



# Research Ethics Policy

## 1. Rationale

The Philippine Christian University Research Office was established in the 1980s under the original name, Research and Publications Office. In 2024, this was renamed the Institute for Research, Innovation, and Sustainability (IRIS). The University Research Ethics Committee (REC) is newly established to uphold the highest ethical standards in research conducted within the University. It ensures that all research involving human participants, animals, and sensitive data is undertaken responsibly, transparently, and by institutional, national, and international ethical guidelines. The key reasons for its establishment include the protection of the research participants by safeguarding their rights, dignity, and well-being of human participants; ensuring that researches are aligned with ethical principles of autonomy, beneficence, non-maleficence, and justice; preventing misconduct such as plagiarism, falsification, fabrication or conflicts of interest; maintaining research integrity and academic excellence; ensuring that university research contributes positively to society without ethical breaches; conduct periodic reviews of on-going research to ensure continued ethical compliance; and ensure that the university research contributes to societal advancement without ethical compromise.

## 2. General Policy

2.2 The Philippine Christian University is committed to upholding the highest ethical standards in research. This policy outlines the principles to ensure that all research conducted under the University's auspices adheres to ethical, legal, and professional standards. It shall ensure that all guidelines mandated by the PCU Research Ethics Committee are implemented and complied with. It has the following objectives:

2.1.1 Establish and maintain the Research Ethics Committee, determine its composition and appoint members to serve as reviewers for all ethics clearance

2.1.1.1 The terms of office of REC officers and members are fixed terms. Terms are staggered, and they do not expire at the same time. (see Policy statement of SOP 1)

2.1.1.2 The REC Officers and members can only be removed before the end of their terms due to cause.

2.1.2 Ensure that the University allocates funds and other resources to enable the REC members to discharge their duties and responsibilities in the most effective way without delay while providing for the annual review of resources.

2.1.3 Ensure the independence of the REC in its review and decision.

2.2.4. Manage conflicts of interest and ensure up-to-date records of how the University resolved issues related to conflicts of interest.

2.2.4.1 The REC can terminate or suspend studies if found to violate any of the REC policies.

2.2.5. Accept legal responsibility for the decisions made by the research ethics committee.

2.2.6. Monitor approved protocol for all research within its governing territory.

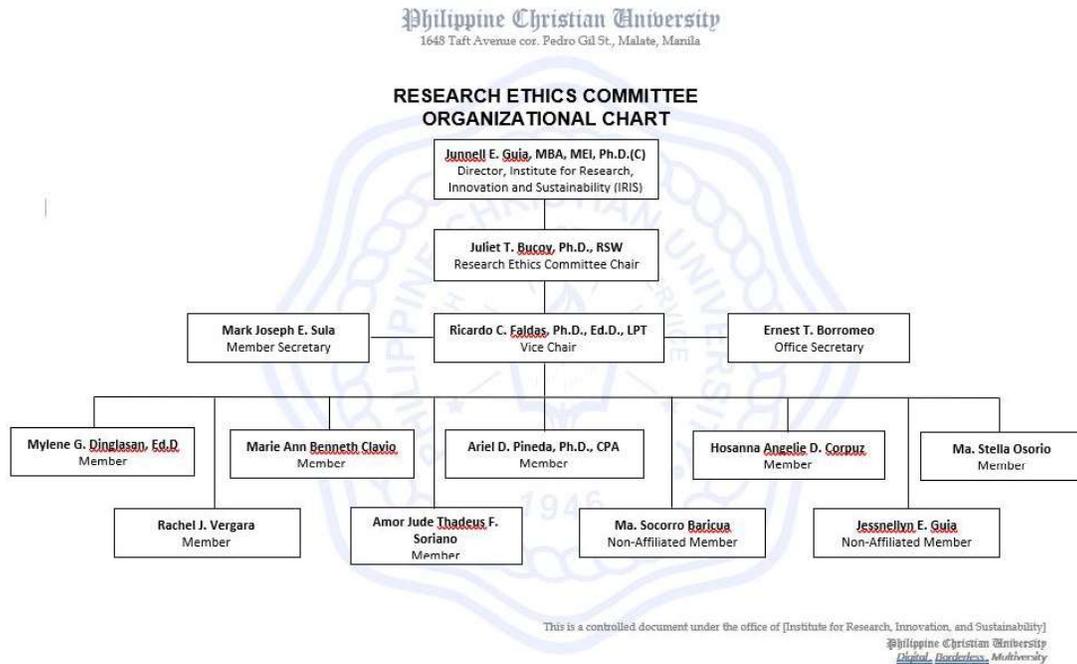
2.2.7. Promote responsible publication and dissemination of research findings.



- 2.2.8. Ensure support for training in human subject protection for investigators, Good Clinical Practice (GCP), research methods involving human experimentation, confidentiality, data storage and records keeping, as well as regulation and governance for researchers and staff, and the requirement for annual training of institutional researchers to be conducted by respective colleges on their responsibilities for ethical conduct of research.
- 2.2.9. Perform and document quality assurance activities to ensure compliance with international and national accreditation bodies.
- 2.2.10. Establish policies and guidelines governing the ownership and access to databases, registries, and records, ensuring compliance with confidentiality requirements, laws, privacy regulations, and other relevant guidelines, including funding agreements.
- 2.3. The Institute for Research, Innovation, and Sustainability (IRIS) is the office responsible for implementing research policies within the University.
- 2.3.1. Functions of the Research Director :
- Leads in formulating policies and guidelines to follow in developing research programs at the University.
  - Oversees, develops and reviews the research agenda and regularly unifies all academic units' research initiatives and activities.
  - Prepare reports on research matters requested by the University and other institutions.
  - Spearheads implementing and monitoring policies, guidelines, programs and procedures developed by the Institute for Research, Innovation, and Sustainability Office.
  - Manifest leadership in promoting the research educational opportunities with the individuals, groups, organizations and the priority program areas of PCU.
  - Maintains a system for disseminating and advocating research findings and outcomes.
  - Exercises the overall supervision of the Research Office and other units represented by different research coordinators and other units that support research by different extension programs of PCU.
  - Manages the institutional publications; for symposia, colloquium/i.e., conferences forum/s, etc.
  - Manages the research programs and activities of the University and, likewise, the performances of his/her subordinates.
- 2.2.2 To perform other functions that the University President may assign.

### 3. The PCU Research Ethics Committee

### 3.1 Organizational chart



### 3.2 Functions

- 3.2.1 To develop, assess, recommend and implement guidelines on the ethical review of research protocols.
- 3.2.2 To assess research protocols to ensure compliance with ethical standards
- 3.2.3 To review informed consent processes to ensure that risks and benefits are covered in the protocol.
- 3.2.3 To ensure the research participants' protection, safety, rights, and well-being.
- 3.2.4 Ensure that institutional policies and legal requirements are enforced.
- 3.2.5 To approve, modify or reject studies to improve ethical compliance.
- 3.2.6 To ensure the protection of the integrity of the scientific data.
- 3.2.7 To address and act on the concerns of research participants and other stakeholders.
- 3.2.8 To conduct periodic reviews to ensure ethical compliance.
- 3.2.9 To issue ethical clearance to approved research protocols.
- 3.2.10 To conduct and educate researchers on research ethics and responsible conduct.

## 4. POLICIES AND GUIDELINES



#### **4.1. Scope of policy**

This policy applies to all faculty under the Basic Education and the different Colleges, both for PCU Manila and Damarinas campuses, administrators, faculty, staff, and students, conducting research regardless of funding source or the geographical area of the research. This is a requirement that all researches will pass through the acquisition of ethics clearance to ensure that the researches are aligned with the University's Vision-Mission and thrusts, and the results are valuable, well disseminated and utilized for the PCU community as well as the community at large.

The Research Ethics Committee (REC) office shall be implemented by the office of the Institute for Research, Innovation and Sustainability (IRIS) under the leadership of Director Junnell E. Guia, MBA, MEI, PhD (c).

The PCU-IRIS implements the university policy on the conduct of institutional research. Institutional research includes any research conducted by regular faculty members, students, clinical faculty members, residents and administrators. All institutional research protocols must undergo ethics review as stipulated in this manual.

#### **4.2. Adherence to international and national guidelines**

4.2.1. PCU Research Committee complies with the requirements of the following international and national guidelines. These guidelines have been developed to protect the human participants in research and to ensure the integrity of the scientific data.

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects (2016)

WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (2011)

National Ethical Guidelines for Research Involving Human Participants (2022)

Philippine Health Research Ethics Board Standard Operating Procedures (2020)

PHREB New Accreditation Policies (2024)

#### **4.3 Technical Review**

4.3.1. All research protocols must undergo technical review prior to submission to the Research Ethics Committee.

4.3.2. Technical review evaluates the relevance and scientific merit of research proposals and is the responsibility of the department and of the college or unit endorsing a study protocol.

4.3.3. Protocols carrying technical approvals must be endorsed by the department and the college/unit to REC for ethics review.

4.3.4. For graduate student research, a member of the student's thesis/dissertation panel may come from the Technical Review Committee of the college/unit where the student is enrolled.

4.3.5. Technical reviewers may be guided by SOP No. 6, Management of Initial Submissions

4.3.6. Investigators must submit evidence of technical review. Applications for ethical approval without prior technical review will not be processed and will be returned to the investigator.



4.3.7. The REC reserves the right to request additional technical review from an independent expert consultant.

#### **4.4. Ethics review**

4.4.1. All research proposals shall be submitted for ethics review.

4.4.2. All research protocols should include a section on Ethical Considerations that details the ethical issues and corresponding measures to reduce the risks to human participants, laboratory animals, and the environment.

4.4.3. Informed consent (IC) and documentation (e.g. signatures) of IC shall be obtained.

#### **4.5. Compulsory registration**

4.5.1. Compulsory registration of research within the University is an expression of the University's rights to:

- Monitor and regulate the utilization of its facilities
- Monitor and regulate the use of its name
- Protect its intellectual property

4.5.2. Registration of research is a requirement of PCU, and non-compliance is subject to university rules and regulations.

#### **4.6. Reviewer's qualifications and responsibilities**

4.6.1. Qualification is determined by education, training, and experience to assume responsibility for the proper conduct of the study.

4.6.2. Updated Curriculum Vitae of the reviewer or committee member.

4.6.3. Reviewers should comply with ethical requirements, good clinical practice requirements (as applicable), and the applicable regulatory requirements with appropriate documentation or certifications.

4.6.4. Qualifications include the authority to facilitate institutional permissions for necessary audit of research or trial sites by the sponsor and inspection by the appropriate regulatory authority (ies).

#### **4.7. Submission procedures and required documents for initial review**

4.7.1. Research protocols should be guided by the requirement set by the REC

4.7.2. All applicable documents indicated in the PCU SOP under the Review Checklist should be included in the Protocol Submission Package. It is the responsibility of the applicant to provide copies as needed.

4.7.3. Investigators are required to submit, together with the Protocol Submission Package, proof of qualifications to conduct the research (e.g., CV, Research Ethics and GCP Training) obtained within three (3) years.

4.7.4. Specific research protocols may require additional documents, permits, and clearances. Investigators will be provided with a checklist of additional documents for submission upon initial protocol screening by the REC Secretariat.

4.7.5. Submissions from non-PCU researchers will not be accepted by the REC unless their research site is within the scope of authority of the PCUREC.



- 4.7.6 A discussion of any specific ethical issues the research may raise and how these will be addressed. This can include concerns about participant vulnerability, cultural sensitivities, or potential conflicts of interest.

#### **4.8. Submission requirements for continuing review**

- 4.8.1. No amendments in an approved protocol shall be implemented without prior approval by the Research Ethics Committee.
- 4.8.2. Any Research protocol amendments will just follow REC SOP 9 on Review of Amendments
- 4.8.3. Operational definitions of revisions, amendments, and resubmissions will follow existing SOPs 12 on continuing review.
- 4.9. Review and approval of study protocols
- 4.9.1. Research protocols will be reviewed based on the following elements:
- Completeness of documentation requirements
  - Scientific soundness
  - Ethical considerations
  - Conflict of interest
  - Informed consent

#### **PCU-REC Additional Guidelines**

- 5.1. Undergraduate student research involving human participants is subject to the same general principles as outlined in this document.
- 5.1.1. Undergraduate students are students enrolled in a bachelor's degree program. Students enrolled in graduate programs and postgraduate programs in law and medicine are considered postgraduate students.
- 5.1.2. All undergraduate student research must be conducted under the supervision of a faculty member of the college in the University.
- 5.1.3. Undergraduate students shall ONLY be allowed to do the following types of research:
- Research that is of minimal risk
  - Research that fulfils the criteria for an expedited review
  - Non-therapeutic or non-interventional
  - Research that poses a risk to the security, safety, or well-being of students will not be permitted.
- 5.1.4. submission of protocols shall follow the general guidelines on protocol submission and review.
- 5.1.5. A review of undergraduate student research shall be undertaken by the college where the student is enrolled, but the student must undergo REC mandatory registration procedures.
- 5.1.6. Undergraduate student research can be discontinued at any time by the faculty adviser if the study is found to be harmful to the study respondents.



5.2. Researchers who use vulnerable populations must ensure compliance with the provisions in international ethical guidelines and the National Ethical Guidelines for Health and Health-Related Research.

5.2.1. Vulnerable populations are those who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests. These include, but are not limited to, the following:

- Children and the elderly
- Persons with psychosocial disabilities and behavioural disorders
- Pregnant and lactating mothers
- Prisoners , drug users and drug dependents
- Persons who are victims of violence and maltreatment due to employment
- Very sick and desperate patients
- children who are victims of child labour in underdeveloped communities, including Indigenous communities

**5.2.2. In general, research involving vulnerable populations must have the following minimal requirements:**

- The purpose of the research is to obtain knowledge relevant to the particular health needs of the vulnerable subject population.
- The research must provide a strong rationale for including vulnerable populations.
- It must demonstrate that the research cannot be conducted with non-vulnerable populations.
- The potential benefits must outweigh the risks for participants.
- Participants (or their legal representatives) must receive clear, accessible, and culturally appropriate information.
- The consent process must ensure that participants fully understand the risks, benefits, and their rights.
- When applicable, proxy or guardian consent must be obtained for incompetent participants.
- Participants must have the ability to withdraw at any time without consequences.
- Ensuring that incentives do not create undue pressure.
- Participants must be fairly selected, avoiding coercion, exploitation, or undue influence.
- Inclusion and exclusion criteria must be clearly defined and justified.
- Safeguards Against Coercion and Undue Influence for prisoner respondents
- Participants must not feel pressured to participate due to financial need, authority figures, or lack of alternatives.
- Incentives must be reasonable and not create undue influence.



- The assent of each subject has been obtained to the extent of his or her capabilities, and a prospective participant's refusal to participate in non-clinical research is always respected
  - For Persons with Disabilities, accessibility considerations and support for decision-making are highly desired.
  - The degree of risk attached to interventions that are not intended to benefit the individual participant is low and commensurate with the importance of the knowledge to be gained.
- 5.2.3. Any member of the research ethics committee who reviews research protocol involving children or persons below 18 years old must have at least one member on board during the board meeting who is a paediatrician or child development specialist and with a lay member who is a parent.
- 5.2.4. research involving prisoners as respondents and those with serious illness or at risk of serious illness should ensure that prisoners are not arbitrarily denied access to investigational drugs, vaccines, or other agents that show promise of therapeutic or preventive benefit. They shall also receive protection from coercion due to institutional power dynamics.
- 5.2.5. Any member of the review ethics committee who reviews research involving underdeveloped communities must have a member or consultant who is knowledgeable of the cultural background of the research under study. Thoroughly familiar with the customs and traditions of the community being researched. The panel must ensure that research in underdeveloped communities should only be carried out with the following criteria:
- The research could be carried out reasonably well in a developed community.
  - The research is responsive to the health needs and the priorities of the community.
  - Informed consent of individual members is obtained, and community permission has been secured.
- 5.2.6. research involving pregnant or breastfeeding women requires heightened ethical and safety considerations to protect both the mother and the fetus/infant. The following protective mechanisms should be in place:
- The research must provide a strong scientific rationale for including pregnant or breastfeeding women. The research must demonstrate that it cannot be conducted with non-pregnant participants.
  - As a general rule, pregnant or breastfeeding women should not participate in any clinical trials unless designed to protect or advance the health of pregnant or nursing women and fetuses or breastfeeding infants.
  - Ethical experts in maternal-fetal health should be consulted for high-risk studies.
- 5.4. Guidance for other research work not detailed above may be found in specific sections of the National Ethical Guidelines for Health and Health-Related Research, such as using live vertebrates other than humans.
- Herbal Research
  - Complementary and Alternative Medicine Research



- Research on Populations Traumatized in Emergencies and Disasters ▪  
Genetic Research
  - International Collaborative Research
  - Research on Assisted Reproductive Technology
- 5.5. Material tissue transfer or transfer of blood components, human tissues, and genetic materials outside of the Philippines shall be governed by RA 8293: An Act Prescribing the Intellectual Property Code and Establishing the Intellectual Property Office, Providing for its Powers and Functions and for other Purposes<sup>14</sup>; and its implementing rules and regulations.
- 5.6. Research projects with biosafety implications shall be processed by the REC and then referred to the Institutional Biosafety and Biosecurity Committee (IBBC) for review and clearance, subject to criteria set by the IBBC Policies and Guidelines.
- 5.7. The REC addresses participant queries and concerns by REC SOP 26
- 5.7.1. Human participants in research are entitled to lodge their complaints or grievances related to research protocols approved by the REC. Examples are:
- Research misconduct (dishonesty, disrespect, coercion, physical "abuse" not in keeping with research procedures, breach of privacy, etc.)
  - Discrimination in the recruitment process
  - Non-compensation
  - Deviation from procedures enunciated in the informed consent
  - Misinformation
  - Severe adverse reactions
  - Injuries (physical, psychological, mental) perceived to be due to the study procedures
- 5.7.2. The REC does not have police powers, but in view of its oversight functions, it can directly receive complaints or grievances relevant to research protocols approved by the REC and address such complaints from participants in coordination with the approving REC.
- 5.7.3. REC-approved informed consent forms should contain the name of the panel and the date signed, which reviewed and approved the protocol, with the contact information of the REC Office.
- 5.7.4. The REC will process respective complaints or grievances by the REC SOPs on handling complaints or grievances and act on them in a prompt, impartial, and confidential manner while recommending a resolution based on existing policies and applicable regulations, with the option to seek legal counsel.
- 5.7.5. The complaints of relevant stakeholders will be escalated to the appropriate authorities when necessary.
- 5.7.6. An institutional mechanism to investigate allegations of unethical conduct by researchers and to impose consequences is being set in place. REC will facilitate the process.