

# **PROPOSED NATIONAL FORUM OF ETHICS REVIEW COMMITTEES**

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# OUTLINE OF PRESENTATION

- ▣ Background on health research ethics in the Philippines
- ▣ Situationer and identified needs
- ▣ Proposed national health research ethics forum

# BACKGROUND

- ▣ Advancements in science and technology in the 1970s have made biomedical research involving human participants a necessity in order to determine the efficacy and safety of new discoveries.
- ▣ Ethical issues involving the rights, safety, and protection of research participants emerged and these brought about the formulation of international guidelines in addition to the Nuremberg Code of 1949 and the Helsinki Declaration of 1964.

# BACKGROUND

- ▣ National Ethics Committee (NEC)
  - ▣ created in 1984 (DOST-PCHRD Special Order No. 84-053) to ensure that all health research and development proposals conformed with ethical standards
  - ▣ for several years conducted initial review for researches done in institutions without a functional research ethics review committee
- ▣ In 2003, the Philippine National Health Research System (PNHRS) led to the creation of the Philippine Health Research Ethics Board (PHREB).

# Philippine Health Research Ethics Board (PHREB)

- ▣ National policy-making body on health research ethics

- ▣ Mandates:

Formulation of guidelines:

- ethical conduct in health research
- establishment and management of ERCs

Monitoring performance of ERCs

Providing advice related to ethical issues in human health research

# Ethics Review Committees

The Ethics Review Committees include:

- ▣ Cluster Ethics Review Committees
- ▣ Institutional Ethics Review Committees

# Cluster Ethics Review Committees (CERCs)

- ▣ Several institutions may form a common ethics review committee if it is not feasible to form their own committees.
- ▣ The management of CERCs and its areas of responsibility should be covered by a memorandum of agreement among the involved institutions.
- ▣ The CERC's functions shall be similar to that of an institutional ethics review committee.

# Institutional Ethics Review Committees (IERCs)

- ▣ Philippine institutions that engage in biomedical and behavioral research shall **establish an IERC which shall provide independent, competent, and timely review of the ethics of proposed studies.**
- ▣ Main purpose of the IERC: to help “**safeguard the dignity, rights, safety, and well-being of all actual or potential human participants**” (WHO Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000)
- ▣ “in its composition, procedures, and decision-making, the IERC shall be **independent of political, institutional, professional, and market influences**” (WHO Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000)



# Institutional Ethics Review Committees (IERCs)

- ▣ Consider both the scientific and ethical aspects of the proposed research even when the IERC is distinct from the technical review committee (Council for International Organizations of Medical Sciences)
- ▣ Responsible for “acting in the full interest of potential research participants and affected communities, taking into account the interests and needs of the researchers, and having due regard for the requirements of relevant regulatory agencies and applicable laws” (WHO Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000)

# Institutional Ethics Review Committees (IERCs)

- ▣ In the Philippines, the regulatory agencies include PNHRS-PHREB, DOH-FDA, and the National Committee on Biosafety.

# PHREB and ICH-GCP

- ▣ National guidelines on clinical trials adhere to ICH-GCP principles.
- ▣ PHREB requirements for ERCs parallel ICH-GCP standards.
  - ERC registration/recognition/accreditation
- ▣ At present, ensuring ICH-GCP compliance is institution-based or sponsor-led.
  - UPM-NIH, UPM-CM and RITM - FERCAP survey and recognition
  - Sponsor-initiated capacity building for IRBs towards recognition

# NATIONAL POLICIES

## DOST AO 001 Series 2007

1. **All institutions that conduct health research** are urged to establish **review committees** that shall be in charge of ethical evaluation and monitoring of research involving human participants. The composition and procedures must be in compliance with the guidelines in the *2006 National Ethical Guidelines for Health Research* (DOST-PCHRD).
2. **All research protocols** for the conduct of biomedical and behavioral researches involving human subjects shall be submitted to **ethics review committees** for coordination, comment, guidance, and approval.

# **NATIONAL POLICIES**

**CHED Memo 34 Series of 2007**

(Endorsement of DOST AO 001, Series 2007)

**DOST AO 001 Series of 2008**

Subject: Registration of all Ethics Committees at the  
PHREB

# SITUATIONER

- ▣ Data from a survey of local institutions conducted by the PNHRS TWG on Ethics (2003-04) show that only 50% of these institutions have an IERC (Reyes, 2004).
- ▣ Of the 80 reported IERCs in the country, almost half (36) are in the National Capital Region.
- ▣ Lack of training in research ethics was cited as a major concern of many IERCs.
- ▣ DOST-PCHRD, DOH, UPM-NIH and UP Fogarty Group organize training courses in research ethics.

# CAPACITY BUILDING IN HEALTH RESEARCH ETHICS IN THE PHILIPPINES

- ▣ DOST-PCHRD – for Regional Health Research and Development Councils
- ▣ DOH – for Centers for Health Development and Regional Medical Centers
- ▣ UPM-NIH Training Center for Research Ethics and Good Clinical Practice
- ▣ UP-Fogarty Group
- ▣ Academic/research institutions
- ▣ Sponsors

# UPM-NIH TRAINING CENTER FOR HEALTH RESEARCH ETHICS AND GOOD CLINICAL PRACTICE

- ▣ Short courses regularly offered since 2005
- ▣ Collaboration with FERCAP, DOST-PCHRD, DOH, academic/research institutions, sponsors
- ▣ Target groups: investigators/researchers, IRB members, research coordinators, sponsors, regulatory authorities
- ▣ Courses offered:
  - Principles of research ethics and good clinical practice
  - Standard operating procedures for IRBs
  - Health research methodologies and research ethics



# UPM-NIH TRAINING CENTER FOR HEALTH RESEARCH ETHICS AND GOOD CLINICAL PRACTICE

Geographic Distribution  
of Ethics Review Committees  
with members participating  
in UPM-NIH training courses

Number of trainings: 42  
Number of trainees: 1474  
IRBs represented: 49  
(30 govt/19 private)



# INITIATIVES FOR QUALITY ETHICS REVIEW

- ▣ Development of registration/recognition policies and standards
- ▣ Establishment of a national database of ERCs
- ▣ Development of a Research Ethics Training program for researchers, ERC members
- ▣ Networking with FDA and regional research ethics organizations
- ▣ Memos/comments on research issues
- ▣ Updating the National Guidelines

# CURRENT CONTEXT OF HEALTH RESEARCH ETHICS IN THE PHILIPPINES

- ▣ Policies from DOST-PCHRD, DOH and CHED
- ▣ Capacity Building from UPM-NIH, UP-Fogarty
- ▣ Growing number of trained researchers and IRB members
- ▣ Higher awareness of ICH-GCP and national guidelines
- ▣ Standardization of ethics review remains as an area of concern
- ▣ Only 3 FERCAP-recognized IRBs in NCR
- ▣ Status of practice and implementation of guidelines largely unknown, major challenges are likely

# IDENTIFIED NEEDS

- ▣ Strengthening of health research ethics education in higher education institutions (HEIs)
- ▣ Regulation of IRBs through a national recognition scheme (IRB inspection?)
- ▣ Organizing a network of recognized IRBs
- ▣ Organizing major stakeholders in health research into a national health research ethics forum

# FORUM FOR ETHICAL REVIEW COMMITTEES FOR ASIA AND WESTERN PACIFIC (FERCAP)

- ▣ Objective: fostering an improved understanding and better implementation of ethical review of behavioral and biomedical researches in the region
- ▣ Result of the realization that ethics requires collective wisdom and there is need for a systems approach to address important health research issues in Asia and the Western Pacific
- ▣ A project supported by the World Health Organization Special Training and Research Programme in Tropical Diseases (WHO/TDR)
- ▣ A regional forum under the umbrella of the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER)

# MAJOR PROGRAMS/PROJECTS OF FERCAP

- ▣ Capacity building of stakeholders and quality improvement of ECs in the Asian and Western Pacific Region
  - International Annual Conference
  - Training Programs
    - ▣ Human Participant Protection Course (HPPC)
    - ▣ Standard Operating Procedure (SOP) Development Course
    - ▣ Surveying and Evaluating Ethical Review Practices Course
- ▣ Together with its partners, FERCAP is involved in the SIDCER Recognition Program for ECs.



## **FERCAP - PHILIPPINES**

### **Forum for Ethics Review Committees in Asia and Western Pacific Region**

#### *Philippine Chapter*

Multi-sectoral, multi-disciplinary,  
non-profit organization

**Objective: fostering an improved understanding and implementation of ethical review of biomedical research in the Philippines towards promoting the welfare and rights of human subjects/participants taking into consideration the cultural values and differences inherent to the local community where the research is being done.**



## **The FERCAP - PHILIPPINES strives to achieve this goal through the following activities:**

- 1. Improving communication among ethics review committees (ERCs) reviewing biomedical research in the Philippines**
- 2. Acting as a forum for discussing research ethics in the Philippines**
- 3. Organizing national meetings and symposia on updates on research ethics and addressing issues in the conduct of research ethics review**
- 4. Facilitating training and education opportunities for members of ERCs in the country**
- 5. Helping other institutions establish and sustain ethics review committees (ERCs)**
- 6. Encouraging the development of Standard Operating Procedures of ethics review committees, taking into consideration the WHO Operational Guidelines and other international guidelines**
- 7. Establishing, coordinating linkages, and networking with local ethics review committees of local institutions conducting clinical research, appropriate government agencies, and international organizations involved in ethical review**



# OTHER NATIONAL IRB NETWORKS

- ▣ Korea Association of Institutional Review Boards (KAIRB), 2002
  - Founded by Korean Academy of Medical Sciences, Korean Society for Clinical Pharmacology and Therapeutics and IRB members
  - To support and standardize the operation of Korean IRBs
  - Non-profit foundation supported by Ministry of Health and Welfare to provide education/training programs and to implement IRB evaluation

# OTHER NATIONAL IRB NETWORKS

- ▣ Forum for Ethical Review Committees in Thailand (FERCIT)
  - Promoting the rights, safety and protection of human dignity and well-being of the volunteers participating in human research
  - Promoting and developing care about research ethics in Thailand
  - Exchange of knowledge and experience of directors care about the ethics of research in humans.
  - Coordination with other countries on care about ethical research in humans

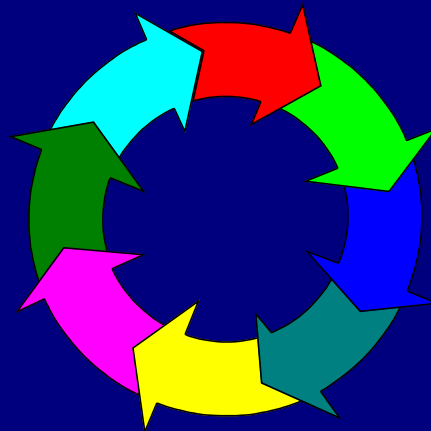
# OTHER NATIONAL IRB NETWORKS

- ▣ Shanghai Association of Medical Ethics
  - Organized by the City Health Bureau
  - Almost all ECs join the association
- ▣ Taiwanese Association of Institutional Review Boards (TAIRB)
  - Hosted by Taipei Medical University (TMU)

# Where do we go from here?

- ▣ Do we want a national forum for health research ethics (Philippine Health Research Ethics Forum)? What about FERCAP-Philippines?
- ▣ What would be the objectives/functions of the national forum?
- ▣ Who should comprise the national forum?
- ▣ What should be the next steps?

**FOR HEALTH RESEARCH ETHICS  
IN THE PHILIPPINES,  
PARTNERSHIPS AND COLLABORATION  
ARE NEEDED MORE THAN EVER.**



Thank you