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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Prof. Dr. Reidar K. Lie  
Professor of Philosophy, University of Bergen, Norway

**Consultants**

Prof. Dr. Vithoon Viyanant  
Dean, Faculty of Allied Health Sciences (FAHS), Thammasat University (Rangsit Campus), Pathumthani, Thailand

Prof. Dr. Reidar K. Lie  
Professor of Philosophy, University of Bergen, Norway

**Resource persons**

Prof. Dr. Reidar K. Lie  
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