I. RATIONALE

Section 12 on the mandate of the *Philippine Health Research Ethics Board (PHREB)* in the *Philippine National Health Research System (PNHRS) Act of 2013* states that "*The PHREB, shall ensure adherence to the universal ethical 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 the conduct of 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-bbeing of human participants and to promote 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 (AI-REC)*

   These are RECs of a university, college, medical school, or other professional schools or institutions. AI-RECs which function independently of other RECs in the same academic institution shall apply for PHREB accreditation separately.

2. *Hospital RECs (H-REC)*

   These are RECs of a hospital or health facility. H-RECs that function independently of the other RECs in a hospital shall 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 Agency-based RECs (G-RECs)*

   These are RECs of an office, department, bureau, or agency in the government. G-RECs that function independently of other RECs under a government office, department, bureau, or agency shall apply for PHREB accreditation separately. Examples are National Ethics Committee (NEC), Single Joint Research Ethics Board (SJREB), and Regional Ethics Monitoring Board (REMB).

   RECs for Regional Health Research and Development Consortia (RHRDC RECs) will be considered as G-RECs for funding purposes but if the different institutions establish their own RECs which function independently of others under the consortium, these institutional RECs must apply for PHREB accreditation.

4. *Cluster RECs (C-RECs)*

   These RECs are formed by a group 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, which are community-based and organized by LGUs. This can include RECs in indigenous/cultural communities.

6. Specialty Clinic-based RECs , Hospital Departments, Out-patient Clinics

   These RECs are based on stand-alone clinics that provide special clinic services (e.g., dermatology, ophthalmology, hematology, dialysis, etc.) and other medical care services including hospital departments that opt to have their own research ethics committee.

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 to health and health-related research and research ethics committees:

1. All research protocols/proposals involving human participants shall be reviewed by a Research Ethics Committee (REC) and approved prior to the recruitment of research participants;

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 obtain approval from the National Commission for Indigenous Peoples (NCIP) (local or regional office). 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 the 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);

   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; and

   5.4. PHREB accreditation may be conducted online or by actual visit.

6. REC Accreditation is a continuing process and its policies need to address specific situations:

6.1. Application for renewal of accreditation shall be done, at the latest, six (6) months before the expiration of the accreditation certificate. Late submission of the application for renewal will have the following consequences:

6.1.1. On the REC: Creation of a gap in reviewing authority; and
6.1.2. On the research: REC review during the "gap period" may not be recognized by regulatory authorities, e.g., FDA, Journal editors, conference organizers, and institutional promotion boards.

6.2. Extension of REC accreditation will be issued to the REC (to avoid the "gap period") when the delay is due to PHREB CSA scheduling and procedures.

6.3. An extension of accreditation means that the REC can continue to function beyond the effectivity period of the current accreditation authorization for a specified period. This is not considered a grant of regular accreditation.

7. Level 2 and 3 accredited RECs who have shown consistent performance for 2 consecutive accreditations may be given four (4)-year terms thereafter.

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 each standard:

Standard 1: Functionality of structure and composition

1.1. Integration within the institutional structure
1.2. Clarity of committee organizational structure, e.g. panels, subcommitees
1.3. Independence in decision-making
1.4. Multi-disciplinarity
1.5. Gender representation
1.6. Age (generational)representation
1.7. Research ethics training (Basic and annual Continuing Research Ethics Training updates)
1.8. Expertise related to protocols commonly reviewed
1.9. Management of Conflict of Interest

Standard 2: Adequacy of standard operating procedures and consistency of implementation

2.1. Overview/Introduction:
2.1.1. The REC SOP manual 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 and research ethics review, history and mandate of the REC, adherence to the international, national, institutional ethics research guidelines and regulations, policy/guidelines on compliance with the Data Privacy Act of 2012,

2.1.2. Structure, constitution, functions, and responsibilities of the REC; terms of Reference (TOR) of REC Members**:** REC members and chairs are protected from being removed prior to the expiration of their terms, except for good cause, REC members declare any conflicts of interest and prohibit members from participating in the review of any study in which they have a conflicting interest.

2.1.3. Statement on the independence of the REC in decision-making,

2.1.4. Authority of REC to terminate or suspend studies,

2.1.5. The institution has requirement that all researchers affiliated with it be trained in their responsibilities for ethical conduct of research,

2.1.6. Statement on the responsibility of the institution and researchers (i.e., faculty, staff, students, and trainees) to provide mechanisms for care for research-related injuries;

2.1.7. The institution has a mechanism to investigate allegations of unethical conduct by researchers and to impose consequences or establish a Research Integrity Office**,**

2.1.8. Institutional commitment to support the operations of the REC (legal, administrative, financial, technological), and

2.1.9. A flow chart showing the general REC procedures from initial submission to archiving.

2.2. Minimum (Basic) SOPs:

2.2.1. Selection and appointment of members (regular and alternate),

2.2.2. Designation of officers

2.2.3. Invitation/Appointment of independent consultants

2.2.4. Management of Initial Submissions

2.2.5. Exemption from Review

2.2.6. Expedited Review

2.2.7. Full Review

2.2.8. Joint Review (Participation in SJREB Review - if applicable)

2.2.9. Review in Public Health Emergencies

2.2.10. Management of Re-submissions

2.2.11. Management of Appeals

2.2.12. Management of Post Approval Submissions

2.2.12.1. Review of Progress Reports

2.2.12.2. Review of Amendments

2.2.12.3. Review of Protocol/Deviations/Violations and Noncompliance

2.2.12.4. Review of Safety Reports (RNEs, SAE/SUSAR)

2.2.12.5. Review of Final Reports
2.2.12.6. Review of Early Termination Reports
2.2.12.7. Management of Applications for Continuing Review

2.2.13. Conduct of Site Visit
2.2.14. Management of Queries, Complaints and Feedback
2.2.15. Preparation for a Meeting
2.2.16. Preparation of the Meeting Agenda
2.2.17. Conduct of Meeting
2.2.18. Preparing the Minutes of the Meeting
2.2.19. Communicating REC Decisions
2.2.20. Management of Incoming and Outgoing Communications
2.2.21. Management of Active Files
2.2.22. Archiving of Files
2.2.23. Access to Confidential Files
2.2.24. Communication and coordination with other research ethics oversight stakeholders (committees, regulatory authorities, and others)
2.2.25. Annual Performance Evaluation (Internal Audit) of Members and Staff, Compliance to SOP, Quality of work, Resolution of Complaints, and Client feedback
2.2.26. Writing and Revising SOPs

2.3. Each SOP shall include the use of the appropriate REC forms (e.g. appointment letters of REC members, templates for REC communications), citation of relevant institutional/hospital circular policies and memoranda, 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 processes

Standard 3: Quality of Review

3.1. Assignment of appropriate reviewers
3.2. Timely accomplishment, consistent and meaningful use of the protocol and ICF assessment forms
3.3. Comprehensive discussions (e.g., technical and ethical issues and ICF) during the REC Meeting
3.4. Consistency in stating findings and decisions in the protocol files (e.g., assessment forms, minutes of meetings, decision letters)

Standard 4: Adequacy of post-approval procedures

4.1. REC requirement for submission of post-approval reports
4.2. Inclusion of reports in the meeting agenda
4.3. Assessment of the reports

Standard 5: Efficiency of the recording and archiving system

5.1. Appropriate protocol coding system
5.2. Use of physical or electronic logbooks that have real-time and tamper-proof records of submissions
5.3. Completeness of physical and/or electronic protocol folders
5.4. Availability of updated databases (e.g., protocol, SAE, etc.)
5.5. Accurate documentation of the proceedings of the REC meeting
5.6. Systematic filing of physical or electronic administrative and protocol-related documents (e.g., active files and archives)

Standard 6: Adequacy of administrative support

6.1. Administrative issuances/offices supportive of the REC functions (Research Integrity Office, Research Training Office, etc.)
6.2. Adequate legal support to carry out REC activities
6.3. Availability of a designated support staff
6.4. Provision of an office and equipment (e.g., provision of security of files)
6.5. Adequate technological support for REC needs
6.6. Approved annual budget for REC operations
6.7. Functioning Website

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 on the PHREB website.

PHREB shall grant any of the following levels of accreditation to a 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 the review of research and to give opportunity to comply with the recommendations of the CSA.

   Level 1 accredited REC reviews all types of research except clinical trials required for FDA registration of new drugs and research involving indigenous cultural communities / indigenous peoples (ICCs/IPs), within the provisional one (1) year accreditation.

   The REC shall submit the 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.

Within the year, the PHREB-CSA/REMB-CSA may recommend either submission of an 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 research except clinical trials required for FDA registration of new drugs.

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

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 research including clinical trials 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. Accomplished PHREB Form No. 1.1: Application for Accreditation
- 1.1.3. Accomplished PHREB Form No. 1.2: Self-Assessment for Level 1
- 1.1.4. Copy of the institutional issuance/s on the following:
  - 1.1.4.1. Ethics Review by the REC of research involving human participants

1.1.4.2. Requirement for training of institutional researchers on their responsibilities for ethical conduct of research.
1.1.4.3. Independence of the REC in decision-making
1.1.4.4. Protection of REC members and chairs from removal prior to the expiration of their terms, except for good cause.
1.1.4.5. Structure, constitution, functions, and responsibilities of the REC and TOR of its members.
1.1.4.5.1. Adherence of the REC to international, national (including the Data Privacy Act of 2012) and institutional guidelines and regulations
1.1.4.5.2. Authority of REC to terminate or suspend studies.
1.1.4.5.3. Declaration by REC members of conflicts of interest and prohibition of members from participating in the review of any study in which they have a conflicting interest
1.1.4.5.4. REC members and chairs are appointed for fixed terms rather than indefinitely. Terms are staggered so that terms do not all expire at the same time
1.1.4.6. Institutional support for the REC operations (legal, administrative, financial, technological)
1.1.4.7. Responsibility of the institution and researchers (i.e., faculty, staff, students, and trainees) to provide mechanisms for care for research-related injuries.
1.1.4.8. Institutional mechanism to investigate allegations of unethical conduct by researchers and to impose consequences or to establish a Research Integrity Office
1.1.5. Institutional organogram showing the location of the REC and its relation to the other units
1.1.6. REC organizational structure
1.1.7. Standard Operating Procedures for REC activities (refer to Section IV. Item No. 3)
1.1.8. Flow chart of REC procedures including timelines from initial submission to approval and a second flow chart for post-approval continuing review until acceptance of final report and archiving
1.1.9. Updated CVs (including current official positions, academic and administrative) in the institution, present and past work experience) and training records, confidentiality & COI agreement of members (signed and dated), and training certificates
1.1.10. Research Ethics training plan for members
1.1.11. Website that includes the following sections: Membership list, Schedule of meetings, SOPs, downloadable REC forms, Review Process flowchart, listing of approved protocols, date of approval, and PIs, international and national references, Queries/Complaints/ Feedback/Survey Forms, Frequently

Asked Questions (FAQs), Funding information available upon request, Research participant's rights refer to (PHREB CPFCE informational materials and other institutional materials)

1.1.12. Pictures of covers of updated international and national ethical guidelines.

1.1.13. Photograph of the office showing the equipment, furniture, and storage system.

1.2. Decision regarding the application will be given by PHREB-CSA within 120 calendar days upon receipt of complete application documents;

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

1.4. The REC shall be included in the list of accredited RECs on the PHREB website;

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

1.5.1. After the first six (6) months by submission of PHREB Form

1.5.1.1. PHREB Form 1.3. Protocol Summary (current year)

1.5.1.2. Three (3) recent, consecutive minutes of REC Meeting

1.5.1.3. Three (3) protocol files (1 or 2 completed expedited review protocols, one (1) or two (2) full review protocols (one (1) active or one (1) completed)

1.5.2. Within the provisional year, the REC shall be re-assessed for possible Level 2 accreditation, see requirements below.

2. **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. 1.2: Self-Assessment for Level 2

2.1.4. Copy of the institutional issuance/s (see Section VI, Item 1.1.4)

2.1.5. Institutional organogram locating the REC and showing its relationship with the other units

2.1.6. REC structural organization

2.1.7. Standard Operating Procedures (refer to Section IV, Items 2.1-2.3)

2.1.8. Flow chart of REC procedures including timelines from initial submission to approval and a second flow chart for post-approval continuing review until acceptance of final report and archiving

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. Three (3) research protocols (at least one full review) that have been reviewed and approved by the REC. Each protocol file shall contain:

2.1.10.1. Index of protocol file contents

2.1.10.2. Initial protocol with ICF; revised protocol and ICF, if any;

2.1.10.3. CVs, training certificates, and Declaration of COI by PI;

2.1.10.4. Filled up Protocol and ICF assessment forms by reviewers;
2.1.10.5. Excerpts of minutes of the meetings where the protocol was discussed (initial and subsequent continuing reviews);
2.1.10.6. Letters/communications with the researchers (decision and approval letter;
2.1.10.7. Post-approval reports (e.g. progress, final, and deviation, etc) and corresponding assessments and decisions;

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;
2.1.13. Functioning Website (see Section VI, Item 1.1.10);
2.1.14. Pictures of the covers of available and updated international and national ethical guidelines, laws, policies, and regulations, and
2.1.15. Annual Report/Previous Accreditation Final Report

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 (basic research training and annual updates) 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, Functioning Website, and a designated staff secretary.

2.3. REC submits a complete evidence of compliance to CSA within 60 calendar days after receipt of the CSA Report. Failure to submit will affect its reviewing authority, see Section III, Items 6.1.1 - 6.1.2.

2.4. 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 regards 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 the 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. Accomplished PHREB Form No. 1.2a Self-Assessment for Level 3;
- 3.1.4. Accomplished PHREB Form No.1.3 Protocol Summary, in the last three years, including the current year;
- 3.1.5. Copy of the institutional issuance/s (see Section VI, Item 1.1.4), and requirement that clinical trials be registered in a registry that complies with the WHO registry criteria before recruitment of participants begins;
- 3.1.6. Institutional organogram locating the REC and showing its relationship with the other units;
- 3.1.7. REC structural organization
- 3.1.8. Standard Operating Procedures (refer to Section IV, Items 2.1-2.3);
- 3.1.9. Flow chart of REC procedures including timelines from initial submission to archiving;
- 3.1.10. CVs and research ethics training certificates, confidentiality & COI agreement (signed and dated); and
- 3.1.11. Annual Report/Previous Accreditation Final Report

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, Member-Secretary, and Staff Secretary shall have training on SOP Writing and Revision. Members shall have a documented orientation on SOPs of their REC; and
- 3.2.4. A dedicated office space, basic office equipment (computer with an Internet connection and printer, telephone, filing cabinets with locks, poster of the general flow chart of REC procedures, a full-time staff secretary, and a Functioning Website (see Section VI, Item 1.1.10).

3.3. The REC shall undergo an Accreditation Visit (virtual and/or face-to-face) that involves the following:

3.3.1. Preliminary coordination between PHREB and host REC regarding the schedule of the visit and logistics; and

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 active, and inactive files, and archives, an observation of a 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, logbook of incoming and outgoing communication, databases and functioning website).

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 evidence of compliance to CSA within thirty (30) calendar days after receipt of the CSA Report;

3.4.3. A clarificatory meeting may be done after the first submission of evidence of compliance;

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. The decision may be:

3.4.5.1. ***Revisit*** – may be decided by the CSA to reevaluate the level of compliance and recommend the appropriate accreditation of the REC;

3.4.5.2. ***Accreditation*** – one (1) year or three to four (3-4) years Level 3 accreditation; or

3.4.5.3. ***Reclassification*** – one (1) year Level 2 accreditation, the REC may reapply not later than six (6) months before the expiration of accreditation.

3.4.6. 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 all the different panels.

2. The 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-scientists, and as non-affiliated. All appointees shall sign the conforme statement.

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 the 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 STAND-ALONE CLINICS, SPECIALTY CLINICS/HOSPITAL DEPARTMENT

1. Introduction:

The level of accreditation of specialty clinics or of individual clinical department 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.

2. Scope:

These policies cover specialty clinics defined as stand-alone healthcare facilities that offer specific medical specialty services only (e.g., dermatology, ophthalmology, hematology, dialysis, etc.) and RECs established in specific hospital departments. These policies do not cover healthcare facilities that offer stem cell therapy/research.

These policies also cover RECs established in specific hospital departments.

3. Policies:

3.1. Application for all levels shall require the accomplishment of the attached Application Form 1.1a that is specific for Specialty Clinics and departments. The application form shall provide information on:

3.1.1. Type of specialty services;

3.1.2. Involvement in the production of health products including food preparations or supplements;

3.1.3. Number of active consultant staff (full-time or part-time) with reference to practice privileges;

3.1.4. Nature of studies conducted;

3.1.5. 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);

3.1.6. Affiliation with / geographic access (within 5KM radius) to a health facility with general medical services;

3.1.7. Copy of Specialty Board Policy on Research Misconduct; and

3.1.8. Other relevant documents as may be required by the PHREB CSA.

3.2. Application for Level 1 shall be processed according to the *2024 PHREB Accreditation Policies and Requirements for Accreditation of Research Ethics Committees.*

3.3. 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. 8.2 *Annual Report* on or before 31 March
   2.2. Submission of PHREB Form 1.3 *Protocol Summary* version or protocol database that includes protocol title and code, name of the researcher, type of review and action, date of approval, and status
   2.3. Internal Performance Audit Report and quality improvement plans

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, Saliksik Building, DOST Compound, Gen. Santos Ave., 1631 Bicutan, Taguig City, Philippines
   Email address: ethics.secretariat@pchrd.dost.gov.ph

X. RENEWAL OF ACCREDITATION CERTIFICATE

RECs should submit an application for renewal of accreditation not less than six (6) months before the expiry of its accreditation 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 a REC may be withdrawn due to the following:

1. Non-compliance with PHREB reportorial/other requirements

   A 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, refer to Annex A for the schedule of fees.

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 the PHREB website (http://ethics.healthresearch.ph/).