



## The 13<sup>th</sup> Nagasaki International Course on Research Ethics

Pompe Hall in Sakamoto Campus, Nagasaki University, Nagasaki, Japan

8-10 May 2014

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

In cooperation with

National Cerebral and Cardiovascular Center, University of Tokyo, National Center for Child Health and Development, Showa University, Tokushima University Hospital, Forum for Ethical Review Committees in Asia and the Western Pacific Region (FERCAP), Strategic Initiative for Developing Capacity in Ethical Review (SIDCER), and Nagasaki University Leadership Program.

### Course description

This international course is an overview of research ethics, focusing on the ethics of health research. This course will cover the following: a) historical background, principles, and guidelines of research ethics; b) structure, roles, and functions of research ethics committees; c) ethical considerations in health research such as those related to informed consent, conflict of interest, and risk and benefit evaluation; and d) ethical issues and methodologies in different health research fields (genetics research, epidemiological and social research, pediatric research; and traditional medicine research) in the context of national, regional, and international collaborative research.

### Course objectives

The general objectives of this course are: a) demonstrate a common understanding of the ethical principles in health research and b) utilize the ethical principles in reviewing different considerations and issues related to various health research fields.

### Course format

This 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 the lectures and presentations. It will be a three-day intensive course. English is a common language in the course, however, the lecturers and mentors are able to communicate in other 5 languages, *i.e.* Japanese, Filipino, Thai, Korean and Spanish. Comprehensive background materials will be provided to the participants.

## Course participants

The target participants for this course are postgraduate students and researchers in biomedical sciences (including health social sciences) and members of research ethics committees.

## Course organizers

Prof. Dr. Juntra Karbwang

Professor and Head, Product Development, NEKKEN, Nagasaki University

Prof. Dr. Hitoshi Sasaki

Professor and Head, Nagasaki University Hospital Pharmacy

Prof. Dr. Kenji Hirayama

Professor and Head, Immunogenetics, NEKKEN, Nagasaki University

## Faculty

*Lecturers:* Vichai Chokvivat (SIDCER), Eiji Uchida (Showa University), Kiichiro Tsutani (University of Tokyo), Cristina Torres (FERCAP-Philippines), Young- Mo Koo (FERCAP-South Korea), Nao Tsuchida (National Center for Child Health and Development), Hiroaki Yanagawa (Tokushima University Hospital), Akiko Matsuyama (Nagasaki University), Kenji Hirayama (Nagasaki University) and Juntra Karbwang (Nagasaki University)

*Other Mentors:* Hiroshi Sato (Niigata University), Hanako Mihara (Abbott Japan Co., Ltd)

## Course venue

Pompe Hall in Sakamoto Campus, Nagasaki University

## Course fee

Free to all participants (meals, accommodation, and travel are not included).

The course is financially supported by the Institute of Tropical Medicine (NEKKEN) and SIDCER to facilitate the ethical conduct of research for health.

## Application

Please send your name, affiliation, e-mail address, accommodation arrangement by e-mail to Ms. Junko Hayashima and cc to Prof. Dr. Kenji Hirayama.

### Ms. Junko Hayashima

Course Office Staff

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### Prof. Dr. Kenji Hirayama

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## Course outline

### First Day

May 8 (Thursday)

08:45 ***Inaugural session***

Facilitators: Juntra Karbwang, Hitoshi Sasaki, Kenji Hirayama

Introduction to the workshop

Presentation of participants

09:15 ***Introduction to research ethics:***

***History and the need of ethical review system***

Vichai Chokvivat (SIDCER)

10:00 Coffee/Tea break

10:30 ***Roles and functions of research ethics committees***

Eiji Uchida (Showa University, Japan)

11:15 ***Informed consent***

Cristina Torres (FERCAP-Philippines)

12:00 Lunch

13:00 ***Conflict of interest***

Young Mo Koo (FERCAP-South Korea)

13:30 ***Risks and benefits evaluation***

Hiroaki Yanagawa (Tokushima University Hospital)

14:15 Coffee/Tea break

14:30 ***Case Study 1: Group discussion***

Facilitators: Vichai Chokvivat, Cristina Torres, Eiji Uchida, Young Mo Koo, Hiroshi Sato, Hanako Mihara, Akiko Matsuyama, Kenji Hirayama, Juntra Karbwang

15:30 ***Case Study 1: Reporting and Plenary discussion***

Moderators: Vichai Chokvivat, Cristina Torres

17:00 End of day one

**Second Day**  
**May 9 (Friday)**

09:00 ***Ethical issues in pharmacogenomics research***

Kenji Hirayama (Nagasaki University Japan)

09:45 ***Ethical issues in traditional medicine research***

Kiichiro Tsutani (University of Tokyo, Japan)

10:30 Coffee/Tea break

11:00 ***Ethical issues in pediatric research***

Nao Tsuchida (National Center for Child Health and Development, Japan)

12:00 Lunch

13:00 ***Ethical issues in epidemiological and social research***

Cristina Torres (FERCAP-Philippines)

14:00 ***Case Study 2: Group discussion***

Facilitators: Kiichiro Tsutani, Cristina Torres, Kenji Hirayama, Akiko Matsuyama, Fabio Zicker, Young Mo Koo, Hiroshi Sato, Hanako Mihara, Juntra Karbwang

15:00 Coffee/Tea break

15:30 ***Case Study 2: Reporting and Plenary discussion***

Moderators: Akiko Matsuyama, Cristina Torres

17:00 End of day two

**Third Day**  
**May10 (Saturday)**

09:00 ***Ethical issues in international health research:***

***Study design, informed consent, level of care, post trial benefit***

Akiko Matsuyama (Nagasaki University)

Cristina Torres (FERCAP-Philippines)

10:15 ***Quality improvement in Ethical Review***

Juntra Karbwang (Nagasaki University, Japan)

10:30 Coffee/Tea break

10:30 ***Plenary discussion***

Moderators: Akiko Matsuyama, Cristina Torres, Juntra Karbwang

12:00 ***Presentation of certificate***

Juntra Karbwang, Kenji Hirayama

**End of the course**