



**Date** : 10 January 2024

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 Facilities Management Department Library

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**SUBJECT** : **Creation of a Center for Health Research and Innovation**

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REPUBLIC ACT No. 10532, otherwise known as, "AN ACT INSTITUTIONALIZING THE PHILIPPINE NATIONAL HEALTH RESEARCH SYSTEM (Congress, 2012)," dated May 07, 2013 through its Implementing Rules and Regulations (IRR), Rule 23 C, Section b requires the establishment of a Research Ethics Committee (REC) and states that, "...the National Ethical Guidelines for Health and Health-related Research shall include the standards for the establishment and management of ethics review committees and the standards for research ethics review ." In Rule 23, Section d of the same IRR, "...RECs shall be categorized as follows:

- (a) Institution-based RECs like those in hospitals, academic and research institutions
- (b) Government Agency-based RECs
- (c) organization-based RECs
- (d) Cluster RECs
- (e) Research site-based RECs (DOST-DOH-CHED, 2022)."

The Gullas College of Medicine is an academic institution generating researches. In compliance thereof, the GCM is establishing an REC under a Center for Health Research and Innovation office.



The REC had been successfully registered with the Philippine Health Research Ethics Board (PHREB) as Level 1 (see Appendix 1). This successful registration requires complying with the standards of PHREB (Appendix 2) in order to be accredited as a Level 1 REC.

In compliance with PHREB Guidelines which states in Section 16 par 16.5, that "...institutions that engage in biomedical, behavioral, and social research shall establish an institutional REC, which shall provide an independent, competent, and timely ethical review of proposed studies. The main purpose of the REC is to help safeguard the dignity, rights, safety, and well-being of all actual or potential research participants. To this end, the REC must be independent of political, institutional, professional, and market influences in its composition, procedures, and decision-making," GCM is hereby creating a Center for Health Research and Innovation (CHRI) office.

The CHRI shall design, operate and evaluate the REC, a Technical Service Panel and a Publication Desk. The CHRI's functions are stated in section 32 of the PHREB guidelines that are as follows: (PHREB, 2022):

- Review the scientific merit and ethical acceptability of the research involving human participants;
  - Undertake the same review process for foreign research protocols even if they have been ethically cleared by a foreign institution, applying ethical standards that are no less stringent than they would be if the research were to be carried out in the country of the sponsoring agency;
  - Ensure that the proposed research is responsive to the priorities and health needs of the country and that it meets the required ethical standards;
  - Issue the ethical approval required for the implementation of any research it has reviewed and approved; 32.5.
  - Promote research integrity by identifying and resolving conflicts of interest; 32.6.
- Establish appropriate mechanisms in all stages of the research to:
- Ensure the safety, protect the rights, and promote the welfare and well-being of research participants;
  - Guide research participants, including proponents and researcher;
  - Ensure prompt reporting of changes in the protocol and unanticipated problems;
  - Ensure the proper documentation of and adherence to the confidentiality rule and policy on informed consent; and ;
  - Monitor the progress of ongoing research until its completion.



Report to the institutional or national authorities any matter that affects the conduct and ethics of research which, in its view, may affect the rights and safety of research participants;

Keep a systematic and organized record of all proposals reviewed, including actions taken and other pertinent information; 32.9. Submit an annual report to the

PHREB (within the first quarter of the year ending on March 31), which shall contain the following:

- o The composition of the REC, including a short curriculum vitae (name of the person, educational attainment, most recent ethics training/seminars attended), and term of office of each member;
- o Members of the REC secretariat, office and email addresses, and contact numbers;
- o Number of meetings (regular and special) held during the year, including the date and venue; 32.9.4. Number of research reviewed by the REC during the year, classified by the types of research, REC decision or action (approval, minor or major modifications, disapproval), and other information required by PHREB. (PHREB, 2022)

It shall report to and be under the supervision of the Office of the Vice President.