



Background and rationale

Research in developing countries is going to become increasingly important in order to solve urgent health problems. As a consequence, it is necessary to strengthen research ethics review capacities in these countries. TDR, WHO, and UNAIDS have all launched a number of initiatives aimed at strengthening such capacities for ethics review. Most notable is the recently proposed operational guidelines for ethics committees reviewing biomedical research. The aim of these guidelines is to provide guidance for ethics committees concerning appropriate operating procedures. It is, however, recognized that this can only be a first, necessary step, and that the most crucial part is capacity building, both among researchers and among research ethics committee members. The proposed course is an attempt to begin that process.

Course format

The course will to a large extent be organized as interactive learning, where the students will work on a number of problem cases which illustrate the main points made in a few introductory lectures. It will be a one week intensive course. Comprehensive background material will be provided to the students ahead of the course week.

Target groups

Target participants are postgraduate students and researchers in biomedical and health sciences and members of research ethics committees.

Objectives

The course participants will be provided with an overview of current research ethics, focusing on the ethics of clinical research. Topics to be covered include the structure, roles, and functions of research ethics committees, informed consent, evaluation of risks and benefits, inducements, and the special issues in research in developing countries.

The course will also cover behavioral and epidemiological research as well as issues of research integrity. The course participants will learn about where there is consensus and where there is controversy in today's research ethics, and will learn how to handle areas of controversy.

Course organizers

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Consultants

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Prof. Dr. Reidar K. Lie

Professor of Philosophy, University of Bergen, Norway

Resource persons

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Institute of Philosophy, University of Bergen, Norway

Prof. Dr. Kenji Matsui

Center for Biomedical Ethics and Law, University of Tokyo, Japan

Prof. Dr. Cristina E. Torres

FERCAP, WHO-TDR Clinical Coordination and Training Center (CCTC), (Rangsit Campus), Pathumthani, Thailand

Assoc. Prof. Dr. Soraj Hongladarom

Faculty of Arts, Chulalongkorn University, Bangkok, Thailand

Maj. Gen. Dr. Aphornpirom Ketupanya

FERCAP and FERCIT, Thailand

Dr. Sanga Intarajak

Chiangrai General Hospital, Chiangrai, Thailand

Venue and accommodation

Conference Room, 9th Floor, Piyachart Building, Thammasat University (Rangsit Campus), Pathumthani, Thailand

Course Fees:

Foreign Participants:

300 USD (includes course materials, coffee/tea breaks, lunch, and accommodation in the university campus during the training period).

Thai Participants:

1,500 THB (includes course materials, coffee/tea breaks, and lunch during the training period).

The number of participants is limited to a maximum of 30.

COURSE OUTLINE

5 October 2009

08:00 Registration of the participants

08:30 Welcome address:

Reidar K. Lie, University of Bergen, Norway

09:00 Inaugural session:

Introduction to the workshop. Presentation of participants

Reidar K. Lie, University of Bergen, Norway

09:45 ***Reidar K. Lie: Introduction to research ethics. Historical background.***

Ethical principles

10:30 Coffee/Tea break

11:00 ***Soraj Hongladarom: Informed decision making***

11:30 ***Reidar K. Lie: Empirical research on informed consent***

12:00 Lunch

13:00 Group work

14:30 Coffee/Tea break

15:00 Plenary discussion

15:30 ***Cristina E. Torres: Roles and functions of research ethics committees***

16:00 ***Cristina E. Torres. Ethics issues in social science research***

16:30 End of day one

6 October 2009

- 09:00 *Reidar K. Lie: Evaluation of risks and benefits*
- 09:45 Group work
- 10:30 Coffee/Tea break
- 11:30 Plenary discussion
- 12:00 Lunch
- 13:00 *Kenji Matsui: Ethical issues in research on stored tissue samples*
- 13:45 Group work
- 15:00 Coffee/Tea break
- 15:30 Plenary discussion
- 16:00 *Aphornpirom Ketupanya: Ethical issues in genetics research*
- 16:30 End of day two

7 October 2009

- 09:00 *Reidar K. Lie: Relationship between advisor/student. Authorships and publications. Research integrity. Plagiarism*
- 09:45 Group work
- 10:30 Coffee/Tea break
- 11:30 Plenary
- 12:00 Lunch
- 13:00 *Sanga Intarajak: Inducements*
- 13:30 Group work
- 14:30 Coffee/Tea break
- 15:00 Plenary discussion
- 15:30 End of day three

8 October 2009

- 09:00 *Reidar K. Lie: Ethical issues in international collaborative research*
- 10:00 Group work
- 11:30 Coffee/Tea break
- 11:00 Plenary discussion
- 12:00 Closing of training and course test