

# National Developments in Quality Ethical Review

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Chair, PHREB Subcommittee on  
Standards and Accreditation

# Developments in Ethics Review:

- Before 2001: Several IRB / EC**  
NEC, UPCM-CRID ERB, RITM, etc
- 2001 Oct :** FERCAP- Phil ERC meeting
- 2003 Mar:** PNHRS established TWG  
in Research Ethics
- 2004** Survey on Res. Ethics Review
- 2006 May:** PHREB established  
National structure for ethics  
review: Regional Boards,  
Cluster Committees, IEC/IRBs

**“National Ethical Guidelines for Health Research”**

# **TWG –Ethics Institutional Survey, 2004**

**94/566 institutions with research activities**

**55 have Technical Review Committees**

**43 have IEC/IRBs**

**22 based in Metro Manila**

**20 have no trained members**

**20 have no support staff**

**53% of Researches are researcher funded.**

**34% funded by Pharmaceutical company**

# Implications of 2004 Survey

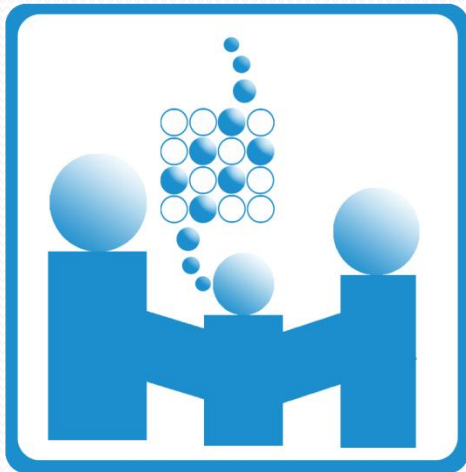
- **Health researches involving human subjects are conducted without ethical review in many institutions.**
- **A significant number of IERC members are not trained in ethics review.**
- **National standards for ethics review are not in place.**

# PHILIPPINE HEALTH RESEARCH ETHICS BOARD (PHREB)

**Created by DOST Special Order No. 91 ser 2006**

**Reconstituted by DOST SO No. 347 Ser 2010**

**\* National policymaking body  
on health research ethics**



Philippine Health Research  
Ethics Board

**Effective protection of  
human research  
participant**

# Recent National Policies

- **DOST Administrative Order 001 S. 2007**

**Subject: *Requirement for review of all health researches involving human subjects/ participants.***

- **CHED Memorandum Order 34 S. 2007**

**Subject: *Policy Requirement in the Conduct of Health Research Involving Human Subjects/Participants***

- **DOST Administrative Order 001 Series of 2008**

**Subject: *Requirement for registration & accreditation of all ethics review committees***

**Phil Health Research Ethics Board (PHREB)**

**Regional Health Research Ethics Boards**

**Ethics Review Committees**

**National**

**Regional**

**Cluster**

**Institutional**

**ETHICS REVIEW COMMITTEES IN  
THE PHILIPPINES**

# **CHALLENGES TO QUALITY ETHICAL REVIEW IN THE PHILIPPINES**

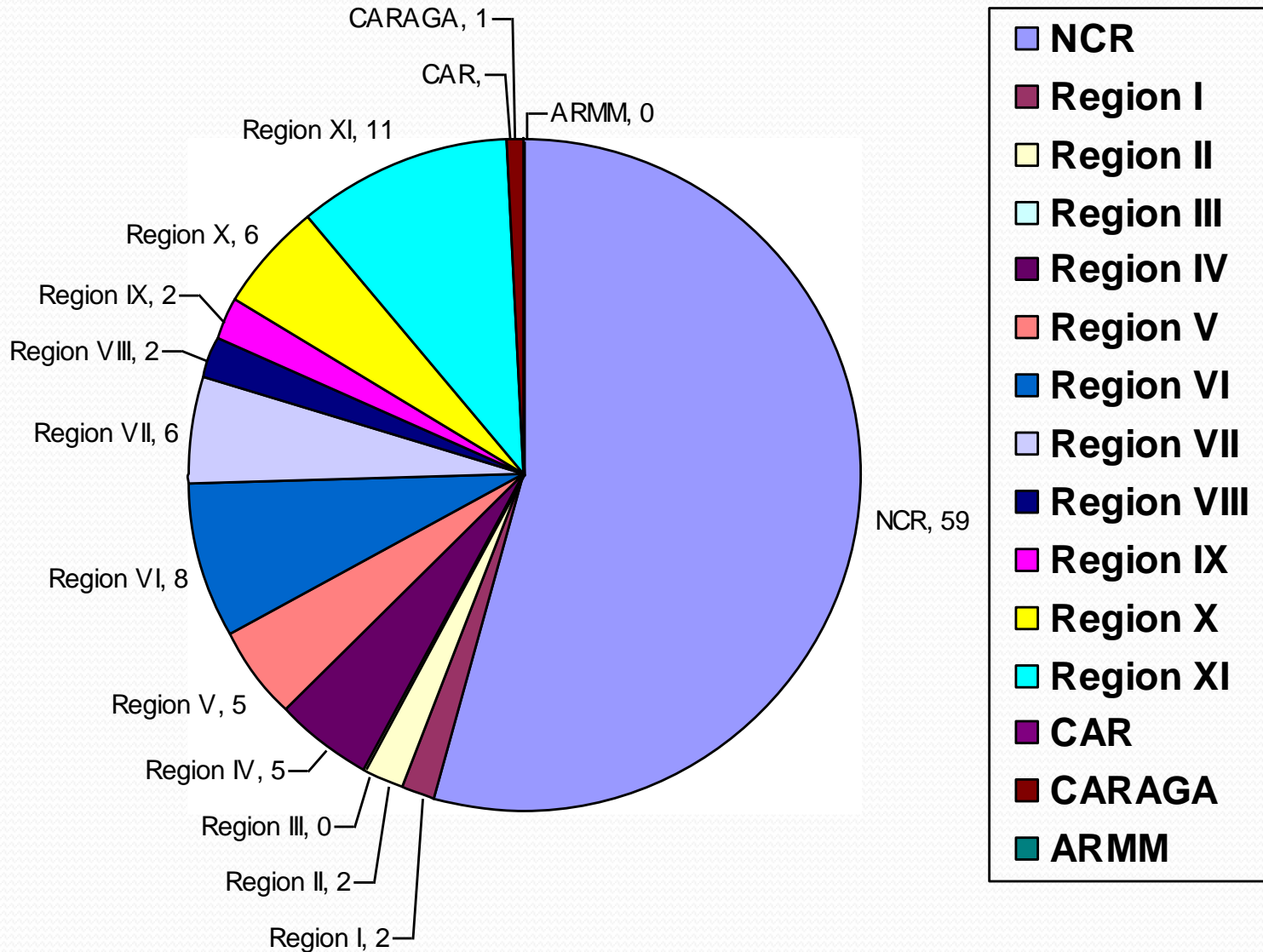
- 1. Adherence of ethical review to international, regional and national guidelines.**
- 2. Beyond the guidelines:**
  - A. Helping build a responsible and accountable health research system**
  - B. Empowerment of human participants in health research**



# **Initiatives for Quality Ethics Review**

- 1. Establishment of a national database of ERCs**
- 2. Update of National Ethical Guidelines – 2011**
- 3. Development of a Research Ethics training program for researchers, ERC members, other stakeholders**
- 4. Development of registration/ accreditation policies and standards.**

# Establishment of a national database of ERCs



# National Ethical Guidelines for Health Research

**1984 PCHRD SO No. 84-053 :**

**Organization of the National Ethics Committee.**

**1985 *National Guidelines for Biomedical Research***

**1996 *National Guidelines for Biomedical /Behavioral Research (2<sup>nd</sup> edition)***

**2000 *(3<sup>rd</sup> edition)***

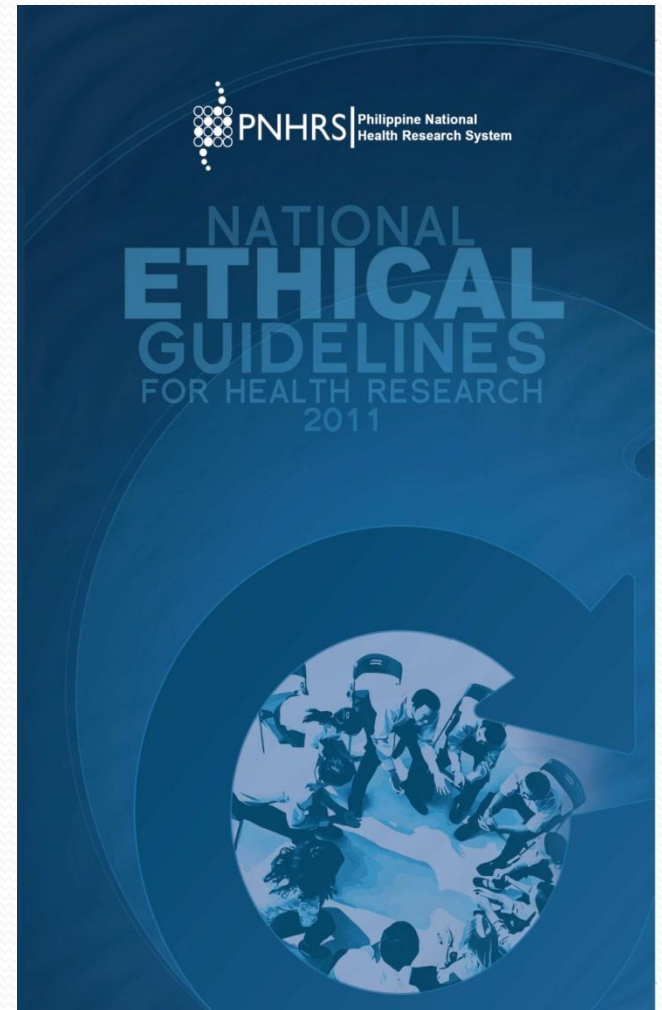
**2006 Organization of PHREB**

**2006 National Ethical Guidelines for Health Research**

**2011 NEGHR**

# NEGHR Topics 2011

- Introduction
- Research Ethics Agencies
- Guidelines for Ethics Review Committees
- General Ethical Guidelines for Health Research
- Special Ethical Guidelines
- Guidelines on the Research Ethics Review Process
- Guidelines on Authorship and Publication
- Glossary



# **Capacity Building in Quality Ethical Review Training Programs**

- **National, Regional, Local**

**PNHRS PHREB**

**UP Fogarty Group**

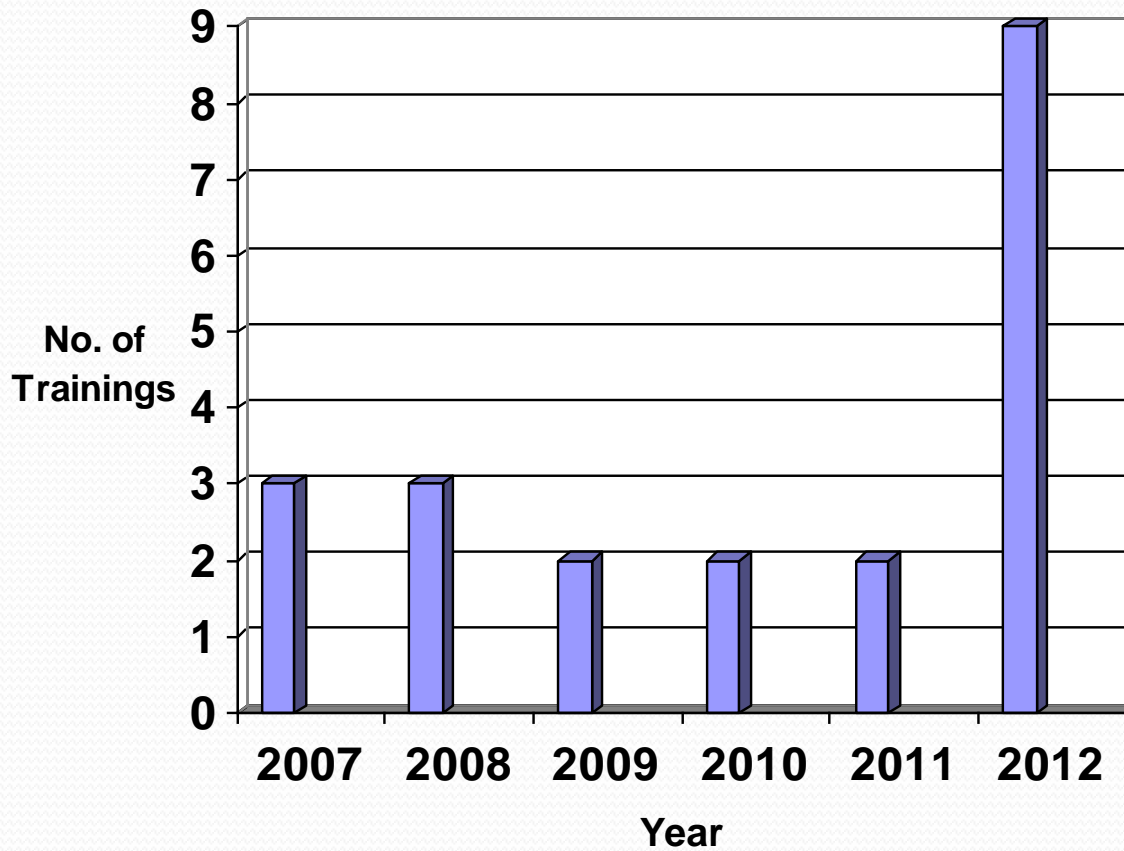
**FERCAP – UP NIH**

**Pharmaceutical sponsored GCP**

**SEACB – UST**

**Institutional training seminars**

# PHREB Trainings



# PHREB Accreditation Program

<b>Level</b>	
<b>Level 1</b>	Qualifies an ERC to review researches involving human participants except clinical trials
<b>Level 2</b>	Qualifies an ERC to review clinical trials not intended for registration of new drugs (e.g. non industry trial by Fellows/ Consultants)
<b>Level 3</b>	<ul style="list-style-type: none"><li>• Gives ERC the privilege of being part of the Ethics Review Resource Committees of the Philippine FDA</li><li>• Allows the ERC to review investigational new drugs (IND) or device protocols</li><li>• Complies with ICH GCP</li></ul>

# **Initiatives for Quality Ethics Review**

- 4. Networking with national regulatory authorities & regional research ethics organizations.**
- 5. Development of the Phil Clinical Trial Registry**
- 6. Fora on research issues**



# PHREB and FDA

- **PHREB Function: to advise... on matters related to ethical issues in health research.**  
**National guidelines on clinical trials emphasize adherence to PFDA (BFAD) regulations [i.e.,DOH AO 47-A (8-30-2001)]**

**P  
H  
R  
E  
B**

**Quality Research Ethics Review  
Permit for Clinical Investigation Use  
Certificate of Product Registration  
SAE Reporting and Management  
Clinical Trial Registry**

**F  
D  
A**

# Philippines: An Emerging Destination for Clinical Trials

*ClinicalTrials.gov*

A service of the U.S. National Institutes of Health

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**Main Category: Locations By Region**

**Location Region: Southeast Asia**

<a href="#">Brunei Darussalam</a>	1 study
<a href="#">Cambodia</a>	27 studies
<a href="#">Indonesia</a>	163 studies
<a href="#">Lao People's Democratic Republic</a>	2 studies
<a href="#">Malaysia</a>	465 studies
<a href="#">Myanmar</a>	5 studies
<a href="#">Philippines</a>	529 studies
<a href="#">Singapore</a>	954 studies
<a href="#">Thailand</a>	1090 studies
<a href="#">Vietnam</a>	116 studies

[http://clinicaltrials.gov/ct2/search/browse?brwse=locn\\_cat\\_SE;](http://clinicaltrials.gov/ct2/search/browse?brwse=locn_cat_SE;)  
Accessed May 26, 2012

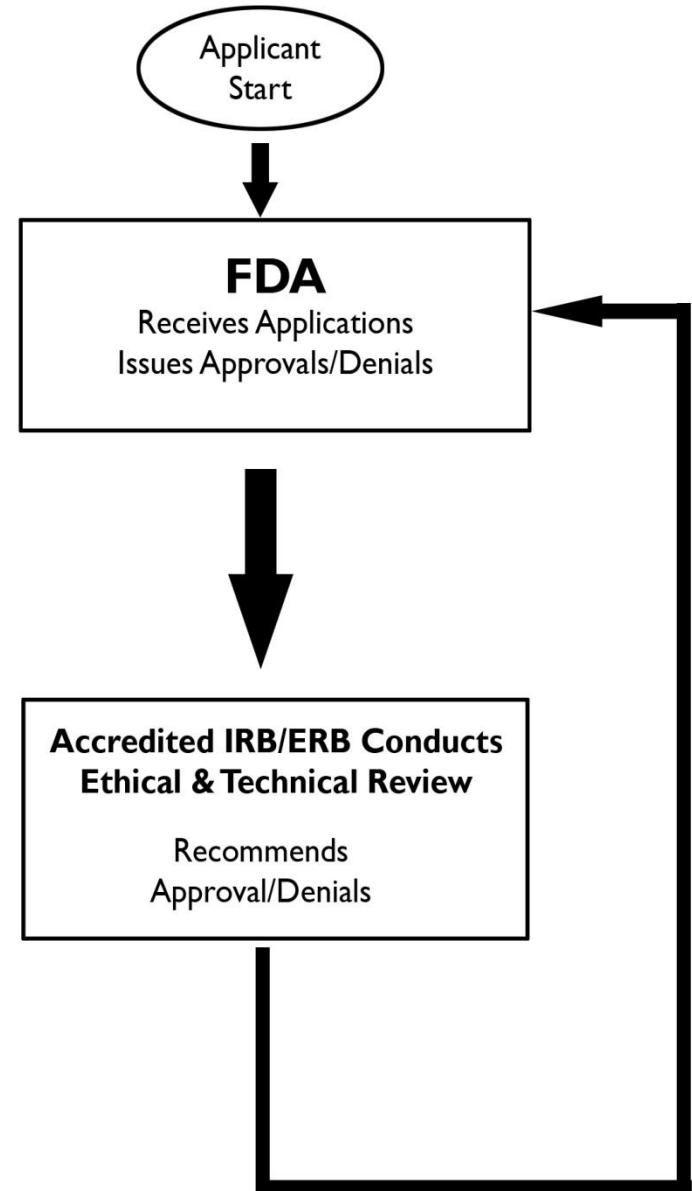
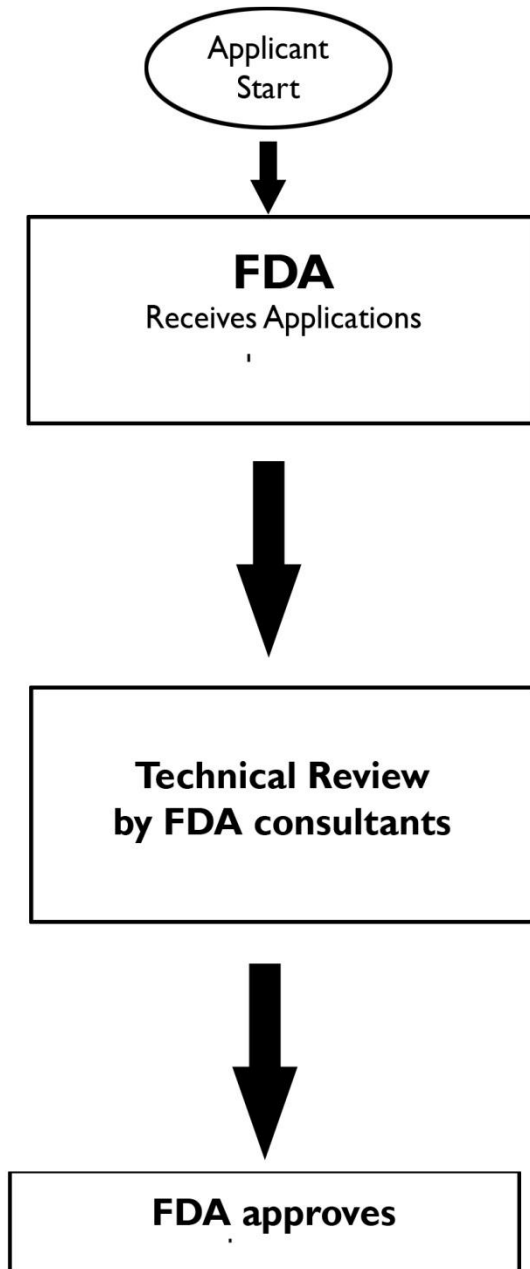
**S H LAZO**

# **FDA Regulatory Review List of ERB/ERCs\* FDA Circular**

- **UP Manila REB**
- **De La Salle Health Sciences Institute**
- **St. Luke's Medical Center**
- **Phil Heart Center IERB**
- **RITM**

**\*Based on PHREB Recommendation**

## System previous...



# **PHILIPPINE CLINICAL REGISTRY**

- **Covers Phase I, II, III and IV clinical trials on medicinal products (drugs, devices, herbals, supplements, etc)**
- **Mandatory inclusion of clinical trials in the Philippine Clinical Trial Registry**

**(<http://registry.healthresearch.ph>)**

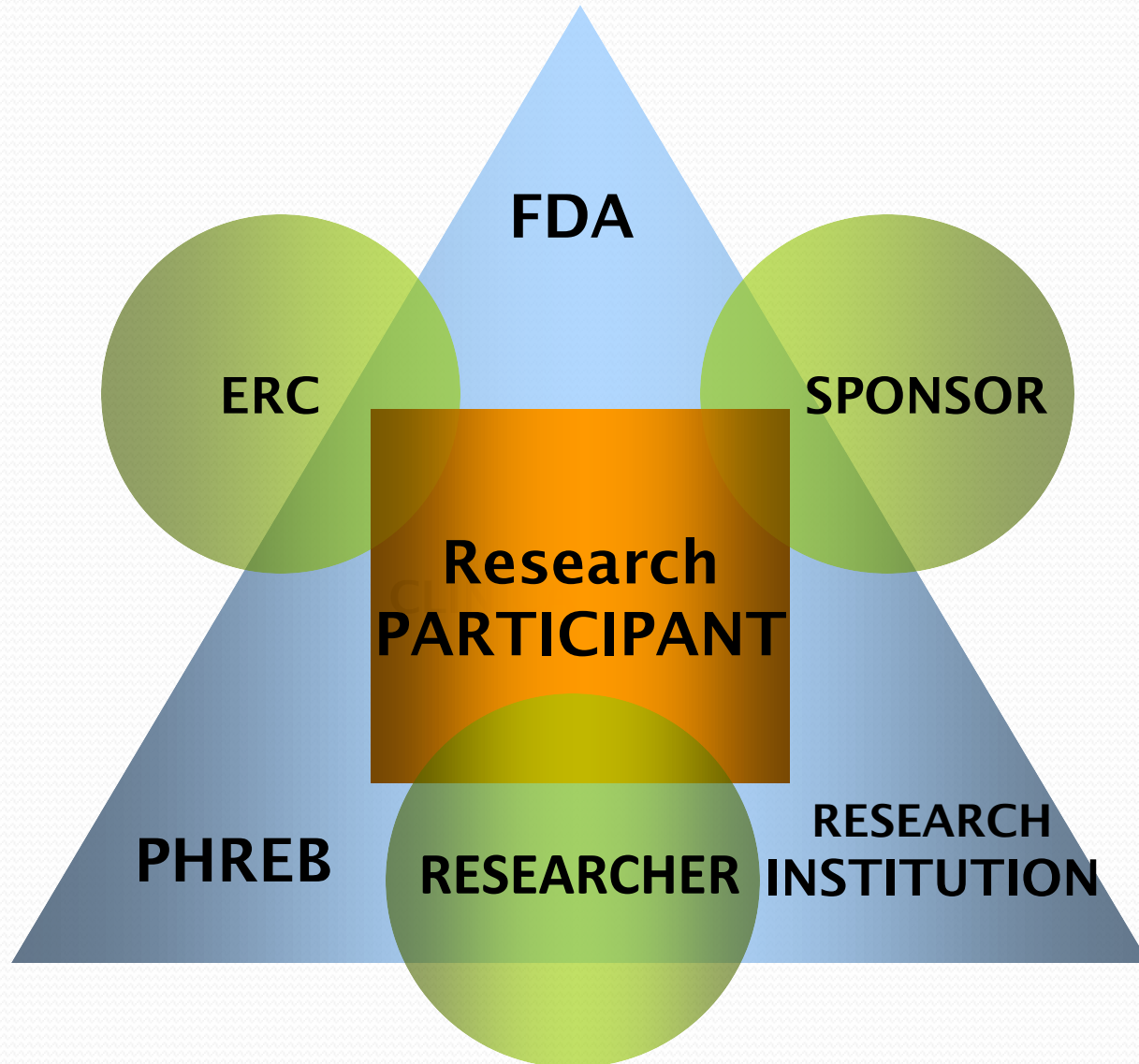
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- 4. Development of registration/ accreditation policies and standards.**
- 5. Networking with national regulatory authorities & regional research ethics organizations.**
- 6. Development of the Phil Clinical Trial Registry**
- 7. Fora on research issues (2 x a year)**

# **CHALLENGES TO QUALITY ETHICAL REVIEW IN THE PHILIPPINES**

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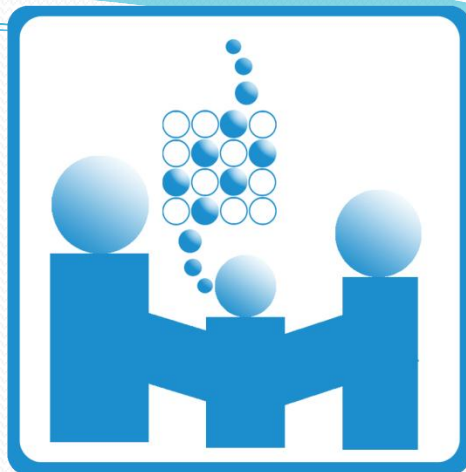
# PHILIPPINE FRAMEWORK FOR HUMAN RESEARCH PARTICIPANT PROTECTION





# Concluding Remarks

- **Quality research ethics review is a vital component of a quality management system in clinical research.**
- **The FDA, PHREB, ERCs, P.I., Sponsors and Research Institutions must be part of the regulation framework of a human protection system in research.**
- **There is a need to develop outcome measures for assessment of performance of the current system.**
- **There is a need for a closer coordination bet. PHREB & govt regulatory agencies (FDA, etc) and continuing dialogue among health research stakeholders**



Philippine Health Research  
Ethics Board

# Thank you!

