether it is acceptable to impose a particular model of mental illness on research participants, given that there are sometimes cultural differences about how certain illnesses are understood. Definitions of mental illness may reflect judgments about what is normal and abnormal and may vary according to cultural differences despite global criteria for mental illnesses. It is therefore essential to respect participants' particular cultural understandings.
   A number of additional measures were suggested. These include recommendations that:
   - Dedicated training modules for mental health research be developed.
   - Specialised review committees for mental health research proposals be established.
   - Cultural factors and one or more decision-makers be identified when considering participants' and families' best interests.
   - The role and interests of the research's sponsor be carefully considered.

Question 5

Each group was encouraged to report on any other issues that arose in its deliberations.

Other issues that arose concerned:

- Conflict of interest
  The role of the pharmaceutical sponsor was questioned (e.g., in relation to the labeling of 'new' psychiatric conditions to market new drugs). The possibility of participants forming dependent relationships with clinicians was also raised.
- The use of placebo
  The question of whether it is ethical to use placebos in research on patients with psychiatric illnesses was raised.
- Methodological concerns
  It was highlighted that a lack of adequate research design and methodologies often result in inadequate and/or poor quality research.
- Improper use of research findings
  Research findings are not necessarily translated correctly when marketing drugs.

Session 5

The Role of International Organisations in Establishing and Supporting Research Ethics Infrastructure and Networking

KEY CONTRIBUTIONS OF INTERNATIONAL ORGANISATIONS TO RESEARCH ETHICS

- Promote debate on ethical issues
- Provide recommendations for policy-making
- Strengthen capacity-building in health research ethics
- Fund projects and training programmes in research ethics
- Support fellowship programmes

Moderators Douglas Wassenaar, Dafna Feinholz-Klip, Joseph Millum, Dinesh Singh

Rapporteurs Liz Shaw, Prabha Chandra, Jean Gibbons, Hugh Whittall

Plenary Session: involving panellists representing a variety of different organisations with a stake in the establishment and support of research ethics infrastructure and networking

Global Forum on Bioethics in Research - Secretariat

Sandra Realpe

The GFBR is the only global platform specifically designed to promote debate on emerging ethical issues in international collaborative health research between developing and developed countries. It was initiated in 1999 by the Fogarty International Center of the National Institutes of Health and the World Health Organisation, with an increasing number of partners since then. Annual meetings of the Forum have now been held eight times, with participants from 40% of the countries in the world. Overall 70% of participants have come from developing or transition countries. The Secretariat of the GFBR is hosted by COHRED and funded by the European Commission within its FP6 Programme.

- Global Forum on Bioethics in Research, **http://www.gfbronline.com/**

World Health Organisation - Ethics and Health

Marie-Charlotte Bouësseau

WHO initiative in Ethics and Health started in 2002, activities involve policy development, capacity strengthening, collection and dissemination of information, and contributions to international debates. At present there are several departments working in research ethics at WHO-HQ as well as regional offices: Research and Training in Tropical Diseases (TDR) with the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER), Initiative for Vaccine

Research (IVR) with UN-AIDS, and the Ethics Review Committee (ERC). In December 2006, the NEBRA project (Networking for Ethics in Biomedical Research in Africa) was completed; based on a consortium of European and African countries and funded by the European Commission; it provided a mapping of research ethics capacities in 15 Sub-Saharan African countries and developed a strategic plan to strengthen ethical review of health research in the region. Following this project WHO is contributing to a number of activities, some of them supported by EDCTP (European and Developing Countries Clinical Trials Partnership) such as Resources in Research Ethics Evaluation for Africa (see: http://www.trree.org/site/en_home.phtml) and various training workshops. WHO's approach in research ethics is to strengthen local capacities, and harmonize regulations, rather than homogenising them, promoting the highest ethical standards of research and respecting local differences and needs.

- World Health Organisation, Ethics and Health **http://www.who.int/ethics/en/**

European Commission, DG Research

Rene Von Schomberg

One of the tasks of the Governance and Ethics Unit of the EU is to assess whether research funded by the EU is consistent with values enshrined in the European Charter. Capacity-building projects funded by the Sixth Framework Programme Research and Technological Development (FP6) include: European and Latin American Ethical Regulation Systems of Biomedical Research (EULABOR); BIONET (21-partner European-Chinese collaboration on ethical governance in the life sciences); European and Developing Countries Clinical Trials Partnership (EDCTP); Genomics and Benefit Sharing with Developing Countries: from Biodiversity to Human Genomics (GENBENEFIT); Networking for Ethics on Biomedical Research in Africa (NEBRA); and the GFBR- Secretariat.

- European Commission DG Research, **http://ec.europa.eu**

European Commission, EGE (European Group of Ethics)

Maurizio Salvi

Recent European Council decisions on European and international policy take into account respect for human rights, democracy and the rule of law. EU policy stresses the importance of HIV/AIDS and the need for pharmaceutical companies to supply affordable medicine. The EU seeks partnership with central Asia, and is developing dialogue with emerging economies like Brazil, India, and China. Twenty three billion has already been devoted to developing countries for a wide range of projects, which includes ethics, and 53 billion will be granted by the Seventh Framework Programme for Research and Technological Development (FP7).

- European Commission, EGE, **http://ec.europa.eu/european_group_ethics**

Council of Europe

Laurence Lwoff

The Council of Europe was established in 1949. It currently has 47 member states. In the field of bioethics, the Council of Europe tries to find the appropriate balance between scientific/medical progress and protection of the human being. Recent documents include the Convention on Human Rights and Biomedicine (Oviedo, 04.04.1997) and the Additional Protocol on Biomedical Research (25.01.2005) which are legally binding once ratified. The former requires ethical review following scientific review. A recommendation addressing research on biological materials is not legally binding. The Council also works on cooperative activities, including the development of RECs, and the development of practical guides.

- Council of Europe, **http://www.coe.int**

Wellcome Trust

Jacob Leveridge

The mission of the Wellcome Trust is "to foster and promote research with the aim of improving human and animal health." The Trust's contribution to research ethics in developing countries and transition societies to date has principally comprised funding for seminars and symposia, most of which have constituted short courses in research ethics in sub-Saharan Africa and the Indian sub-continent. Now there is a shift in focus towards more advanced capacity development, and support for scholarship in ethics research: the Trust will no longer fund basic research ethics training. The Wellcome Trust will provide personal support to PhD students, and project support for studies on research ethics, and smaller ethics research grants. Projects must demonstrate local relevance, have a research component, a normative ethics component and not be purely descriptive.

- Wellcome Trust, **http://www.wellcome.ac.uk**

Fogarty International Center

Barbara Sina

The Fogarty International Center at the US NIH supports the building of research ethics capacity in developing countries. Its International Research Ethics Education and Curriculum Development Award is for training developing country professionals in research ethics theory and practice. Typically, it supports the development of a curriculum and training for 1–2 year Masters or certificate courses. Applications from new regions or areas where NIH has investments in research are encouraged.

- Fogarty International Center, **http://www.fic.nih.gov**

Medical Research Council, UK

Catherine Elliott

The Medical Research Council (MRC) is a government funder of health research in the United Kingdom. This means that the research it funds must be related to UK health, though this includes international research on problems that may impact UK health, e.g., emerging infectious diseases. It provides no direct funding for biomedical ethics, though it has a specific interest in ethical review capacity-building in Africa and advocating for good practice in clinical trials. Currently, the MRC funds two units in Africa; it also provides funding for the Global Forum on Bioethics in Research, and the Networking for Ethics on Biomedical Research in Africa (NEBRA) project.

- Medical Research Council, **http://www.mrc.ac.uk**

Nuffield Council on Bioethics

Hugh Whittall

Founded by the Medical Research Council, Wellcome Trust and the Nuffield Foundation, the Nuffield Council on Bioethics is an independent body which examines ethical questions raised by advances in biology and medicine, with the aim of contributing to policy-making and stimulating debate. The Nuffield Council released a report in 2002, The Ethics of Research Related to Healthcare in Developing Countries, which covers the themes of consent, standards of care, ethical review of research, what happens once the research is over, and strengthening capacity in developing countries.

- Nuffield Council on Bioethics, **http://www.nuffieldbioethics.org**

CIOMS

Gottfried Kreutz

The Council for International Organisations of Medical Sciences (CIOMS) was founded in 1949 after consultation between UNESCO and WHO. It is now a non-governmental organisation with financial assistance from the two parent organisations. CIOMS is concerned with questions of medical nomenclature, medical research ethics, pharmacovigilance and new therapeutic or diagnostic approaches. The objective of CIOMS in the area of medical research ethics is to provide recommendations on ethics in medical research. Its main contributions are the International Ethics Guidelines for Biomedical Research Involving Human Subjects, 2002, and International Ethical Guidelines for Epidemiological Studies, 1991. These latter guidelines are currently being revised.

- CIOMS, **http://www.cioms.ch**

Annex 1

Programme

June 26 (Tuesday)

6:00-08:00 pm.	Registration
8:00 pm.	Reception (hotel)

June 27 (Wednesday)

8:00-8:30 am.	Registration
8:30-9:00 am.	Welcome and Introductory Remarks • Representatives from the Lithuanian Parliament, Ministry of Health, Vilnius University, COHRED/Global Forum
9:00-9:45 am.	Keynote Speeches: Challenges Facing Developing and Transition Countries in Establishing an Effective System of Research Ethics Infrastructure • Florencia Luna • Ruth Macklin
9:45-10:30 am.	Panel Discussion: Regional Perspectives to Keynote Challenges Africa, Douglas Wassenaar - Asia, Xiaomei Zhai - Europe, Eugenijus Gefenas - North America, Rosamond Rhodes - Latin America, Rodrigo Salinas.
	Session 1: **Challenges in Operationalising Research Ethics Review: Establishment, Composition and Organizational Aspects**
10:30-10:45 am.	Introduction to breakout groups by panel discussants
10:45-11:15 am.	Coffee break
11:15 am-12:30 pm.	**Sub-sessions:** Break-out groups discussing issues and cases related to previously introduced challenges. Each group to appoint a rapporteur for feedback to the plenary session at 2:00pm.
Sub-session 1.1. Registration	**Establishing RECs,** Moderator Marie-Charlotte Bouësseau • Should the state aim to establish Regional RECs or Institutional Review Boards? • Composition of RECs: Ratio of scientists/health care professionals/lawyers, profile of lay members.
Sub-session 1.2. Registration	**How to Enhance RECs' Work?** Moderator Carel IJsselmuiden • What national policy instruments can be used to expand REC review to include private and public research? • Are RECs over-regulating research and stifling rather than promoting ethical research? • Financing RECs and reimbursing secretariat and members: Should their service be voluntary, or should they be paid for their contributions?

Sub-session 1.3. Registration	**Relationships Between RECs in multi-center, International Studies – Problems and Solutions,** Moderator Karen J.Hofman • One tier vs. two-tier model of ethical review for multi-center trials: Which is more preferable? • What are the relationship and linkage between RECs from developed and developing countries?
Sub-session 1.4. Registration	**Research Governance – Where Does Ethics Review Fit?** Moderator Rene Von Schomberg • What relationship should there be between RECs and other bodies responsible for regulating research, e.g., between RECs and so-called "competent authorities" (in Europe these are usually state drug agencies that issue approvals for clinical trials)? • Legal status of research protocol review by RECs: Should the approval be legally binding or should it rather serve as a recommendation?
12:30-2:00 pm.	Lunch
2:00-3:15pm.	Feedback and debate at the plenary from break-out groups
	Session 2: **Challenges in Operationalizing Research Ethics Review: Domain and Competencies**
3:15-4:15pm.	**Sub-sessions:** Break-out groups continued. Each group to appoint a rapporteur for feedback to the plenary session at 4:30pm.
Sub-session 2.1. Registration	**Scope of Research Requiring REC Approval,** Moderator Jacob Leveridge • What sorts of studies should be considered by RECs? • How should "research" be defined for the purposes of REC review? • Where is the boundary between clinical research and clinical/managerial quality improvement projects? • How to review social science research (e.g., questionnaires)? • Should student research projects be reviewed by the same process and standards as non-student research?
Sub-session 2.2. Registration	**Challenges and Limitations to Oversight,** Moderator Catherine Elliott • Supervision and oversight of research by RECs: - informed consent process - adverse events - violations of the protocol • Should the domain of RECs include the monitoring of ongoing research?
Sub-session 2.3. Registration	**How and Where to Obtain Specialized Technical Expertise?** Moderator Eugenia Lamas • Should the scientific quality of protocols be part of the domain of a REC, or should this be assigned to another body? • Are RECs competent enough to evaluate insurance and financial contracts of the projects, especially pharmaceutical ones? • How to prevent "rubberstamping" or "bullying" in those cases when RECs do not have much in-house capacity to judge complicated trial protocols?

Sub-session 2.4. Registration	Minimizing Conflicts of Interest, Moderator Matthias Kaiser • How to resolve conflicts between patient care and research interests in cases of clinical trials sponsored by pharmaceutical companies? • How to resolve conflicts in evaluating protocols from sponsors who also contribute to salary? • How to resolve conflicts related to evaluating research projects of colleagues from the same institutions?
4:15-4:30 pm.	Coffee break
4:30-5:30 pm.	Feedback and debate at the plenary from break-out groups
5:30-6.00 pm.	Concluding remarks on Best Practices to Meet Challenges and Build Infrastructure, Robert Baker
6.30 pm.	Dinner at Restaurant "Belmontas"

June 28 (Thursday)

	Session 3: Models for Training in Research Ethics – includes plenary session, poster-sub-session, and concurrent break-out sub-session
8:30-9:00 am.	Plenary Session: Building an Infrastructure Through Training: Best Practices and Lessons Learned from Africa, Asia, Central/Eastern Europe, Latin America Panelists: Clement Adebamowo, Ren-Zong Qiu, Jiri Simek, Mayra Achio
10:00-10:15 am.	Introduction to Best Practices in Training, Martin Strosberg
10:15 am. – 1.00 pm. (including coffee break)	Sub-session 3.1. Best Practices in Training Poster (laptop) Sub-session (market-place format): Demonstrations in Pedagogy, Technology, Content, Resources, Distance Learning, and more
10:15-11:15 am.	Sub-session 3.2. Student Perspectives on Training Programs Panelists: Elizabeth Kwagala, Joanna Rozynska, Dirce Guilhem
1:00-2:30 pm.	Lunch - WHO/UNAIDS report
	Session 4: Ethics of Mental Health Research
2:30-2:40 pm.	Introduction to this session and introduction of plenary speaker, Douglas Wassenaar
2:40-3:00 pm.	Plenary speaker: Rodrigo Salinas
3:00-3:15 pm.	Questions from floor
3:15-4:30 pm.	Break-out groups (four). Moderators: Dafna Feinholz-Klip, Joseph Millum, Dinesh Singh, Athula Sumathipala. Each group to appoint a rapporteur for feedback to the plenary session at 5:00pm. • From the point of view of researchers and research ethics committees, what, if any, are the major ways in which mental illness itself differs from other health problems? • What, if any, are the main ethical implications for research, of the problems with capacity and competence that are likely to be associated with mental disorder?

	• Should there be special precautions and/or procedures for the ethical conduct of research with mentally disordered persons who have diminished capacity and competence? If so, what should these special precautions and procedures be? • Are there any special issues in research on mental disorder that arise in developing country/under-resourced settings? If so, what are these and what additional measures do they require?
4:30-5:00 pm.	Coffee break
5:00-5:45 pm.	Report back from breakaway groups
5:45-6:00 pm.	Discussion from floor & close
6:30 pm.	Tour, concert and dinner at Vilnius University, http://www.vu.lt/lt/

June 29 (Friday)

	Session 5: The Role of International Organizations in Establishing and Supporting Research Ethics Infrastructure and Networking
9:00-11 am.	**Plenary Session.** Panelists representing organizations such as: • Global Forum on Bioethics in Research, Carel IJsselmuiden, Sandra Realpe • WHO, Marie-Charlotte Bouësseau • European Commission DG Research, Rene Von Schomberg • European Commission, EGE, Maurizio Salvi • Council of Europe, Laurence Lwoff • Wellcome Trust, Jacob Leveridge • Fogarty International Center, Barbara Sina • Medical Research Council, Catherine Elliott • Nuffield Council on Bioethics, Hugh Whittall • CIOMS, Gottfried Kreutz
11:00-12:30 pm. (including coffee break)	**Consultation Session** (At this session, individuals may interact directly with the representatives of the international organizations in small break-out groups)
12:30-1 pm.	Conference Wrap-up

Annex 2

Programme with Web Links to PowerPoint Presentations

Programme	Web links to PowerPoint Presentations
Keynote Speeches: Challenges Facing Developing and Transition Countries in Establishing an Effective System of Research Ethics Infrastructure	Florencia Luna, Ruth Macklin http://www.gfbronline.com/PDFs/A%20Florencia-Macklin.ppt
Panel Discussion: Regional Perspectives to Keynote Challenges	Africa - Douglas Wassenaar http://www.gfbronline.com/PDFs/01%20Wassenaar%208GBF%20Africa.ppt Asia - Xiaomei Zhai http://www.gfbronline.com/PDFs/02%20Global%20Forum%20(070627)%20v3.ppt Europe - Eugenijus Gefenas http://www.gfbronline.com/PDFs/03%20Regional%20Perspective%20GF8%20-%20Europe.ppt North America- Rosamond Rhodes http://www.gfbronline.com/PDFs/04%20USA.ppt Latin America - Rodrigo Salinas http://www.gfbronline.com/PDFs/05%20vilnius_rsalinas.pdf
Session 1: Challenges in Operationalizing Research Ethics Review: Establishment, Composition and Organizational Aspects	
Establishing RECs	Marie-Charlotte Bouësseau http://www.gfbronline.com/PDFs/01%20LITUANIA1-1-17-06-07.ppt
How to Enhance RECs' Work?	Carel IJsselmuiden http://www.gfbronline.com/PDFs/02%20What%20can%20make%20REC%20function%20better.pdf
Relationships between RECs in Multi-center, International Studies - Problems and Solutions	Karen J.Hofman http://www.gfbronline.com/PDFs/03%20Group%201.3%20discussion.ppt
Research Governance - Where Does Ethics Review Fit?	Rene Von Schomberg http://www.gfbronline.com/PDFs/04%20Research%20Governance.ppt

Session 2: Challenges in Operationalizing Research Ethics Review: Domain and Competencies

Scope of Research Requiring REC Approval	Jacob Leveridge http://www.gfbronline.com/PDFs/01%20group%202.1%20what%20should%20RECs%20review.ppt
Challenges and Limitations to Oversight	Catherine Elliott http://www.gfbronline.com/PDFs/02%20oversight%20function%20of%20REC.ppt
How and Where to Obtain Specialised Technical Expertise?	Eugenia Lamas http://www.gfbronline.com/PDFs/03%20SESSION%202_MAREK%20_2_.pdf
Minimising Conflicts of Interest	Matthias Kaiser http://www.gfbronline.com/PDFs/04%20group%202.4%20Conflicts%20of%20interest.ppt

Session 3: Models for Training in Research Ethics - includes plenary session, poster-sub-session, and concurrent break-out sub-session

Plenary Session: Building an Infrastructure through Training: Best Practices and Lessons Learned from Africa, Asia, Central/Eastern Europe, Latin America	Africa - Clement Adebamowo http://www.gfbronline.com/PDFs/01%20Building%20an%20infrastructure%20through%20training%20GFB%20Vilnius%2007.ppt
	Asia - Ren-Zong Qiu http://www.gfbronline.com/PDFs/02%20Vilnius070628final.ppt
	Eastern Europe - Jiri Simek http://www.gfbronline.com/PDFs/03%20Building%20an%20Infrastructure95.ppt
	Latin America - Mayra Achio http://www.gfbronline.com/PDFs/04%208%20global%20forum-Mayra%20Achio.ppt

Session 4: Ethics of Mental Health Research

Plenary speak: Ethics of Mental Health Research	Rodrigo Salinas http://www.gfbronline.com/PDFs/A-%20Salinas.pdf
Breakout Groups	Group 1 http://www.gfbronline.com/PDFs/01%20mental%20health%20group%201.ppt
	Group 2 http://www.gfbronline.com/PDFs/02%20Ethics%20of%20Mental%20Health%20Research_Group%202%20report_Joe.pdf
	Group 3 http://www.gfbronline.com/Presentations/03%20Ethics%20of%20Mental%20Health%20Research.ppt
	Group 4 http://www.gfbronline.com/PDFs/04%20%20liz-session%20mental%20health.ppt

Session 5: The Role of International Organizations in Establishing and Supporting Research Ethics Infrastructure and Networking

Global Forum on Bioethics in Research	Carel IJsselmuiden, Sandra Realpe http://www.gfbronline.com/PDFs/01PresentationGFBR8Vilnius.ppt
World Health Organisation	Marie-Charlotte Bouësseau http://www.gfbronline.com/PDFs/02%20GFBR%20Vilnius_marie-charl.ppt
European Commission DG Research	Rene Von Schomberg http://www.gfbronline.com/PDFs/03%20vilnius2.ppt
European Commission, EGE	Maurizio Salvi http://www.gfbronline.com/Presentations/04%20salvi-vilnious-short.ppt
Council of Europe	Laurence Lwoff http://www.gfbronline.com/PDFs/05%20COE%208thG.%20Forum.ppt
Wellcome Trust	Jacob Leveridge http://www.gfbronline.com/PDFs/06%20jacob_session5.ppt
Fogarty International Center	Barbara Sina http://www.gfbronline.com/PDFs/07%20B.sina.ppt
Nuffield Council on Bioethics	Hugh Whittall http://www.gfbronline.com/PDFs/08%20hw%20-Nuffield.ppt
Council for International Organizations Of Medical Sciences	Gottfried Kreutz http://www.gfbronline.com/PDFs/09_%20CIOMS.ppt

Annex 3

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