I. RATIONALE

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, 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."

To fulfill the above functions, PHREB has set requirements to guide in the conduct of quality ethical review of health and health-related research. To this end, PHREB accreditation is a requirement for all RECs.

A Research Ethics Committee (REC) is a body 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 and promotes integrity of research data. It shall be constituted by a duly recognized authority and shall adhere to national and international research ethics guidelines.

II. COVERAGE

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

1. Academic Institution RECs

   These are RECs of 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 RECs

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

   In the case of specialty clinics/departments, additional and specific requirements shall be fulfilled as described in Section VII.

3. Government RECs

   These are RECs of 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

   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 RECs

   These RECs operate within and for research sites including specialty clinics. 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

Health research encompasses all research that seeks to understand the impact of processes, policies, actions, or events originating in any sector on the well-being of individuals and communities; and to assist in developing interventions that will help prevent or mitigate their negative impact, and in so doing, contribute to the achievement of health equity and better health for all (adapted from the RA 10532 Joint IRR). It implies that improving health outcomes requires the involvement of many sectors and disciplines. On the other hand, a research is considered "health-related" if it is outside of the aforementioned description for health research, but where the research procedures and outcomes can affect the well-being of the participants and the community.

In regions with functional Research Ethics Monitoring Boards (REMBs), accreditation of levels 1 and 2 shall be conducted by the respective boards.

The following policies shall be applicable:

1. All health and health-related research protocols/proposals involving human participants shall be reviewed by a Research Ethics Committee (REC).
2. 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). In case NCIP is able to establish its own REC, ethical clearance shall be issued by the same depending on feasibility.

3. Research protocols/proposals involving use of Animals are reviewed by an Institutional Animal Care and Use Committee (IACUC).

4. Protocols with biosafety issues or pose hazards to the environment including those involving animals and plants need review and approval by the institutional or National Committee on Biosafety of the Philippines (NCBP).

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;

5. All RECs shall undergo accreditation based on standards set by PHREB (Section IV: Accreditation Criteria).

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

   5.2. Members of the PHREB Accreditation Team shall be selected from the list of qualified accreditors who meet the criteria set by PHREB Committee on Standards and Accreditation (PHREB CSA); and

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

6. RECs whose accreditation have expired

   6.1 The list of RECs whose accreditation have expired shall be submitted to concerned institutions like the Food and Drug Administration (FDA), Commission on Higher Education (CHED), Department of Science and Technology (DOST), Department of Health (DOH), National Commission on Indigenous Peoples (NCIP), Commission on Human Rights (CHR), National Museum and other agency members of the ethics network.

   6.2 The RECs whose level 3 accreditation has expired are not authorized to review new applications of clinical trials intended for FDA registration.

   6.3. The RECs with expired accreditation shall continue to monitor previously approved protocols.

IV. ACCREDITATION STANDARDS

The PHREB CSA shall evaluate adherence of RECs to international and national research ethics guidelines according to six (6) standards using indicators listed below:

1. Functionality of structure and composition
   - 1.1 Integration within the institutional structure
   - 1.2 Independence
   - 1.3 Multi-disciplinarity
   - 1.4 Gender representation
   - 1.5 Age representation
   - 1.6 Ethics training
   - 1.7 Related expertise to protocols commonly reviewed
   - 1.8 Management of Conflict of Interest

2. Adequacy of standard operating procedures and consistency of implementation
   - 2.1 The REC SOP shall include 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.

   - 2.2 Minimum SOPs:
     - 2.2.1 Selection and appointment of members (regular and alternate), officers and independent consultants
     - 2.2.2 Management of Initial Submissions
     - 2.2.3 Management of Re-submissions
     - 2.2.4 Management of Post Approval Submissions
       - 2.2.4.1 Review of Progress Reports
       - 2.2.4.2 Review of Amendments
       - 2.2.4.3 Review of Protocol Deviations
       - 2.2.4.4 Review of Safety Reports
       - 2.2.4.5 Review of Final Reports
       - 2.2.4.6 Review of Early Termination Reports
       - 2.2.4.7 Management of Applications for Continuing Review
     - 2.2.5 Exemption from Review
     - 2.2.6 Expedited Review
     - 2.2.7 Full Review
     - 2.2.8 Management of Appeals
     - 2.2.9 Preparation for a Meeting including the Meeting Agenda
     - 2.2.10 Conduct of Meeting
     - 2.2.11 Documentation of REC Actions
     - 2.2.12 Management of Active Files
     - 2.2.13 Archiving of Files
     - 2.2.14 Site Visits
     - 2.2.15 Management of Queries/Complaints
     - 2.2.16 Writing and Revising SOPs

   - 2.3 Each SOP shall include the use of the appropriate REC forms e.g. appointment letters of REC members, forms, templates of REC communications, relevant institutional/hospital circular policies and memoranda, and others, glossary, history of the SOP and the list of References, approval date and approving authority.
   - 2.4 Consistency of implementation:
     - 2.4.1 Time frame
     - 2.4.2 Decision points and process

3. Completeness of review process
   - 3.1 Assignment of appropriate reviewers
   - 3.2 Complete accomplishment, consistent and meaningful use of the protocol and ICF assessment forms
   - 3.3 Comprehensive discussion (e.g., technical and ethical issues and ICF) during the REC Meeting

4. Adequacy of post-approval procedures
   - 4.1 REC requirement for submission of reports

4.2 Inclusion of reports in the meeting agenda
4.3 Assessment of the reports

5. Efficiency of the recording and archiving system
   5.1 Appropriate protocol coding system
   5.2 Use of physical or electronic logbooks that has real time and tamper-proof record of submissions
   5.3 Completeness of protocol folders
   5.4 Availability of updated databases (e.g., protocol, SAE, etc.)
   5.5 Systematic filing of administrative and protocol-related documents (e.g., active files and archives)

6. Adequacy of administrative support
   6.1 Availability of a designated support staff
   6.2 Provision of an office and equipment (e.g., provision of security of files)
   6.3 Approved annual budget for REC operations

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. The formal awarding of the certificate shall be held either in March or in August of the year. The REC shall be included in the list of accredited RECs in the PHREB website.

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

1. Level 1 Accreditation

Level 1 accreditation is a provisional accreditation given to new REC applicants. Provisional accreditation allows new RECs to acquire experience in review of researches and to give opportunity to comply with the recommendations of the CSA.

Level 1 accredited REC reviews all types of researches except clinical trials required for FDA registration of new drugs within the provisional one (1) year accreditation.

The REC shall submit required documents according to Section VI.1.4 of the PHREB Policies and Requirements for Accreditation of Research Ethics Committees (RECs) within the first six (6) months.

Failure to comply with the six (6)-month reporting requirement shall mean termination of the accreditation process and REC delisting from the list of PHREB Accredited RECs.

Within the year, the PHREB-CSA/REMB-CSA may recommend either submission of application for Level 2 or extension of Level 1 provisional accreditation and require further training and submission of additional evidence of compliance.

2. Level 2 Accreditation

Level 2 accredited REC reviews all types of researches except clinical trials required for FDA registration of new drugs.

RECs who have demonstrated satisfactory performance as a Level 1 REC (ie., functional structure and composition, adequate SOPs, adequate administrative support, effective management of files and archiving) may apply for Level 2.

RECs who have not been accredited but have been operating for more than six (6) months can apply for Level 2 accreditation provided they can submit all the necessary requirements.

Level 2 accreditation may be granted for one (1) or three (3) years depending on the degree of satisfactory compliance with the CSA recommendations with regard to quality and documentation of review.

3. Level 3 Accreditation

Level 3 Accredited REC reviews all types of researches including studies required in applications for marketing authorization of food, drugs and devices by a regulatory agency (i.e., FDA).

Level 3 accreditation may be granted for one (1) or three (3) years depending on the degree of satisfactory compliance with ICH-GCP standards and CSA recommendations with regard to quality and documentation of review.

VI. REQUIREMENTS AND PROCEDURES FOR ACCREDITATION

1. Level 1 Accreditation

The REC shall have a functional membership structure and composition, appropriate SOPs, adequate administrative support and effective management of files and archiving.

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/s on the following:
  - a. statement that all research involving human participants shall undergo ethics review by the REC
  - b. constitution, functions and responsibilities of the REC
  - c. Terms of Reference (TOR) of REC Members
  - d. statement on the independence of the REC in decision-making
  - e. commitment to support the operations of the REC.
- 1.1.3 Institutional organogram showing the location of the REC and its relation to the other units
- 1.1.4 Standard Operating Procedures for REC activities (refer to Section IV. Item No. 3)
- 1.1.5 Accomplished PHREB Form No. 1.1: Application for Accreditation

1.1.6 Updated CVs (including present official position in the institution) and training records of members (signed and dated)
1.1.7 Research Ethics training plan for members
1.1.8 Accomplished PHREB Form No. 1.4: Self-Assessment for Level 1 or 2 Application for Accreditation

1.2 A provisional Level 1 accreditation shall be issued by PHREB for one (1) year after evaluation of the submitted documents.

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

1.4 During the provisional year of accreditation, the REC shall be assessed:

1.4.1 After the first six (6) months by submission of PHREB Form 1.3. *Protocol Summary* that include REC decisions, minutes of the meeting and three protocol files.
1.4.2 Within the provisional year, the REC shall be re-assessed for possible Level 2 accreditation by submission of the following:
1.4.2.1. PHREB Form 1.1 Accreditation Application
1.4.2.2. PHREB Form 1.5 Self-assessment for Level 2
1.4.2.3. Resubmission of institutional policies relevant to the operations of the REC
1.4.2.4. PHREB Form No. 1.2: Annual Report;
1.4.2.5. CVs and ethics training records of members (signed and dated), if there are changes in membership
1.4.2.6. Institutional organogram showing the location of REC and its relation to the institution
1.4.2.7. PHREB Form No. 1.3: Protocol Summary;
1.4.2.8. Three (3) Protocol Files (at least one (1) full review) where each file shall contain: a) initial protocol; b) revised protocol, if any; c) initial informed consent; d) revised informed consent, if any; e) excerpt of minutes of the meetings where the protocol was discussed; f) decision letters; g) approval letter; h) assessment forms; and, i) reports (e.g. progress, final, and deviation);
1.4.2.9. Copy of the minutes of the three (3) most recent REC meetings; and
1.4.2.10. Other documents that may be required by PHREB based on its assessment after the first six (6) months
1.4.2.11. Resubmission of photographs of the office space, furniture, equipment, filing cabinets, screenshot of database, picture of the page of the logbook with the last entries

1.5. An REC who fails to achieve level 2 accreditation within three (3) years shall be delisted.

2. Level 2 Accreditation

RECs who have been operational for more than 6 months can apply for Level 2 accreditation.

2.1 A Level 2 REC shall comply with the six (6) accreditation standards, Section IV. *Accreditation Standards*. REC applicants for Level 2 accreditation shall submit the following documents:

- 2.1.1 Cover Letter of application
- 2.1.2 Accomplished PHREB Form No. 1.1: Application for Accreditation
- 2.1.3 Accomplished PHREB Form No. 1.4: Self-Assessment for Level 1 or 2 Application for Accreditation
- 2.1.4 Copy of the institutional issuance on the constitution and terms of reference (TOR) of REC, including a statement of administrative support for the operations of the REC
- 2.1.5 Copy of an institutional policy statement that all researches involving human participants shall undergo ethics review
- 2.1.6 Institutional organogram locating the REC and showing its relationship with the other units
- 2.1.7 Standard Operating Procedures (refer to Section IV: Item No. 3)
- 2.1.8 Flow chart of REC procedures including timelines from initial submission to approval
- 2.1.9 Protocol summary for the past two years including the current year based on PHREB Form No. 1.3: *Protocol Summary*
- 2.1.10 Files of three (3) research protocols that have been reviewed and approved by the REC. The protocol file should include:
  - 2.1.10.1 Copy of the initial and revised protocols, initial and revised informed consent forms, accomplished assessment forms (technical/scientific and informed consent review);
  - 2.1.10.2 Minutes of the meeting when the research protocol was discussed (initial and subsequent continuing reviews);
  - 2.1.10.3 Letters/communications with the researchers (decision and approval letters); and
  - 2.1.10.4 Progress/final reports and corresponding assessments.
- 2.1.11 Copies of the agenda and minutes of the most recent three (3) REC meetings.
- 2.1.12 Photograph of the office showing the equipment, furniture, screenshot of the database, page of the logbook with last entries and storage system

2.2 The REC applicant shall comply with the following:

- 2.2.1 Inclusion of members with expertise necessary for the type of research protocols being reviewed, at least one (1) non-affiliated member and one (1) non-scientist or lay/community member.
- 2.2.2 Members shall have training that includes topics on the elements of research ethics based on the national and international ethical guidelines and local regulations, and ethics review of protocols using a combination of didactics and small group discussions. The Chair, the Member-Secretary and Staff Secretary shall have training on SOP Writing and Revision. Members shall be oriented in the REC SOPs.
- 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.

Level 2 accreditation may be granted for one (1) or three (3) years depending on the degree of satisfactory compliance with the CSA recommendations with regard to quality and documentation of review.

3. Level 3 Accreditation

A Level 3 REC shall comply with the six (6) accreditation standards, Section IV. *Accreditation Standards* and must be GCP compliant.

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.

3.1 REC applicants for Level 3 accreditation shall submit the following documents:
- 3.1.1 Cover letter of application
- 3.1.2 Accomplished PHREB Form No. 1.1 *Application for Accreditation*
- 3.1.3 CVs and research ethics training certificates (signed and dated)
- 3.1.4 Accomplished PHREB Form No.1.3 *Protocol Summary*, in the last three years, including the current year
- 3.1.5 Accomplished PHREB Form No. 1.6 *Self-Assessment for Level 3*
- 3.1.6 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 shall have research ethics training.
- 3.2.2 The Chair and majority of the members, shall have GCP training within the past three (3) years.
- 3.2.3 The Chair, the Member-Secretary and Staff Secretary shall have training on SOP Writing and Revision. Members shall have a documented orientation on SOPs of their REC.
- 3.2.4 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 involves 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 of incoming and outgoing communication, and databases).

3.4 Post-visit activities
- 3.4.1 PHREB-CSA sends the Accreditation Report to the REC within 30 calendar days after the visit;

3.4.2 REC submits an action plan and evidence of compliance to CSA within 30 calendar days after receipt of the CSA Report;
3.4.3 A revisit may be scheduled by the CSA to determine compliance with the action plan and recommend the appropriate accreditation of the REC;
3.4.4 The CSA communicates the final evaluation/decision regarding the accreditation within 30 days after receipt of the evidence of compliance;
3.4.5 PHREB awards a certificate of accreditation with a specified period of validity.

VII. ACCREDITATION OF ACADEMIC (UNIVERSITY) RECs

The following policies shall be applicable to Academic (University) RECs:

1. In universities where the REC consists of panels, only one set of SOPs shall be used by the different panels.
2. In universities where a college or unit sets up its own REC, its accreditation application shall be justified and approved by the institutional authority.
3. The level of independence in decision-making of each panel shall be clearly described and justified in the administrative order constituting the REC and in the SOP of the REC.
4. The Academic (University) applicant RECs shall comply with the following membership requirements:

    4.1 All members of the university REC panels shall be appointed by the institutional appointing authority with the terms of reference, including responsibilities as officers, as members, as non-scientist and non-affiliated. All appointees shall sign the conforme.
    4.2 Faculty/staff who have retired for at least one (1) year from the university may be appointed as non-affiliated members of the REC.
    4.3 All members of the university REC, college REC or panel members shall be listed and identified separately in the PHREB No. 1.1 *Application Form.*
    4.4 All required membership documents, i.e., letter of appointment & conforme, CV, training record and training certificates, shall be included in the application package of the institution.

5. The description of management of submissions shall be clearly described in the SOP, e.g. centralized secretariat, database, coding system, filing of documents

VIII. ACCREDITATION OF RECs IN SPECIALTY CLINICS/HOSPITAL DEPARTMENTS

Introduction:

The level of accreditation of specialty clinics needs special attention because of concerns in the provision of 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.

These policies also cover RECs established in specific hospital departments.

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, one (1) affiliated medical/scientific member, officers, specialty, affiliation, scientist/non-scientist, gender, age representation and record of research ethics training)
    - 1.6 Affiliation with / geographic access (within 5 km radius) to a health facility with general medical services.
    - 1.7 Copy of Specialty Board Policy on Research Misconduct
    - 1.8 Other relevant documents as may be required by the PHREB CSA

2. Application for Level 1 shall be processed according to the 2020 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 1:10) of active consultant members of the research ethics committee to potential researchers (i.e., if there is less than 10 then all REC members should be non-affiliated with the center) and the accessibility of a health facility that offers general medical services to research participants, if needed.

IX. 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
   2.1 PHREB Form No. 1.2 *Annual Report* on or before 31 March

2.2 Submission of PHREB Form 1.3 *Protocol Summary* version 3 or protocol database that includes protocol title and code, name of researcher, type of review and action, date of approval and status

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

Annual report and other reports should be addressed to the PHREB Chair:
Mailing address: PCHRD, Executive Lounge, Department of Science and Technology, General Santos Avenue, Bicutan, Taguig City 1631
Telephone: (02) 8-837-75-37 loc. 403 / TeleFax: (02) 8-837-29-24
Email address: ethics.secretariat@pchrd.dost.gov.ph

X. RENEWAL OF ACCREDITATION CERTIFICATE

Within six (6) 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).

XI. BASES FOR SUSPENSION 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 suspended 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 may or may not have resulted in harm to participants.

XII. FEES

PHREB shall charge application and accreditation processing fees based on the level of accreditation applied for.

The accreditation fee shall include but not limited to the following: (1) accreditor's honorarium; (2) accreditor's accommodation, and airfare/transportation as needed; and (3) travel and health insurance for the duration of the accreditation visit.

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