9th Nagasaki International Course on Research Ethics

June 28 - 30, 2010
Institute of Tropical Medicine (NEKKEN), Nagasaki University
Nagasaki, Japan

Organized by
Nagasaki Forum on Medical Research Ethics,

In cooperation with
Institute of Tropical Medicine, Nagasaki University,
The University of Bergen, National Institutes of Health (NIH) of USA, The University of Toyama Center for Clinical Ethics, The University of Tokyo, National Center for Child Health and Development, Showa University, The Forum for Ethical Review Committees in Asia and the Western Pacific Region (FERCAP), and The Special Programme for Research and Training in Tropical Diseases (TDR), Nagasaki University Global COE Program

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. 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** (Center for Clinical Ethics, Toyama Univ.), **Kenji Hirayama** (Nekken, Nagasaki Univ.)
Lecturers : Reidar Lie (Bergen Univ., Norway; NIH, USA), Kenji Matsui (Toyama Univ.), Shimon Tashiro (Tokyo Univ.), Ki-ichirou Tsutani (Tokyo Univ.), Nao Tsuchida (National

Center for Child Health and Development), Eiji Uchida (Showa Univ.), Young-Mo Koo (Univ. of Ulsan College of Medicine, Korea), Kenji Hirayama (Nekken, Nagasaki Univ.)
Facilitator: Hiroshi Satoh (Niigata University Medical and Dental Hospital), Hiroaki Yanagawa (Tokushima University Hospital), Hanako Mihara (Center for Cancer Control and Information Services National Cancer Center), Massie Ikeda (School of Medicine, Nagasaki University)

Venue
Pompe Hall in Sakamoto Campus, Nagasaki University

Application:
Please send your name, affiliation, E-mail address, necessity of accommodation arrangement by E-mail to Ms. Junko Hayashima, and CC to Prof. Kenji Hirayama.

Ms. Junko Hayashima
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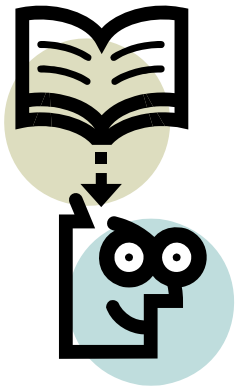
Tuition Fee: Free of charge (does not include meals, accommodations, and Travel)



COURSE OUTLINE

June 28 (Mon), 2010

9:00-9:30 Inaugural session: *Kenji Hirayama & Reidar K. Lie*
Introduction to the workshop. Presentation of participants

9:30-10:15 **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..

10:15-10:45 Coffee/Tea

10:45-11:30 **Informed Consent**
Reidar K. Lie
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). Information usually required to be covered in the informed consent process. Overviews will be provided on exceptions to informed consent requirements. Emphasis will also be on cross-cultural concerns.

11:30-12:30 Group work: informed consent

12:30-13:30 Lunch

13:30-14:15 Presentation of group work

14:15-15:00 **Difference between research and clinical care & ethics of innovative therapy**
Shimon Tashiro
Researchers as well as research subjects often consider research as a part of clinical care. This misconception sometimes leads to ethical conflicts and problems. This section will discuss how a research activity is different from a clinical practice, and why understanding of such distinction is ethically important both for researchers and research subjects.

15:00-15:30 Coffee/Tea

15:30-16:00 **IRB regulations regarding clinical trials in Japan**
Eiji Uchida

16:00-16:45 **Clinical trials and placebo & Acceptance of placebo**
Ki-ichiro Tsutani

16:45 End of the day one

June 29 (Tue), 2010

9:00-9:45 **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.

9:45-10:10 **Research on children: what are special concerns for pediatric research?**
Nao Tsuchida

10:10-10:25 Coffee/Tea

10:25-11:00 **Ethics of research on children and vulnerable subjects**
Reidar K. Lie

11:00-12:00 Group work: Evaluation of risks and benefits in children

12:00-12:30 Presentation of group work

12:30-13:30 Lunch

13:30-14:15 **Ethics on research with stored samples**
Reidar K. Lie & Kenji Matsui

14:15-15:15 Group work: stored sample

15:15-15:45 Coffee/Tea & group photo

15:45-16:15 Presentation of group work

16:15-16:45 **Conflict of interest in clinical research**
Young-Mo Koo

16:45-17:10 **Ethical considerations in the community based study**
Kenji Hirayama

17:10 End of the day two

June 30 (Wed), 2010

9:00-9:45 **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 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?

9:45-10:15 Plenary discussion

10:15-10:45 Coffee/Tea

10:45-12:00 **Mock IRB**
Reidar K. Lie

12:00- Presentation of certificates
Reidar K. Lie & Kenji Hirayama

End of the course