The10th Nagasaki International Course on Research Ethics

July 7 - 9, 2011
Pompe Hall in Sakamoto Campus, Nagasaki University, Nagasaki, Japan

Organized by
Institute of Tropical Medicine (NEKKEN), Nagasaki University
Nagasaki, Japan

In cooperation with
The University of Bergen, National Institutes of Health (NIH) of USA, The University of Toyama Center for Clinical Bioethics, The University of Tokyo, National Center for Child Health and Development, Showa University, Tokushima University Hospital, The Forum for Ethical Review Committees in Asia and the Western Pacific Region (FERCAP), The Special Programme for Research and Training in Tropical Diseases (TDR) and
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 K. Lie (Bergen Univ. & U.S. NIH), Kenji Matsui (Center for Clinical Bioethics, Toyama Univ.), Kenji Hirayama (Nekken, Nagasaki Univ.)

Lecturers : Reidar Lie (Bergen Univ. & U.S. NIH), David Wendler (U.S. NIH), Seema Shah (U.S. NIH), Kenji Matsui (Toyama Univ.), Shimon Tashiro (Tokyo Univ.), Hidefumi Nakamura (National Center for Child Health and Development), Eiji Uchida (Showa Univ.), Kiichiro Tsutani (Tokyo Univ.), Hiroaki Yanagawa (Tokushima University Hospital), Kenji Hirayama (Nekken)

Other Mentors: Hiroshi Sato (Niigata Univ.), Hanako Mihara (Abbott Japan Co., LTD)

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)

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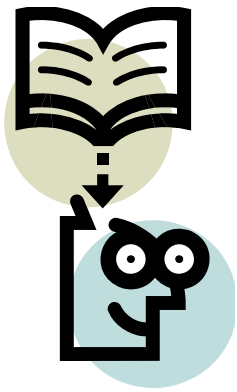

COURSE OUTLINE

July 7 (Thu), 2011

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**
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). 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 **Distinction between research and practice**
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 concerning clinical trials in Japan**
Eiji Uchida

16:00-16:45 **Issues on placebo use in clinical trial**
Kiichiro Tsutani

16:45 End of the day one

July 8 (Fri), 2011

9:00-9:45 **Ethics on research with stored samples**
David Wendler & Kenji Matsui

9:45-10:45 Group work: stored sample

10:45-11:00 Coffee/Tea

11:00-11:30 Presentation of group work

11:30-12:20 **Evaluation of risks and benefits**
David Wendler
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.

12:20-13:10 Lunch

13:10-13:20 Group photo

13:20-13:50 **Practical concerns for pediatric research** *(tentative title)*
Hidefumi Nakamura

13:50-14:30 **Ethics of research on children**
Seema Shah

14:30-15:30 Group work: Evaluation of risks and benefits in children

15:30-15:45 Coffee/Tea

15:45-16:15 Presentation of group work

16:15-16:50 **Ethics reviews and education: an example model at Tokushima University Hospital** *(tentative title)*
Hiroaki Yanagawa

16:50-17:15 **Ethical considerations in community based study**
Kenji Hirayama

17:15 End of the day two

July 9 (Sat), 2011

9:00-9:45 **Ethical issues in international research**
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