PNHRS Philippine National Health Research System

PHREB POLICIES AND REQUIREMENTS FOR ACCREDITATION OF RESEARCH ETHICS COMMITTEES (01 April 2016)

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Philippine Health Research Ethics Board

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- Section 12 of the Philippine National Health Research System (PNHRS) Act of 2013 on the constitution of the Philippine Health Research Ethics Board (PHREB) states that "*The PHREB, created under DOST Special Order No. 091 s. 2006, shall ensure adherence to the universal principles for the protection of human participants in research*."

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THE REC

A Research Ethics Committee (REC) is a body, constituted by a duly recognized authority that

- makes independent decisions regarding the review, approval, and implementation of research protocols/proposals
  - in order to ensure the protection of the rights, safety, and well-being of human participants
  - promote integrity of research data.

I. RATIONALE
(PHREB MANDATE)

1. Formulate and update guidelines for the ethical conduct of human health research
2. Develop guidelines for the establishment and management of RECs and standardization of research ethics review
3. Monitor and evaluate the performance of RECs in accordance with PHREB approved procedures outlined in a prior agreement including requiring an annual report.

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- PHREB has set requirements for accreditation of RECs in the Philippines in order to guide them in the conduct of quality scientific and ethical review of research protocols.

- PHREB accreditation is a requirement for all RECs.

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II. COVERAGE

1. Academic Institution-based RECs (AI-RECs)
2. Hospital-based RECs (H-RECs)
3. Government-based RECs (G-RECs)
   - office, department, bureau, or agency in the government
   - consortia for regional health and development RECs (CHRD RECs)

Coverage

4. Cluster RECs (C-RECs)
   - groups of institutions that cannot form individual RECs
   - management and administration of a C-REC is determined by the memorandum of agreement among these institutions
   - C-REC shall register and may apply for PHREB accreditation as one REC

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Coverage

5. Research Site-based RECs (R-RECs)
   - These RECs operate within and for research sites. An R-REC shall apply for PHREB accreditation as a whole unit regardless of the number of sites or facilities the research will engage.
   - Community research (e.g. Indigenous areas, disaster areas)
6. Health facility-based REC to include *Specialty Clinics*

Definition of Health Research

- *National Ethical Guidelines for Health Research 2011 p.143*: Health research is generation of data that may contribute to new knowledge to identify and deal with health problems, health systems and policies as well as those that impact on health such as socioeconomic, environment, energy and agricultural policies

Definition of Health Research

- *World Health Organization (WHO) Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011 Preface* states: *that Health-related research includes biomedical, behavioral, social science, and epidemiological research*

III. GENERAL POLICIES

1. All health-related research protocols/proposals involving human participants shall be reviewed by a Research Ethics Committee (REC)
   - Research proposals involving indigenous cultural communities / indigenous peoples (ICCs/IPs) shall secure ethical clearance from a PHREB Level 2 or 3 Accredited REC and approval from the National Commission for Indigenous

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- Research protocols/proposals involving use of Animals are reviewed by an Institutional Animal Care and Use Committee (IACUC)
- Protocols with biosafety issues or pose hazards to the environment including those involving animals and plants need review and approval by the National Committee on Biosafety of the Philippines (NCBP)
- the above functions (human and animal involvement and biosafety) may be performed by a single committee, provided the appropriate expertise exists in the said committee;

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GENERAL POLICIES

2. All RECs shall undergo accreditation by PHREB according to a set of criteria

   The REC shall apply for the appropriate level of accreditation based on the requirements

3. Members of the Accreditation Team shall be identified following a process of selection and compliance with training requirements

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GENERAL POLICIES

4. Accreditation fees shall be determined and approved by PHREB.

   Other expenses associated with an Accreditation Visit shall be shouldered by the applicant REC

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IV. ACCREDITATION CRITERIA

1. Functionality of structure and composition
2. Adherence to international, national guidelines and policies
3. Adequacy of standard operating procedures and consistency of implementation

SOP Chapters

- REC Structure and Composition
- Management of Initial Submissions (including Re-submissions)
- Management of Post Approval Submissions
- Review Procedures (Expedited and Full Review)
- Meeting Procedures
- Documentation of REC Actions
- Management and Archiving of Files
- Site Visits
- Management of Queries/Complaints
- Writing and Revising SOPs

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ACCREDITATION CRITERIA

4. Completeness of review process
5. Adequacy of after review process
6. Adequacy of administrative support
7. Efficiency of the recording and archiving system

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V. ACCREDITATION LEVELS

- The level of accreditation is indicative of the:
  - type of research
  - degree of risk involved in the protocols/proposals reviewed by the REC.
- PHREB shall grant any of the levels of accreditation to an REC after an evaluation process

Minimal risk: when the probability and magnitu of harm or discomfort anticipated in the propos research are not greater in and of themselves, than those ordinarily encountered in daily life o during the performance of routine physical or psychological examinations or tests

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ACCREDITATION LEVELS

Level 1	Level 2	Level 3
• reviews researches with **minimal risk** to participants • Level 1 accreditation is applicable to newly constituted RECs	• reviews all types of researches **except** clinical trials required for FDA registration of new drugs • may entail **more than minimal risk** to participants • Post-marketing studies may be reviewed	• reviews all types of researches including studies required **for FDA registration** of food, drugs and devices • may be invited by the FDA to conduct regulatory reviews • Level 3 Accredited RECs shall comply with ICH-GCP standards

ACCREDITATION LEVELS REQUIREMENTS

Level 1	Level 2	Level 3
The REC must demonstrate • sufficient competency and efficiency in ethical review, • adhere to a set of appropriate standard operating procedures • have adequate administrative support as shown by an assigned office with standard equipment • a budget that supports honoraria for training of REC members		
	• Functional database • At least a part time dedicated staff	• Functional database • Full time staff • GCP compliant

Systematic filing system

VI. Requirements and Procedures of Accreditation

http://www.ethics.healthresearch.ph/index.php/registration-and-accreditation

Level 1: Documentary submission by REC and review by accreditors

Level 2: Documentary submission by REC and review by accreditors; ± site visit

Level 3: Documentary submission by REC + 3 day accreditation site visit

VII. Responsibilities of an Accredited REC

1. Posting of PHREB Accreditation Certificate
2. Submission of Annual Report within the first quarter of the following year
3. Reporting of any controversial or important ethical issues in the course of its work
4. Willingness to be monitored by PHREB

VIII. Renewal of Accreditation Certificate

- Within two (2) months before the expiry of its accreditation, a REC shall apply for renewal by complying with the requirements/responsibilities of accredited RECs

IX. Bases for Withdrawal of Accreditation

1. Non-Compliance with PHREB Reportorial/Other Requirements

   – *An REC that fails to submit an annual report for two (2) consecutive years shall have its certification withdrawn and its name delisted from the PHREB accredited RECs.*

2. Unjustified issuance of ethical clearance (e.g. violation of national laws and guidelines, lack of due diligence, etc.) that resulted in harm to participants.

X. FEES

- PHREB shall charge application and accreditation processing fees based on the level of accreditation applied for.
- Other expenses which may be incurred during Accreditation Visits (for Level 3) may vary depending on site specific logistical requirements (e.g. travel and accommodation).
- The mechanism of payment is facilitated by PCHRD may vary depending on site specific logistical requirements (e.g. travel and accommodation).

2015 vs 2016

- Automatic registration upon application for accreditation
- On-going accreditation
- Provision for a probationary accreditation of one (1) year
- Sanctions for non-compliance