PHREB POLICIES AND REQUIREMENTS FOR ACCREDITATION OF RESEARCH ETHICS COMMITTEES
(Version Date: 07 September 2016)

I. RATIONALE

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. It promotes integrity of research data.

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." In order to promote and establish an effective health research protection system, 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 RECs and standardization of research ethics review; and
3. Monitor and evaluate the performance of RECs in accordance with PHREB approved procedures outlined in a prior agreement including requiring an annual report.

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.

To this end, PHREB accreditation is a requirement for all RECs.

II. COVERAGE

The requirements for PHREB accreditation shall cover all RECs in the Philippines, which may be any of the following:

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

2. Hospital-based RECs (H-RECs). These RECs are under a hospital. A H-REC that functions independently of others under a hospital must apply for PHREB accreditation separately;

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

   Consortia for regional health and development RECs (CHRD RECs) will be considered as G-RECs for funding purposes but if the different institutions establish their own REC which functions independently of others under the consortium, these institutional RECs must apply for PHREB accreditation;

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

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.

III. GENERAL POLICIES

The following policies shall be applicable:

1. All health-related research protocols/proposals involving human participants shall be reviewed by a Research Ethics Committee (REC). As defined in the *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. The *World Health Organization (WHO) Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011 Preface*, states on its preface that Health-related research includes biomedical, behavioral, social science, and epidemiological research.

   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 Peoples (NCIP). Ethical review of the protocol shall follow the guidelines stipulated in the *National Ethical Guidelines for Health Research 2011 p. 91*.

   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) as stipulated in the *National Ethical Guidelines for Health Research 2011 p.42*.

   In some institutions, 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;

2. All RECs shall undergo accreditation by PHREB according to a set of criteria (Section IV: Accreditation Criteria).

   The REC shall apply for the appropriate level of accreditation based on the requirements described in Section VI: Procedures and Requirements for PHREB Accreditation;

3. Members of the Accreditation Team shall be identified following a process of selection and compliance with training requirements under the supervision of the PHREB Committee on Standards and Accreditation (PHREB CSA); and

4. Accreditation fees shall be determined and approved by PHREB. Other expenses associated with an Accreditation Visit shall be shouldered by the applicant REC.

IV. ACCREDITATION CRITERIA

The PHREB CSA shall evaluate the REC according to seven (7) criteria using specific characteristics / elements as indicators, as follows:

1. Functionality of structure and composition
   - 1.1 Independence
   - 1.2 Multi-disciplinarity
   - 1.3 Gender representation
   - 1.4 Age representation
   - 1.5 Ethics training
   - 1.6 Expertise
   - 1.7 Management of Conflict of Interest

2. Adherence to international, national guidelines and policies
   - 2.1 Membership structure
   - 2.2 Policy on review of researches involving human participants
   - 2.3 Regularity of meetings
   - 2.4 Quorum
   - 2.5 Standard Operating Procedures (SOPs)
   - 2.6 Institutional support

3. Adequacy of standard operating procedures and consistency of implementation
   - 3.1 The SOP Manual should have an OVERVIEW that presents the environment where the REC operates, the Vision-Mission of the Institution, an organizational chart showing the location of the REC and how it relates with the other units, institutional policies related to human research protection, research ethics review, history and mandate of the REC and the international and national ethics research guidelines and regulations guiding the REC.

   - 3.2 SOP Chapters:
     - 3.2.1 REC Structure and Composition
     - 3.2.2 Management of Initial Submissions (including Re-submissions)
     - 3.2.3 Management of Post Approval Submissions
     - 3.2.4 Review Procedures (Expedited and Full Review)
     - 3.2.5 Meeting Procedures
     - 3.2.6 Documentation of REC Actions
     - 3.2.7 Management and Archiving of Files
     - 3.2.8 Site Visits
     - 3.2.9 Management of Queries/Complaints
     - 3.2.10 Writing and Revising SOPs

   - 3.3 SOP Manual includes REC forms such as appointment letters of REC members, forms, templates of REC communications, and others deemed necessary by REC.

   - 3.4 Consistency of implementation:
     - 3.4.1 Timeliness
     - 3.4.2 Decision making process

4. Completeness of review process
   - 4.1 Adequate assessment forms
   - 4.2 Consistent and meaningful use of assessment forms
   - 4.3 Comprehensive discussion of technical and ethical issues
   - 4.4 Assignment of appropriate reviewers

5. Adequacy of after review process
   5.1 REC requirement for submission of reports
   5.2 Inclusion of reports in the meeting agenda
   5.3 Assessment of the reports

6. Adequacy of administrative support
   6.1 Availability of a regular support staff
   6.2 Provision of an office and equipment (e.g. provision of security of files)
   6.3 Support for REC operations

7. Efficiency of the recording and archiving system
   7.1 Availability of updated logbooks
   7.2 Availability of updated database
   7.3 Systematic filing of administrative and protocol-related documents (e.g. active files and archives)

V. ACCREDITATION LEVELS

The level of accreditation is indicative of both the type of research and the degree of risk involved in the protocols/proposals reviewed by the REC.

PHREB shall grant any of the following levels of accreditation to an REC after an evaluation process:

1. Level 1 Accreditation

Level 1 accredited REC reviews researches with minimal risk to participants.

A risk is minimal when the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (*National Ethical Guidelines for Health Research 2011, p. 150*).

Level 1 accreditation is applicable to newly constituted RECs (i.e. less than one year of operations)

2. Level 2 Accreditation

Level 2 accredited REC reviews all types of researches except clinical trials required for FDA registration of new drugs. These may entail more than minimal risk to participants. Post-marketing studies may be reviewed by Level 2 RECs.

3. Level 3 Accreditation

Level 3 Accredited REC reviews all types of researches including studies required for FDA registration of food, drugs and devices. Level 3 RECs may be invited by the FDA to conduct regulatory reviews on behalf of the latter. Level 3 Accredited RECs shall comply with ICH-GCP standards.

VI. REQUIREMENTS AND PROCEDURES FOR ACCREDITATION

1. Level 1 Accreditation

The REC must demonstrate sufficient competency and efficiency in ethical review, adhere to a set of appropriate standard operating procedures, and have adequate administrative support as shown by an assigned office with standard equipment, a budget that supports honoraria for and training of REC members.

1.1 REC applicants for Level 1 accreditation shall submit the following documents:

1.1.1 Cover Letter

1.1.2 Copy of the institutional issuance on the constitution and terms of reference (TOR) of REC

1.1.3 Manual of Standard Operating Procedures for REC activities (refer to Section IV. Item No. 3)

1.1.4 Accomplished PHREB Form No. 1.1: Application for Accreditation

1.1.5 Accomplished PHREB Form No. 1.3: Protocol Summary, in the past year (if available)

1.1.6 Accomplished PHREB Form No. 1.4: Self-Assessment for Level 1

1.2 A provisional certificate of Level 1 accreditation for one year shall be issued by PHREB after evaluation of the submitted documents. The formal awarding of the certificate shall be held either in March or in August of the year.

1.3 The REC shall be included in the list of accredited RECs in the PHREB website.

1.4 After the first year, the REC may apply for either one of the following:

1.4.1 An extension of Level 1 accreditation for another two (2) years, approval of which will be based on an evaluation of the following submissions:

1.4.1.1 PHREB Form No. 1.2: Annual Report;

1.4.1.2 PHREB Form No. 1.3: Protocol Summary; and

1.4.1.3 Copy of the minutes of the three (3) most recent REC meetings.

1.4.2 Level 2 or Level 3 Accreditation, with the submission of appropriate requirements (see Section VI: Item No. 2 or 3, respectively)

2. Level 2 Accreditation

The REC must demonstrate sufficient competency and efficiency in ethical review, adhere to a set of appropriate standard operating procedures, have systematic filing, have adequate administrative support as shown by an assigned office with standard equipment, at least a part time dedicated support staff, a budget that supports honoraria for and training of the REC members, and a functional database.

2.1 REC applicants for Level 2 accreditation shall submit the following documents:

2.1.1 Cover Letter

2.1.2 Copy of the institutional issuance on the constitution and terms of reference (TOR) of REC

2.1.3 Manual of Standard Operating Procedures (refer to Section IV: Item No. 3)

2.1.4 Accomplished PHREB Form No. 1.1: Application for Accreditation

2.1.5 Accomplished PHREB Form No. 1.3: Protocol Summary, for the past two years, including the current year

2.1.6 Accomplished PHREB Form No. 1.5: Self-Assessment for Level 2

2.1.7 Files of three (3) research protocols that have been reviewed and approved by the REC. The protocol file should include:

2.1.7.1 Copy of the initial and revised protocols, initial and revised informed consent forms, accomplished

assessment forms (technical/scientific and informed consent review);

2.1.7.2 Minutes of the meeting when the research protocol was discussed (initial and subsequent continuing reviews);

2.1.7.3 Letters/communications with the researchers (decision and approval letters); and

2.1.7.4 Progress/final reports and corresponding assessments.

2.1.8 Copies of the agenda and minutes of the most recent three (3) REC meetings.

2.1.9 Photograph of the office showing the equipment and storage system

2.2 The REC applicant shall comply with the following:

2.2.1 Inclusion of a member who is a health or allied health practitioner and a social scientist, familiar with the types of research protocols being reviewed by the REC.

2.2.2 Review of at least ten (10) protocols, five (5) of which should have undergone full review, within the past year.

2.2.3 A dedicated office space, with basic equipment (computer with internet connection and printer, telephone, filing cabinets with locks), contents of the active and inactive cabinets or filing system, poster of the general flow chart of REC procedures, and a designated staff secretary.

2.3 Issuance of a certificate of Level 2 accreditation shall be based on the evaluation of compliance with the requirements:

2.3.1 If compliance is satisfactory, the REC shall be given a Certificate of PHREB Level 2 Accreditation for three (3) years.

2.3.2 If there are deficiencies, the REC shall be issued a one (1) year provisional Certificate of PHREB Level 2 Accreditation, within which, the REC shall comply with the recommendations to address the deficiencies. Extension of its accreditation for another two (2) years will be based on satisfactory REC compliance.

2.3.3 The formal awarding of the certificate shall be held either in March or in August of the year.

2.3.4 The REC shall be included in the list of accredited RECs in the PHREB website.

2.4 A Level 2 accredited REC may apply for Level 3 Accreditation, with the submission of appropriate requirements (see Section VI, Item No. 3) including inclusion of a medical member who is an experienced clinical trialist and another medical member who has been or is currently a member of a Level 3 accredited REC.

A provisional Level 3 accreditation for one year may be issued that shall allow the REC to accept review of sponsored clinical trials.

3. Level 3 Accreditation

The REC must demonstrate sufficient competency and efficiency in ethical review, adhere to a set of appropriate standard operating procedures, have systematic filing, have adequate administrative support as shown by, but not limited to, an assigned office with standard equipment, a full time dedicated support staff, a budget that supports honoraria for and training of the REC members, and a functional database.

3.1 REC applicants for Level 3 accreditation shall submit the following documents:

3.1.1 Cover letter
3.1.2 Accomplished PHREB Form No. 1.1: Application for Accreditation
3.1.3 Accomplished PHREB Form No.1.3: Protocol Summary, in the last two years, including the current year
3.1.4 Accomplished PHREB Form No. 1.6: Self-Assessment for Level 3
3.1.5 REC Manual of Standard Operating Procedures (refer to Section IV: Item No. 3)

3.2 The REC applicant shall comply with the following:
3.2.1 All members should have basic research ethics training.
3.2.2 Majority of the members, including the Chair, should have GCP training within the past three (3) years.
3.2.3 At least one (1) member should have training in SOP writing.
3.2.4 All members should provide evidence of training in the use of the REC SOPs.
3.2.5 A dedicated office space, basic office equipment (computer with internet connection and printer, telephone, filing cabinets with locks, poster of the general flow chart of REC procedures and a full-time staff secretary).

3.3 The REC shall undergo an Accreditation Visit that will involve the following:
3.3.1 Preliminary coordination between PHREB and host REC regarding schedule of visit and logistics;
3.3.2 The accreditation visit shall include: opening and closing meetings, interview of REC members and staff, inspection of the REC office, including the archives, an observation of an REC meeting and review of documents (e.g. standard operating procedures, membership files, selected protocol files, SAE files, file of agenda and minutes of meetings, communications file, log book and databases).

3.4 Issuance of Accreditation Certificate will be processed as follows:
3.4.1 CSA will send the report to the REC within forty-five (45) calendar days after the visit;
3.4.2 REC shall submit an action plan to CSA within forty-five (45) calendar days after receipt of the CSA Report;
3.4.3 A follow-up visit may be scheduled by the CSA to determine compliance with the action plan; and
3.4.4 CSA shall recommend the appropriate accreditation of the REC.
3.4.5 PHREB shall award a certificate of accreditation with a specified period of validity of three (3) years. The formal awarding of the certificate shall be held either in March or in August of the year.
3.4.6 The REC shall be included in the list of accredited RECs in the PHREB website.

VII. RESPONSIBILITIES OF AN ACCREDITED REC

1. Posting of PHREB Accreditation Certificate

   A REC shall post or display its duly-secured certificate of PHREB accreditation in a conspicuous area within its office.

2. Submission of Annual Report within the first quarter of the following year using the PHREB Form No. 1.2: Annual Report which will reflect the following:
   2.1 changes in committee chair and membership;

2.2 trainings attended by current members;
2.3 number and type of protocols reviewed, approved, revised, and disapproved;
2.4 summary of recognitions received by the REC or significant events that have affected the performance of its duties; and
2.5 Challenges / issues encountered.

3. Reporting of any controversial or important ethical issues in the course of its work

4. Willingness to be monitored by PHREB
Annual report and other reports should be sent to the PHREB Secretariat, through:
Mailing address:c/o PCHRD, 3rd Floor, Room 306
DOST Main Building, General Santos Avenue, Bicutan, Taguig City 1631
Telephone: (02) 837 75 37 / TeleFax: (02) 837 29 24
Email address: ethics.secretariat@gmail.com

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 (Section VI: Procedures and Requirements for PHREB Accreditation).

IX. BASES FOR WITHDRAWAL OF ACCREDITATION

The accreditation of an REC may be withdrawn due to the following:
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.

The mechanism of payment is facilitated by the Philippine Council for Health Research and Development (PCHRD) which will issue periodic advisory on the matter in PHREB website (http://ethics.healthresearch.ph/).

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).

XI. ACCREDITATION OF SPECIALTY CLINICS

Introduction:

The level of accreditation of specialty clinics needs special attention because of concerns in providing appropriate care to research participants who may need medical care that is not covered by the specialty offered in the facility, and in the management of conflict of interest when the pool of consultants where both researchers/ investigators

and REC members are derived, is small. The following policies have been formulated to address the aforementioned issues.

Scope:

These policies cover specialty clinics defined as stand-alone health care facilities that offer specific medical specialty services only (e.g., dermatology, ophthalmology, hematology, dialysis, etc.). These policies do not cover health care facilities that offer stem cell therapy/research.

Policies:

1. Application for all levels shall require accomplishment of the attached Application Form 1.1a that is specific for Specialty Clinics. The application form shall provide information on :
   - 1.1 Type of specialty services
   - 1.2 Involvement in the production of health products including food preparations or supplements
   - 1.3 Number of active consultant staff (full time or part-time) with reference to practice privileges
   - 1.4 Nature of studies conducted
   - 1.5 Description of the Research Ethics Committee (number of members with at least one non-affiliated medical member in the same specialty, officers, specialty, affiliation, scientist/non-scientist, gender, age representation and record of research ethics training)
   - 1.6 Affiliation with / geographic access to a health facility with general medical services.

2. Application for Level 1 shall be processed according to the 2016 PHREB ACCREDITATION POLICIES AND REQUIREMENTS.

3. Processing and approval of an application for Levels 2 and 3 Accreditation shall take into consideration among others: an acceptable ratio (at least 10:1) of active consultant members of the research ethics committee to potential researchers and the accessibility of a health facility that offers general medical services to research participants, if needed.