8th Nagasaki International Course on Research Ethics

June 29 - July 1, 2009
Institute of Tropical Medicine (NEKKEN), Nagasaki University
Nagasaki, Japan

Organized by
Nagasaki Forum on Medical Research Ethics,

In cooperation with
The University of Bergen, National Institutes of Health (NIH) of USA, Nagasaki University, The University of Tokyo Center for Biomedical Ethics and Law (UT-CBEL), 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)

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 (The University of Tokyo Center for Biomedical Ethics and Law), Kenji Hirayama (Nekken, Nagasaki Univ.)
Lecturers : Reidar Lie (Bergen Univ., NIH), Kenji Matsui, Shimon Tashiro (The University of Tokyo), Ki-ichirou Tsutani (The University of Tokyo), Hidefumi Nakamura (National Center for Child Health and Development), Eiji Uchida (Showa Univ.),
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. June 15(Mon), 2009.
Application deadline: **June 19(Fri), 2009.**

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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

June 29 (Mon), 2009

9:00-9:30 Inaugural session: *Kenji Hirayama*
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, and how to deal with persons with limited capacity to consent. Emphasis will also be on cross-cultural concerns.

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

12:30 -13:30 Lunch

13:30-14:00 Presentation of group work

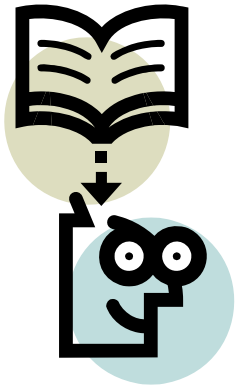
14:00-14:45 Ethical considerations in the community based study
Kenji Hirayama

14:45-15:15 Coffee/Tea

15:15-16:00 Difference between research and clinical care, ethics of innovative therapy
Shimon Tashiro

16:00-16:45 Placebo and ethics
Ki-ichirou Tsutani

16:45 End of day one



June 30 (Tue), 2009

9:00-9:30 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.

9:30-10:00 Research on children
Hidefumi Nakamura

10:00-10:30 Coffee/Tea

10:30-11:30 Group work: Evaluation of risks and benefits in children

11:30-12:00 Presentation of group work

12:00-13:00 Lunch

13:00-14:00 Ethics on research with stored samples
Kenji Matsui

14:00-15:00 Group work: stored sample

15:00-15:30 Coffee/Tea & group photo

15:30-16:00 Presentation of group work

16:00-16:45 IRB regulations regarding clinical trials in Japan
Eiji Uchida

16:45 End of day two

July 1 (Wed), 2009

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 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

12:00- Presentation of certificates
Reidar K. Lie

End of day three