



Gullas College of *Medicine*
**RESEARCH ETHICS
COMMITTEE**



Ethos Universitas
HONORARY COMPANION

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SOP NO. 1 - SELECTION AND APPOINTMENT OF REC MEMBERS

Section 1. Policy Statement (PHREB, 2020 PHREB SOP, 2020) .

The selection of REC members shall be through a nomination/screening process that makes sure of representation from different disciplines (scientists and non-scientists, medical and non-medical members), sectors (male and female, older and younger age groups) and member/s who are affiliated and not affiliated with the institution. Members shall be classified as regular or alternate members. The regular members shall serve for 6 years but may be renewed. The pioneer members may change the term of service by SOP 2 (Election of Officers). The alternate members shall serve every year and attend meetings whenever called to ensure that meetings are conducted with sufficient members.

Each duly appointed regular or alternate member will be asked to sign a non-disclosure agreement, data privacy agreement, and a declaration that they have no conflict of interest (COI). The decisions they make regarding the ethical impact of GCM research and their operations to conduct it shall be independent of the academic department, the Executive Committee, and the Management Committee.

In compliance with the latest regulation by the Philippine Health Research Ethics Committee (PHREB), the tenure of REC regular, alternate & independent consultants is protected and safeguarded.

PURPOSE

- To determine if an act constitutes fabrication, falsification, or plagiarism (FFP)
- To impose consequences if misconduct is proven.

SUMMARY OF ALLEGATIONS

Research misconduct is suspected when there seems to be :

- Fabrication: making up data or results and recording or reporting them (ORI, 2026)
- Falsification: manipulating research materials, equipment, or processes, or changing or omitting data or results, such that the research is not accurately represented in the research record (ORI, 2026).
- Direct Plagiarism: presenting work or ideas from another source as one's own, with or without consent of the original author, by incorporating it into your work without full acknowledgment (Oxford, 2026).
- Intentional Misrepresentation refers to communicating honestly reported data in a deceptive manner, which may include using misleading statistics, drawing unwarranted inferences, or presenting data in a way that exaggerates its significance (Resnik, 2001).
- Citation Bias/Suppression refers to preferentially citing research that supports their own findings or claims, or research that showed what they had hoped to find but didn't find in their research (Gotzsche, 2022).
- Non-adherence to approved research protocols.
- Failure to disclose conflict of interest.

Research misconduct does not include honest error or differences of opinion (ORI, 2026).

THE RESEARCH INTEGRITY

The investigating team shall be composed of a team leader and two members nominated by the REC Chairperson. The Chair must include the REC reviewer who suspected the misconduct and one other member. Results of the investigating team shall be reported to the REC at the REC's next meeting.



INVESTIGATION WORK FLOW

- The Chair prepares a mission order creating the Team.
- The team leader shall secure all relevant research records, raw data, lab notebooks, and correspondence relating to the project or study.
- The team shall now review all the relevant research records, raw data, lab notebooks, and correspondence relating to the project or study.
- Members interview the respondent(s) and any relevant witnesses, ensuring all evidence is treated as confidential.
- They then determine if a significant departure from accepted practices occurred and if it was done intentionally, knowingly, or recklessly.
- Assess whether the allegations are proven by a preponderance of evidence.
- Report their findings to the REC.
- The REC decides on the allegations and recommends actions.

INTERIM PROTECTIVE MEASURES

To protect the integrity of the research record, the following measures are effective immediately:

- The researcher(s) are temporarily suspended from access to the laboratory or electronic data systems for their project or proposal.
- The investigating team shall sequester all physical and electronic notebooks/files related to the research.
- The team leader shall report their relevant funding to the REC bodies or other stakeholders if necessary and approved by the REC.

POTENTIAL CONSEQUENCES

If the investigation concludes that misconduct occurred, the following actions will be considered, depending on the severity:

- Formal retraction or correction of publications, and/or draft proposal.
- Letters of reprimand or suspension of research privileges.
- Recommend expulsion of student, faculty or non-teaching staff from GCM.
- Restitution of funds or debarment from future projects to the research team and staff or GCM, as the case may be.

TIMELINE AND CONFIDENTIALITY

A preliminary inquiry report is expected 30 days from the composition of the team. Proceedings must maintain strict confidentiality to protect the reputations of all parties involved.

REFERENCES

- Gotzsche, P. C. (2022). Citation: questionable in research practise or acientific msconduct. *Journal of the Royal Society of Medicine*, 31 -35.
- ORI. (2026, April 28). *Definition of Research Misconduct*. Retrieved from The Office of Research Integrity: <https://ori.hhs.gov/definition-research-misconduct>
- Oxford, University. (2026, April 28). *Plagiarism*. Retrieved from University of Oxford: <https://www.ox.ac.uk/students/academic/guidance/skills/plagiarism>
- Resnik, D. B. (2001). 5.3. *Misrepresentation of Data*. Retrieved from ScienceDirect.com: https://www.google.com/search?q=intentional+misrepresentation+in+research&sca_esv=74e8f3377864fd67&sxsrf=ANbL-n6yjdQWXc7so6OssHzjD6EKA5MX5w%3A1777359987034&source=hp&ei=clzwadPNPNSKseMPS_ez2A8&iflsig=AFdpzrgAAAAAafBqg2UCrww4NFGSDpp_NHvTBaKtwPYE&ved=0ahUKE

Section 2. Objective(s)

This SOP will describe selecting and appointing qualified, committed, and responsible REC members.

Section 3. Scope (PHREB, 2020 PHREB SOP, 2020).

This SOP begins with the call for nominations and ends with filing the appointment documents of REC members in Form 21.1 – Active file management file and in Form 1.9 – ARTS).

Section 4. Workflow.

ACTIVITY	--+	TIMELINE
Step 1: Identification and Listing of Nominees	CHRI, GCM Dept. Chairs, VGMMH Director, Dean REC chair for subsequent members	6 weeks
Step 2: Evaluation and Shortlisting of Nominees	Vice-President REC chair for subsequent members	1 day
Step 3: Issuance of Invitations	Vice President	4 weeks
Step 4: Drafting and Forwarding of Appointment Papers	Member Secretary for pioneer members Administrative Secretary for subsequent members	1 day
Step 5: Acknowledgment and Receipt of Appointment	Member Secretary for pioneer members Administrative Secretary for subsequent members	4 days
Step 6: Execution of Legal, Ethical, and Confidentiality Agreements	New Member/s	7 days
Step 7: Archiving and Administrative Tracking	Member Secretary for pioneer members Administrative Secretary for subsequent members	1 day
TOTAL		14 WEEKS

Section 5. Description of Procedures (PHREB, 2020 PHREB SOP, 2020).

Step 1: Identification and Listing of Nominees

The initial search and call for nominees to constitute the pioneer membership of the planned Research Ethics Committee (REC) shall be collaborative. The Center for Health Research and Innovation (CHRI) Adviser, Gullas College of Medicine (GCM) Department Chairs, the Vicente Gullas Memorial Hospital (VGMH) Director, the Dean, and the Member Secretary shall actively scout for and solicit nominations.

Candidates will be pooled from internal and external stakeholders, including the GCM, Local Government Units (LGUs), and affiliate external institutions. This talent search will leverage the professional networks and established contacts of the CHRI, GCM Chairs, the Dean, the Vice President, and the VGMH Director to ensure a highly qualified pool of candidates.

Step 2: Evaluation and Shortlisting of Nominees

The selection workflow is divided into two protocols based on the developmental stage of the committee:

- Stage A: Pioneer REC Formation. The CHRI Adviser will evaluate the pool of nominees to determine who will be invited as founding members, assessing them based on objective credentials, expertise, and willingness to serve. The CHRI Adviser and/or the Member Secretary may conduct preliminary visits or consultations with these candidates to gauge their interest.

The finalized list of pioneer nominees will be forwarded to the Vice President for initial review. Upon securing institutional clearance, the CHRI will draft the formal Invitation Letter (Form 1.1) and Conforme (Form 1.2), which will be routed to the Vice President for final approval and signature.

- Stage B: Subsequent REC Recruitment. Once the REC is fully established, the responsibility of sourcing and shortlisting additional members shifts to the REC Chair. The Chair will present prospective candidates to the active REC general membership. The committee will collectively deliberate on the candidates' credentials, professional background, and potential conflicts of interest (COI).

A majority vote by the existing members is required to endorse a nominee. Following a successful vote, the Member Secretary will prepare the endorsement

list alongside the Invitation Letter (Form 1.1) and Conforme (Form 1.2) and submit the complete packet to the Vice President for executive approval and signature.

Step 3: Issuance of Invitations

Upon receiving the endorsed list and prepared documents, the Vice President retains the final authority to approve the nominations and sign the formal letters of invitation.

For Pioneer Members, the Member Secretary shall retrieve the signed invitation packets and dispatch them to the candidates. Nominees must formally communicate their decision to accept or decline by completing and returning the Conforme form (Form 1.2) to the CHRI. For Subsequent Members, the REC Chair issues the invitation, and the Administrative Secretary manages the logistical distribution and tracking of the correspondence to the nominees.

Step 4: Drafting and Forwarding of Appointment Papers

Upon receipt of a signed and affirmative Conforme (Form 1.2) indicating a nominee's formal acceptance, the official appointment process is initiated, as follows:

- For Pioneer Members: The Member Secretary will draft the official Appointment Letter (Form 1.3). The Vice President will execute the appointment by signing the papers and instructing the Member Secretary to forward the completed appointment documents to the newly designated member.
- For Subsequent Members: The Administrative Secretary assumes the responsibility of drafting, routing for the Vice President's signature, and forwarding the subsequent appointment papers to the incoming members.

Step 5: Acknowledgment and Receipt of Appointment

The designated secretary (Member Secretary for pioneer members; Administrative Secretary for subsequent members) will formally transmit the signed Appointment Letter (Form 1.3) to the accepting nominee. To finalize the process, the appointee must formally sign the acknowledgment of the appointment and return the executed document to the REC office.

Step 6: Execution of Legal, Ethical, and Confidentiality Agreements

Prior to assuming official duties, all newly appointed members must bind themselves to the committee's ethical and legal standards. The Member Secretary will prepare the necessary Committee documentation, which includes:

- Conflict-of-Interest (COI) Disclosure Form (Form 1.5)
- Data Privacy Agreement (Form 1.6)
- Comprehensive Curriculum Vitae Update (Form 1.7)
- Confidentiality and Non-Disclosure Agreement (NDA) (Form 1.8)

These forms will be routed to the Vice President for initial signature. Once signed by leadership, the packets will be distributed to the appointees (by the Member Secretary for pioneer members and by the Administrative Secretary for subsequent members). The appointees must review, execute, and return all signed agreements to the REC.

Step 7: Archiving and Administrative Tracking

To ensure compliance with institutional record-keeping and audit standards, all membership documentation must be systematically filed:

1. Physical and Secure Archiving: The Administrative Secretary is responsible for archiving all physical appointment papers, signed COIs, updated CVs, DPAs, and NDAs in a secure, restricted-access repository within the REC office, in strict accordance with SOP 23: Management of Active Files.
2. Digital Logs (Pioneer Members): The Member Secretary will log the documents into the Active Filing Form Log (Form 4.7a) and update the credentials within the Administrative Research Tracking System (Form 1.9 - ARTS). Each reviewer will have a separate and independent folder
3. Digital Logs (Subsequent Members): The encoding, digital filing, and continuous updating of the ARTS database for all subsequent members shall be managed entirely by the Administrative Secretary.

Section 6. Forms

- Form 1.1 - Invitation letter
- Form 1.2 - Conforme
- Form 1.3 - Appointment letter
- Form 1.5 - COI Declaration Form,
- Form 1.6 - Data Privacy
- Form 1.7 - Curriculum Vitae
- Form 1.8 - Confidentiality Agreement
- Form 21.2 - Active File Mgt
- Form 1.9 - ARTS – Administrative Research Tracking System

Section 7. History

Version Number	Date	Authors	Change/s
1	9.30.23	Nino Ismael s. Pastor	None

2	9.25.24	Nino Ismael s. Pastor	Form numbering, Workflow
3	06.04.26	Nino Ismael s. Pastor	Very few content

Section 8. References

CIOMS. (2016). *Intl Ethical guidelines for Health-Related Research Involving Humans*. Geneva: CIOMS.

ICH-GCP. (2019). *Guidance: International Conference on Harmonization Good Clinical Practice*. Geneva: IICH GCP.

NCPHBBR. (1979). *The Belmont Report*. Washington: DHHS.

North, H. S. (2020, Dec 09). *Research Ethics Board Chair*. Retrieved Sep 27, 2023, from Clinical Trial Ontario:
<https://www.ctontario.ca/cms/wp-content/uploads/2020/12/Research-Ethics-Board-Chair-Job-Description-V5-14Dec2020.pdf>

PHREB. (2020). *2020 PHREB SOP*. Taguig: PHREB.

PHREB. (2022). *NATIONAL ETHICAL GUIDELINES FOR RESEARCH INVOLVING HUMAN PARTICIPANTS*. Taguig: DOST.

UPMREB. (2012). *SOPs & Forms*. Retrieved from UPMREB:
<https://reb.upm.edu.ph/sops-and-forms>

WHO. (2011). *Standards & Operational Guidance for Ethics Review of Health-related Research with Human Participants*. Geneva: WHO.

WHO. (2024, November 12). *ERC templates for Informed Consent*. Retrieved from WHO ERC: <https://www.who.int/groups/research-ethics-review-committee/guidelines-on-submitting-research-proposals-for-ethics-review/templates-for-informed-consent-forms>

WMA. (1964). Declaration of Helsinki. *18th WMA General Assembly* (p. 4). Helsinki: WMA.