6th Nagasaki International Course on Research Ethics
July 9-11, 2007
Institute of Tropical Medicine (NEKKEN), Nagasaki University
Nagasaki, Japan

Organized by
Nagasaki Forum on Medical Research Ethics
In cooperation with
Nagasaki University, University of Bergen, NIH of USA, University of Tokyo, Forum for Ethical Review Committee members in Asia and Pacific regions (FERCAP) and WHO

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 format
The course is 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 three day intensive course. English is a common language in the course but all the lecturers and tutors will take care the communication within the participants whose English is a second language.

Target groups
Ph.D. students in health sciences, researchers, members of research ethics committees, Undergraduate students at medical and health sciences.

Teaching Staffs
Course Coordinators : Reidar Lie (Bergen Univ., NIH), Kenji Matsui (University of Tokyo), Kenji Hirayama (NEKKEN, Nagasaki Univ.)
Lecturer : Reidar Lie (Bergen Univ. Norway), Hidefumi Nakamura (National Center for Child Health and Development), Young Mo Koo (Ulsan University), Ki-ichirou Tsutani (Univ Tokyo), Kenji Matsui (University of Tokyo), Shimon Tashiro (JSPS), Kenji Hirayama (NEKKEN, Nagasaki Univ.)

Venue
Pompe Hall, Sakamoto Campus, Nagasaki University
1-12-4 Sakamoto, Nagasaki 852-8523

Application:
We have closed applications. Thank you for many applications.
Please send your name, affiliation, E-mail address, necessity of accommodation arrangement by E-mail to
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Tuition Fee: 10,000JPY (does not include meals, accommodations, and travel)
Undergraduate and post-graduate students are free of charge.

COURSE OUTLINE

July 9, 2007

9:00 Inaugural session:
Introduction to the workshop. Presentation of participants

9:30 *Framework for research ethics*
Reidar K. Lie
One could argue that modern research ethics started in the mid 1960s with the documentation of some serious cases of research abuse in the US and other countries. A classic article is the one published by Beecher in 1966, although this article was in part based on cases brought forward by Pappworth in the UK. The public discussion following these publications led to the introduction of research ethics committees in the US and the UK, and subsequently in other countries. The aim of this section is to let the participants get a feel for the types of cases that led to the development of current research ethics guidelines, such as the Helsinki Declaration and the CIOMS guidelines..

10:15 Coffee/Tea

10:45 *Informed Consent*
Kenji Matsui
This section will discuss what is informed consent, why it is needed. It will make a distinction between the informed consent process and the signature on the informed consent form. Examples of deficiencies in informed consent forms (incomplete, misleading, too technical). Informations usually required to be covered in the informed consent process. Overviews will be provided on exceptions to informed consent requirements, and how to deal with persons with limited capacity to consent. Emphasis will also be on cross-cultural concerns.

11:30 Group work

13:00 Lunch

13:45 Presentation of group work

14:30 Evaluation of risks and benefits.
Reidar K. Lie
Types of risks and benefits. Inconvenience vs. risk. Benefits to participants vs.

benefits to others. Evaluations of risks and benefits when starting a study vs. evaluation of risks and benefits during the study. Reasons for discontinuation of a study.

15:00 Group work
16:30 Presentation of group work.
17:30 End of day one

July 10, 2007

9:00 Research on children or vulnerable persons: Hidefumi Nakamura
9:45 Plenary discussion. Evaluation of risks and benefits in children. Break.
10:30 Coffee/Tea
11:30 Reidar K. Lie: Researched on stored tissue samples
12:30 Lunch
13:15 Shimon Tashiro. Distinction between research and therapy.
13:45 Young Mo Koo: IRB on clinical trials.
WHO *Operational Guidelines for Ethics Committees Reviewing Biomedical Reseach*
The operation of the Asan Medical Center IRB, Seoul, KOREA
14:15 Kiichiro Tsutani Pharmacogenomics genetics and ethics.
15:15 Group work. Break
16:00 Presentation of group work
16:30 Kenji Hirayama. Ethical considerations in the community based study
17:00 End of day two

July 11, 2007

9:00 Issues in international research ethics. Reidar K. Lie.
Is it permissible to carry out a trial in a developing country, but not in a developed country, or can one permit differences in trial design. Specifically, the controversy over level of care will be discussed, as well as the the best proven and highest attainable standards. Is there a responsibility to ensure the availability of the product being tested after the trial? What options are there for facilitating access to the investigational drugs and vaccines after the trial? What are the strengths and weaknesses of the various options? In particular, the Thai experience with the phase III HIV vaccine trial will be examined

10:00 Mock IRB
11:15 Plenary discussion
12:00 Presentation of certificates
End of day three