
PHREB REQUIREMENTS FOR
REGISTRATION AND ACCREDITATION OF
RESEARCH ETHICS REVIEW COMMITTEES
Effectivity date: February 2, 2014

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Philippine Health Research Ethics Board

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## I. RATIONALE AND GOAL

Section 12 of the Philippine National Health Research System (PNHRS) Act of 2013 states that the Philippine Health Research Ethics Board (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 studies conducted in the Philippines. In order to promote and establish an effective research human protection the PHREB, among other things, shall:

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

Hence, the PHREB has set requirements for registration and accreditation of Research Ethics Review Committees (RERCs) in the Philippines.

Pursuant to the requirements, research ethics committees shall observe procedures and standards in the conduct of quality scientific and ethical review of research protocols to ensure the safety and protect the rights and welfare of the participants in research.

To this end, all RERCs SHALL APPLY for registration and accreditation at the PHREB.

## II. COVERAGE

The requirements for registration and accreditation shall cover all RERCs in the Philippines, which are categorized as follows:

1. Academic Institution-based RERCs (AI-RERCs). These RERCs are under a university, college, medical school, or other professional school or institution. An AI-RERC which functions independently of others under the same academic institution must apply for registration and accreditation separately.

2. Hospital-based RERCs (H-RERCs). These RERCs are under a hospital. A H-RERC that functions independently of others under a hospital must apply for registration and accreditation separately.

3. Government-based RERCs (G-RERCs). These RERCs are under an office, department, bureau, or agency in the government. A G-RERC that functions independently of other RERCs under a government office, department, bureau, or agency must apply for registration and accreditation separately.

Consortia for regional health and development RERCs (CHRD RERCs) will be considered as G-RERCs for funding purpose but if the different institutions establish their own RERC which functions independently of others under the consortium, these institutional RERCs must apply for registration and accreditation.

4. Cluster RECs (C-RERCs). These RERCs are formed by groups of institutions that cannot form individual RERCs. The management and administration of a C-RERC is determined by the memorandum of agreement among these institutions. A C-RERC shall register and may apply for accreditation as one RERC.
   4.1. Institutions desiring level 3 accreditation but which receive less than twenty (20) new research protocols a year may also form a C-RERC.

5. Research Site-based RERCs (R-RERCs). These RERCs operate within and for research sites. A R-RERC shall register and may apply for accreditation as a whole unit regardless of the number of sites or facilities the research will engage.

6. All other forms of RERCs not covered by the above categories.

## III. GENERAL POLICIES

The following policies shall be applicable:

1. A Research Ethics Review Committee (RERCs) is a committee constituted to review the ethical aspects of a research proposal and its possible implementation (NEHGR 2011). It is an independent body whose responsibility is to ensure the protection of the rights, safety, and well-being of human participants involved in the research and to provide public assurance of that protection.

   Animal research protocols will be reviewed and approved by the Institutional Animal Care and Use Committee (IACUCs) and not by RERCs (NEGHR p. 42).

   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) (NEGHR p.42).

2. All research ethics review committees (RERCs) which currently conduct review for ethical soundness of research proposals (or intend to review researches) involving human participants must register and undergo accreditation by PHREB by December 30, 2015.

3. RERCs shall be evaluated according to a set of criteria that shall be used to determine their level of accreditation and corresponding functions and extent of authority to review.

4. Different procedures shall be required based on the present registration status of the RERCs as follows:

   4.2. Newly constituted RERC: a RERC that is newly organized and has functioned for not more than 12 months.

   4.3. Unregistered RERC: a RERC that has been functional for more than a year but has not registered yet.

4.4. Registered but non-compliant RERC: a previously registered RERC but has not complied with the submission of the required annual reports.

4.5. Registered and compliant RERC: a previously registered RERC which has dutifully complied with the submission of annual reports.

5. Currently registered RERCs which have complied with the PHREB requirement for submission of annual reports may update their status with an application for either a Level 2 or 3 Accreditation.

6. Levels 1 and 2 Accreditation may be granted based on a stringent documentary review but an actual accreditation visit may be required at the discretion of the PHREB.

7. An accreditation visit is required for a level 3 Accreditation.

8. Members of the accreditation team shall be identified following a process of selection and compliance with training requirements under the supervision of the PHREB Subcommittee on Standards and Accreditation (PHREB SSA).

9. A minimum application processing fee of PhP3,000.00 shall be paid by applicant RERCs for applying for Level 1 and 2 and PhP5,000.00, for Level 3, during the first year of implementation (2014). Subsequent processing fees after 2014 shall be determined and approved by PHREB.

10. Fees for level 3 accreditation assessment visits shall be determined and approved by PHREB.

11. PHREB accreditation is mandatory for all RERCs in the Philippines. Any other accreditation, international or national, is at the discretion of the RERCs but there is no PHREB reciprocity of accreditation with other bodies or organizations.

## IV. PHREB ACCREDITATION CRITERIA

The PHREB Sub-Committee on Standards and Accreditation (SSA) shall evaluate the RERC according to seven (7) criteria, as follows:

1. Functionality of structure and composition
2. Adherence to international, national, institutional guidelines and policies
3. Adequacy of standard operating procedures and consistency of implementation
4. Completeness of review process
5. Adequacy of after review process
6. Adequacy of administrative support
7. Efficiency of the recording and archiving system

## V. ACCREDITATION LEVELS

PHREB may issue any of the following levels of accreditation to an RERC after an evaluation process:

1. **Level 3** – The RERC has demonstrated sufficient competency and efficiency in ethical review, adheres to a set of appropriate standard operating procedures, has adequate administrative support, maintains an updated database of reviewed protocols, and has established an informative and very good archival system.

1. 1. Level 3 accredited-RERC can review all types of researches including clinical drug trials (Phases 1 to 4). A level 3 RERC has the privilege to be part of the Ethics Review Research Committees of the Philippine Food and Drug Administration (FDA). This means that it can be called upon by the FDA to conduct regulatory reviews for the purposes of FDA or in behalf of the latter.

1. 2. Level 3 accreditation shall be required for RERCs that review investigational new drugs (IND) or device protocols where results will be submitted in support of registration for marketing authorization.

1. 3. Level 3 accredited- RERCs are required to comply with ICH Good Clinical Practice (GCP) standards.

2. **Level 2** – The RERC has demonstrated sufficient competency and efficiency in ethical review, adheres to a set of appropriate standard operating procedures, and has adequate administrative support like its own office, standard equipment, and administrative staff but may not have a functional database and a good archival system.

2. 1. Level 2 accredited- RERC can review most health researches including highly sensitive social behavioral researches and clinical trial protocols not intended for FDA registration of new drugs. Examples are clinical trials conducted by doctors in hospitals (including residents and fellows in training) to test safety and efficacy of clinical interventions, products, among others.

3. **Level 1** – The RERC has demonstrated sufficient competency and efficiency in ethical review and adheres to a set of appropriate standard operating procedures. However, it may not have an office and staff of its own.

3. 1. Level 1 accredited-RERC can only review low risk researches involving human participants but not clinical trials.

4. Level 1 or Level 2 accredited RERC may apply for an upgrading of its accreditation to Level 3 by demonstrating compliance with the additional requirements for Level 3 RERCs.

## VI. PROCEDURES AND REQUIREMENTS FOR REGISTRATION AND ACCREDITATION

1. **Newly constituted RERC**

1. 1. This refers to a RERC which has just been constituted and has not functioned for more than a year. The following documentary requirements need to be submitted with the application for registration and accreditation:
   1.1.1. Evidence of institutional policy regarding constitution and terms of reference (TOR) of RERC including an institutional organizational structure that shows location of the RERC, list of members, specialties, and roles
   1.1.2. Certificates of training in basic research ethics of the Chair and at least 2 members
   1.1.3. Manual of Standard Operating Procedures for basic RERC activities:
      a. Constitution of the ERC and staff and functions
      b. Processing of applications for review

c. Initial review – full review and expedited review
d. Preparation for and conduct of regular meetings, including preparation of agenda and minutes of RERC meetings
e. Communication with researchers
f. Continuing Review – progress reports, amendments, final report
g. Management of Files

In the SOP Manual, the RERC shall include the copies of RERC forms that it will use in the performance of its work, such as appointment letters of RERC members, protocol submission checklist, protocol and informed consent review assessment forms, templates of RERC communications, and others deemed necessary by RERC.

1. 2. PHREB shall evaluate the RERC submission of requirements (a) to (d) and if found to be satisfactory and compliant with PHREB requirements, the RERC shall be given a provisional Certificate of Registration and Level 1 Accreditation with an expiration date of one (1) year after approval. It can start its work of reviewing research protocols.

1. 3. A newly registered and Level 1 accredited-RERC is required to submit an annual report to PHREB using the Annual Report Form No. 002.

1. 4. After a new RERC has reviewed a **minimum of 10 research protocols** in the initial year of its operation according to its SOP and submitted its annual report, PHREB shall review its accreditation for extension for another 2 years.

**NOTE:** *PHREB shall have regular basic research ethics training per year schedule – 1 North Luzon, 1 South Luzon , 1 NCR, 1 Visayas, 1 Mindanao. Training maybe delegated to a Regional group (e.g. Metro-Manila HRDC) or institution.*

2. **Unregistered RERC**

2. 1. This refers to a duly constituted RERC which has not yet applied for registration and accreditation at the PHREB but has been operational for more than 12 months.
This existing RERC must submit the requirements similar to a newly constituted RERC (#1). In addition, this RERC can apply for Level 2 accreditation by satisfying the following additional requirements:

2.1.1. A member who is a health practitioner familiar with the types of research protocols being reviewed by the RERC;

2.1.2. At least 3 RERC members with basic health research ethics training and GCP training within the past three (3) years ;

2.1.3. Dedicated office space, basic office equipment (computer with internet connection and printer, telephone, filing cabinets with locks), and staff secretary

2.1.4. Has a Manual of SOPs on the procedures listed in Section VI 1.1.3 and the SOP on continuing review in addition must include review of the following:
a. Progress report
b. Amendments
c. Final Report
d. Monitoring including reporting of adverse events
e. Protocol deviation/Protocol non-compliance
f. Early termination of study

2.1.5. Documentation of three (3) research protocols that it has reviewed and approved by the RERC. This protocol file submission shall include:

a. Protocol Package - complete protocol submission by proponent, completed RERC review assessment forms (technical/scientific and informed consent review) done by the RERC members, checklists used for the protocol review .
b. Agenda and Minutes of the Meeting when the research protocol was discussed (initial and subsequent continuing reviews)
c. Letters / communications with the researchers

2. 2. PHREB shall evaluate the RERC submission of requirements and if found to be satisfactory and compliant with PHREB requirements, the RERC shall be given a provisional Certificate of Registration and Level 2 Accreditation with an expiration date of one (1) year after approval. It can start its work of reviewing research protocols.

2. 3. A newly registered and Level 2 accredited-RERC is required to submit an annual report to PHREB using the Annual Report Form No. 002.

2. 4. After the RERC has reviewed a **minimum of 10 research protocols** in the initial year of its accreditation according to its SOP and submitted its annual report, PHREB shall review its accreditation for an extension period of another 2 years.

2. 5. The scope of RERC review may include protocols from hospital residents, fellows in training doing clinical trials of already registered or marketed drugs; graduate students planning interventional studies with human participants but with minimal risks involved.

3. **Registered/ non-compliant RERC**

This is either a non-functioning RERC or a functioning RERC.

3. 1. A **non-functioning RERC** is an RERC which has had no activities for the past year (no annual report submitted, no reviews/meetings for the past year). This RERC will be treated like a new RERC and has to re-register and follow guidelines for newly constituted RERC (#1).

3. 2. A **functioning RERC** is an RERC which has not submitted an annual report for the past year but has continued to function as an RERC.

3.2.1. If it is only a registered but not yet accredited RERC, either it will follow guidelines for newly constituted RERC (#1) for Level 1 accreditation or it can follow requirements for unregistered existing RERC (#2) for Level 2 accreditation.

3.2.2. If it is a Level 3 accredited-RERC, it shall submit the following requirements to maintain its accreditation:

a. annual report for the past two (2) years using PHREB Annual Report Form No. 002;
b. existing or revised complete SOPs (combined Level 1 and 2 SOPs);
c. copies of the minutes of the immediate past 6 RERC meetings; and
d. evidence of regular monthly meetings.

3.2.3. To remain as a level 3 accredited RERC, a functioning RERC must review at least twenty (20) (minimum) new protocols the previous year. Otherwise, it may qualify for level 2 accreditation, not as level 3.

**4. Registered, compliant RERC**

4.1. The RERC may apply for any level of accreditation including Level 3. For level 1, it can submit the requirements for newly constituted ERCs (#1) and for level 2 , see #2. The RERC may also be eligible for level 3 accreditation, in which case, the following steps are involved in its application:

4.2. **Steps for Level 3 accreditation**

4.2.1. **Self-assessment** consists of reviewing a list of items/ requirements deemed essential for an RERC to function effectively, efficiently, and independently. In accomplishing the PHREB Self-assessment Form, the RERC indicates the degree to which it has complied with these requirements and its readiness for accreditation. This procedural step, therefore, makes the RERC aware of its deficiencies and presents an opportunity to correct them. This step may take up to six months, after which the RERC shall communicate whether it is ready for the next step or it wishes to defer its application.

Communications must be sent to the PHREB Secretariat, through any of the following:

Mail: 3rd Floor, Room 306, DOST Main Bldg., Bicutan, Taguig City
Telephone: (632) 837-75
Telefax: (632) 837-2924
E-mail: ethics.secretariat@yahoo.com

4.2.2. **Accreditation Team Assessment Visit**

a. A team from the PHREB SSA shall conduct a scheduled on-site visit to ascertain the degree of compliance with the seven criteria of accreditation and to evaluate the correctness of the documents, the consistency of these documents with the actual practices of the ERC, and the manner in which documents are filed and stored.

b. Prior to the visit, the accreditation team shall identify the documents for review (e.g., written standard operating procedures, membership files, terms of reference of the members, representative protocols, minutes of meetings, communications, log book, if any) and the persons for interview (RERC Chair and members, appointing authority and administrative staff).

c. The team shall specify the activities to be undertaken during the visit, e.g. opening and closing meetings, interviews, documents to be reviewed and inspection of the RERC office, including the archives. The visit lasts for three days.

d. Accreditation team shall present its findings to the RERC during the closing meeting during which matters can be clarified for inclusion in the final report.

e. Final Report. The accreditation team will submit its final report with its recommendations to PHREB SSA within two (2) weeks.

4.2.3. **Communication of Recommendations to RERC**

a. SSA will send the report to the RERC visited. Significant findings (areas for improvement) during the visit shall be addressed by the RERC which shall submit an action plan to SSA within 30 days after the visit.

b. A follow-up visit may be scheduled by the SSA to determine the implementation of the action plan.

c. If deficiencies remain during the follow-visit, SSA may help RERC in addressing these findings by giving additional training.

d. When the SSA accreditation team determines that the RERC satisfies the PHREB criteria or the action plan has been implemented satisfactorily, SSA shall recommend the approval of the RERC accreditation to PHREB.

e. If these findings continue to show deficiencies despite two (2) follow-up visits, SSA may recommend appropriate level of accreditation to either level 1 or 2 for the RERC.

4.2.4. **Issuance of Accreditation Certificate**

The applicant RERC shall be notified of the final action and status of its application within 60 days after the on-site visit.

## VII. ISSUANCE AND RENEWAL OF ACCREDITATION CERTIFICATE

1. Issuance of accreditation certificate

PHREB shall issue a Certificate of Accreditation to the RERC:

a. Certificates of Level 1 and Level 2 accreditation will be sent by PHREB to the RERCs. Their names will be included in the list of PHREB accredited RERCs.

b. Accreditation certificate for Level 3 RERCS shall be formally awarded to RERC either in March or in August of each year after the PHREB approval is granted. Their names will be included in the list of ERCs submitted to the FDA.

c. The list of accredited RERCS (Levels 1, 2, and 3) will be posted in the PHREB website.

2. Renewal of accreditation certificate

   Within two months before the expiry of its accreditation, a RERC shall apply for renewal by complying with the requirements/ responsibilities of accredited RERCs.

## VIII. RESPONSIBILITIES REQUIRED OF REGISTERED AND ACCREDITED RERC

1. Submission of Annual Report

   Using the PHREB Annual Report Form No. 002, all registered and accredited RERCs are required to submit an annual report to PHREB which will reflect the following:

   a) changes in committee chair and membership;
   b) trainings attended by current members;
   c) list of protocols reviewed, approved, revised, and disapproved (Month received, Research Proposal Title and Proponent, and RERC decision)
   d) summary of the criteria for disapproval;
   e) summary of recognitions received by the ERC or significant events that have affected the performance of its duties;
   f) complaints/inquiries received.

   Annual report and other reports should be sent to the PHREB Secretariat, either through:

   Mail: 3rd Floor, Room 306, DOST Main Bldg., Bicutan,Taguig City

   Email: ethics.secretariat@yahoo.com

2. Reporting of any controversial or important ethical issues in the course of its work.
3. Preparedness to be monitored or audited by PHREB.
4. Posting of accreditation certificate. An RERC shall post or display its duly-secured certificate of registration or accreditation in a conspicuous area within its office.

## IX. NON-COMPLIANCE WITH PHREB REPORTORIAL/OTHER REQUIREMENTS

1. Failure to submit annual reports for one (1) year.

   A registered RERC that fails to submit an annual report shall receive a notice of non-compliance from PHREB.

2. Failure to submit annual reports for two (2) consecutive years.

   A RERC that fails to submit an annual report for two (2) consecutive years shall be suspended and cease to conduct an initial review until suspension is lifted. The committee should, however, continue to do continuing review and monitoring of previously approved protocols.

3. Any posting or display of an outdated, revoked, defaced or fraudulent certificate of registration or accreditation that might deceive or mislead researchers, sponsors, prospective participants, and other persons is considered a serious offense for its potential to harm the public. Appropriate legal action may be instituted against the responsible person under existing law.

## X. PHREB REGISTRATION AND ACCREDITATION FEES

1. A processing fee of PhP3,000.00 will be charged RERCs applying for Levels 1 and 2, and PhP5,000.00 for Level 3 PHREB registration and accreditation in 2014.

2. Financial support for Level 3 accreditation of RERCs will be based on fees approved by PHREB.