





## The 12<sup>th</sup> Nagasaki International Course on Research Ethics

## Pompe Hall in Sakamoto Campus, Nagasaki University, Nagasaki, Japan 7-9 July 2013

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

In cooperation with

The Tropical Disease Research (WHO/TDR), University of Tokyo, National Center for Child Health and Development, 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 Program for Nurturing Global Leaders in TECD.

#### **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**

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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: Fabio Zicker (WHO/TDR, Geneva, Switzerland), 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 (Sanofi Pasteur KK)

#### Course venue

Pompe Hall in Sakamoto Campus, Nagasaki University

#### **Course fee**

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

The course is financially supported by National Program to support the specific academic community of the Institute of Tropical Medicine (NEKKEN), Nagasaki University program for nurturing global leaders in tropical and emerging infectious diseases 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.

Registration deadline: June 21 (Fri), 2013

#### Ms. Junko Hayashima

Course Office Staff

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#### Prof. Dr. Kenji Hirayama

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#### **Course outline**

#### First Day July 7 (Sunday)

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
	Fabio Zicker (WHO/TDR, Switzerland)
10:00	Coffee/Tea break
10:30	Roles and functions of research ethics committees
	Cristina Torres (FERCAP-Philippines)
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
	ators: Fabio Zicker, Cristina Torres, Young Mo Koo, Hanako Mihara, Akiko Matsuyama rama, Juntra Karbwang
15:30	Case Study 1: Reporting and Plenary discussion
	Moderators: Fabio Zicker, Cristina Torres
17:00	End of day one

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#### **Second Day**

### July 8 (Monday)

09:00	Ethical issues in human genome research	
	Kenji Hirayama (Nagasaki University Japan)	
09:45	Ethical issues in pediatric research	
	Nao Tsuchida (National Center for Child Health and Development, Japan)	
10:30	Coffee/Tea break	
11:00	Ethical issues in traditional medicine research	
	Kiichiro Tsutani (University of Tokyo, Japan)	
12:00	Lunch	
13:00	Ethical issues in epidemiological and social research	
	Cristina Torres (FERCAP-Philippines)	
14:00	Case Study 2: Group discussion	
	tors: Kiichiro Tsutani, Cristina Torres, Kenji Hirayama, Akiko Matsuyama, Fabio Zicker, 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	
<u>Third Day</u> July 9 (Tuesday)		

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
11:00	Plenary discussion
	Moderators: Akiko Matsuyama, Cristina Torres, Juntra Karbwang
12:00	Presentation of certificate
	Juntra Karbwang, Kenji Hirayama
	End of the course

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