Gullas College of Medicine

RESEARCH ETHICS COMMITTEE

STANDARD OPERATING PROCEDURES MANUAL

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INTRODUCTION

Institutional Framework and the Role of Ethics Review

To achieve the rigorous objectives of scientific inquiry, research institutions must employ diverse and comprehensive review processes. Among these, the research ethics review stands as a foundational pillar. This critical evaluation is governed by meticulously structured Standard Operating Procedures (SOPs), which serve as the operational mechanism to guarantee the safety, rights, dignity, and overall well-being of human participants involved in any study.

By standardizing these protocols, SOPs provide Research Ethics Committees (RECs) with a clear roadmap. This administrative framework is essential for maintaining the highest benchmarks of:

- **Consistency:** Ensuring all research protocols undergo an identical, unbiased evaluation process.
- **Transparency:** Openly demonstrating accountability to the public, investigators, and regulatory bodies.
- **Quality:** Elevating the scientific and ethical integrity of institutional research.

Core Ethical Pillars: The Belmont Report

In drafting this comprehensive SOP manual, the **Gullas College of Medicine** anchored its ethical framework on the three foundational pillars established by the landmark *Belmont Report* (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979). These principles serve as the moral compass for all human subject research:

- **Respect for Persons:** This principle asserts that individuals must be treated as autonomous agents capable of making deliberate, informed choices about their participation. A critical corollary to this principle is the mandatory protection of vulnerable populations—such as minors, prisoners, or individuals with cognitively diminished autonomy—who require specialized safeguards to prevent exploitation or coercion.
- **Beneficence:** Beyond the simple obligation to do no harm, beneficence imposes a proactive duty on researchers to maximize potential benefits while systematically

minimizing inherent risks. This requires a rigorous, ongoing risk-benefit analysis to secure the holistic well-being of the participants.

- **Justice:** This principle addresses the moral dimension of fairness in both the distribution of the burdens of research and the allocation of its benefits. It demands that the selection of research subjects be scrutinized to ensure that specific demographics are not systematically targeted due to easy availability or vulnerability, nor excluded from the therapeutic fruits of research.

Alignment with International Standards and Guidelines

To ensure global compliance and relevance, the manual integrates the core doctrines and operational procedures outlined in several seminal international instruments:

- **Declaration of Helsinki (World Medical Association, 1964):** The cornerstone document detailing ethical principles for the medical community regarding human experimentation.
- **International Council for Harmonization - Good Clinical Practice (ICH-GCP, 2019):** An international quality standard for designing, conducting, monitoring, and reporting clinical trials to safeguard data credibility and participant safety.
- **International Ethical Guidelines for Health-Related Research Involving Humans (CIOMS, 2016):** Guidelines designed to apply the universal ethical tenets of Helsinki specifically to low- and middle-income country contexts and public health research.
- **Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (World Health Organization, 2011):** A global template utilized to foster high-quality, efficient, and accountable ethical oversight.

Domestic Compliance and National Regulatory Harmonization

Furthermore, the formulation of this manual and its accompanying workbook directly aligns with the legal mandates and regulatory frameworks of the Philippines. It integrates the specific directives of the following state policies:

- **Republic Act No. 10532 (Philippine National Health Research System Act of 2013):** Specifically adhering to its Implementing Rules and Regulations (IRR) jointly promulgated on July 10, 2013, by the Department of Health (DOH), the Commission on Higher Education (CHED), the University of the Philippines Manila (UPM), and the Department of Science and Technology (DOST).
- **DOST Special Order No. 091, Series of 2006:** The historic state directive that institutionalized national ethical oversight through the creation of the Philippine Health Research Ethics Board (PHREB).
- **National Ethical Guidelines for Research Involving Human Participants (PHREB, 2022):** The definitive national compendium ensuring that localized research respects cultural nuances while upholding universal ethical truths.

- **PHREB SOP Workbook (2020):** The primary practical benchmark used to structure institutional workflows, ensuring the Gullas College of Medicine REC operates in full lockstep with national accreditation requirements.

THE RESEARCH ETHICS COMMITTEE

The GCM is under the University of the Visayas (UV)as one of the programs under UV. Ethical reviews of GCM's research were done by the UV Center for Research and Innovation (UV-CRI) before GCM applied for PAASCU accreditation this year. However, when GCM applied for certification with PAASCU, the UV-CRI REC underwent a re-accreditation process and could not respond to our needs. This prompted GCM to register its own REC last January 2024 and apply for accreditation with the Philippine Health Research Ethics Board (PHREB).

It was necessary to establish a REC because GCM envisions being a top medical college for competent and compassionate physicians who can deliver excellent service globally. Research is a priority activity of GCM. One of GCM's missions is to develop an ethically and scientifically sound research culture. In line with this mission, GCM's management created the Center for Health Research & Innovation (CHRI) through a memorandum order last Jan 20, 2024. The relationship of the CHRI to other departments is shown in Figure 1.

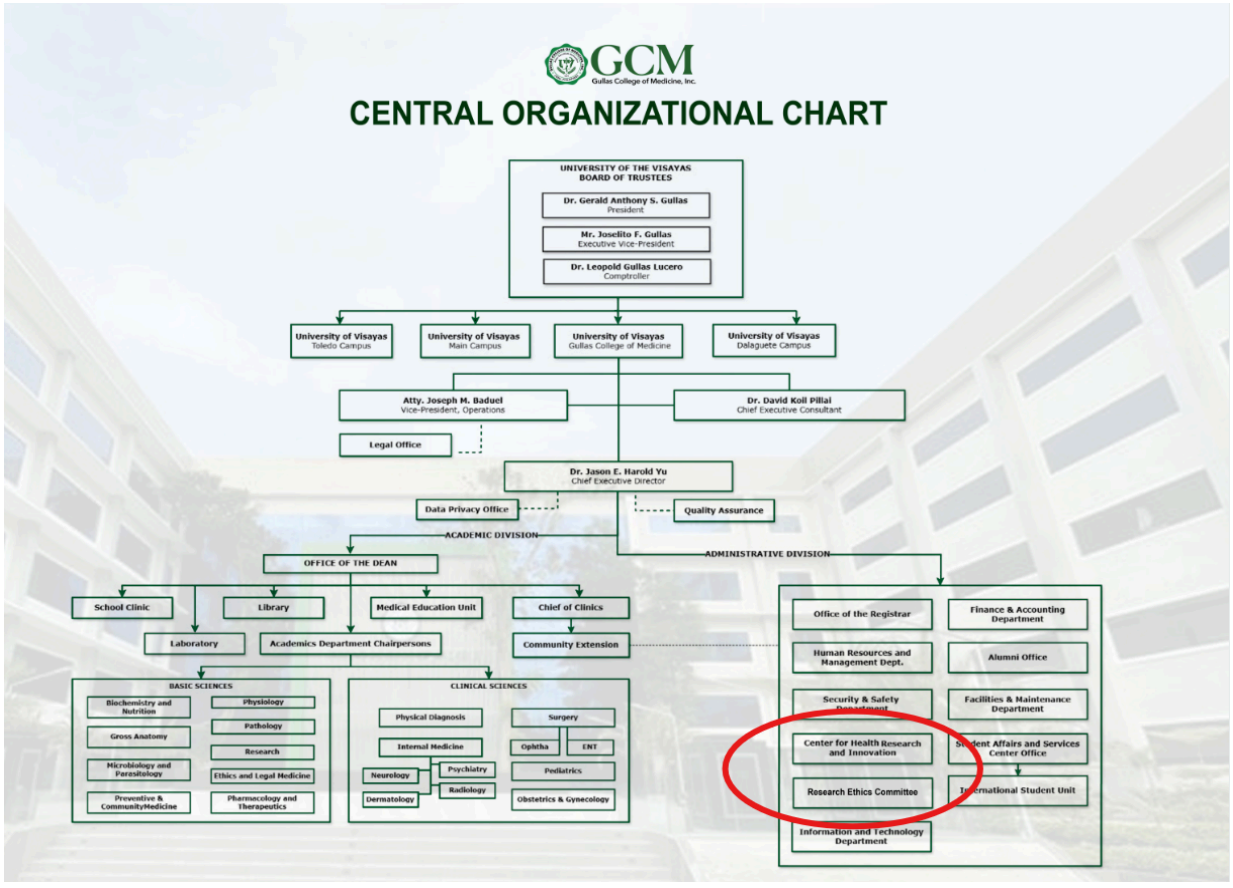
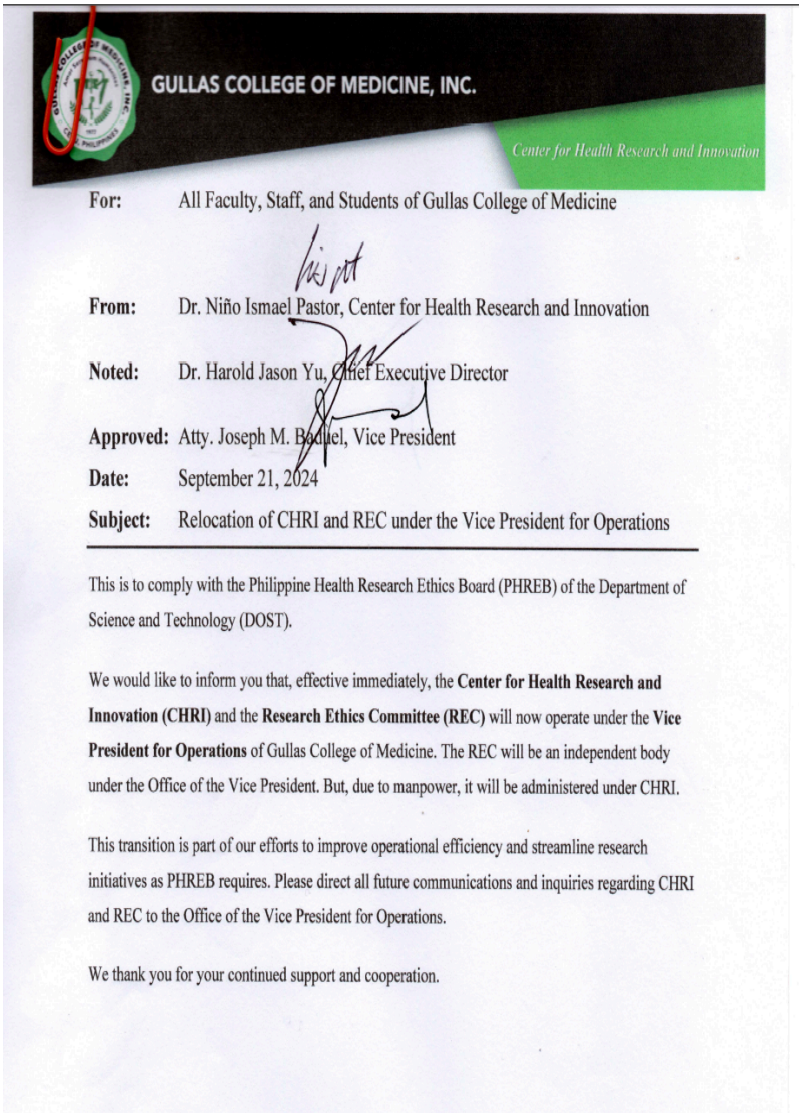


Figure 1: GCM Organizational Chart

This was, however, changed by a memorandum relocating CHRI directly under the Office of the Vice-President. It shall be independent of any academic, non-academic, and management departments. It shall also be independent from the CHRI and shall be directly under the Vice President for Operations.



GULLAS COLLEGE OF MEDICINE, INC.

Center for Health Research and Innovation

For: All Faculty, Staff, and Students of Gullas College of Medicine

From: Dr. Niño Ismael Pastor, Center for Health Research and Innovation

Noted: Dr. Harold Jason Yu, Chief Executive Director

Approved: Atty. Joseph M. Boduel, Vice President

Date: September 21, 2024

Subject: Relocation of CHRI and REC under the Vice President for Operations

This is to comply with the Philippine Health Research Ethics Board (PHREB) of the Department of Science and Technology (DOST).

We would like to inform you that, effective immediately, the **Center for Health Research and Innovation (CHRI)** and the **Research Ethics Committee (REC)** will now operate under the **Vice President for Operations** of Gullas College of Medicine. The REC will be an independent body under the Office of the Vice President. But, due to manpower, it will be administered under CHRI.

This transition is part of our efforts to improve operational efficiency and streamline research initiatives as PHREB requires. Please direct all future communications and inquiries regarding CHRI and REC to the Office of the Vice President for Operations.

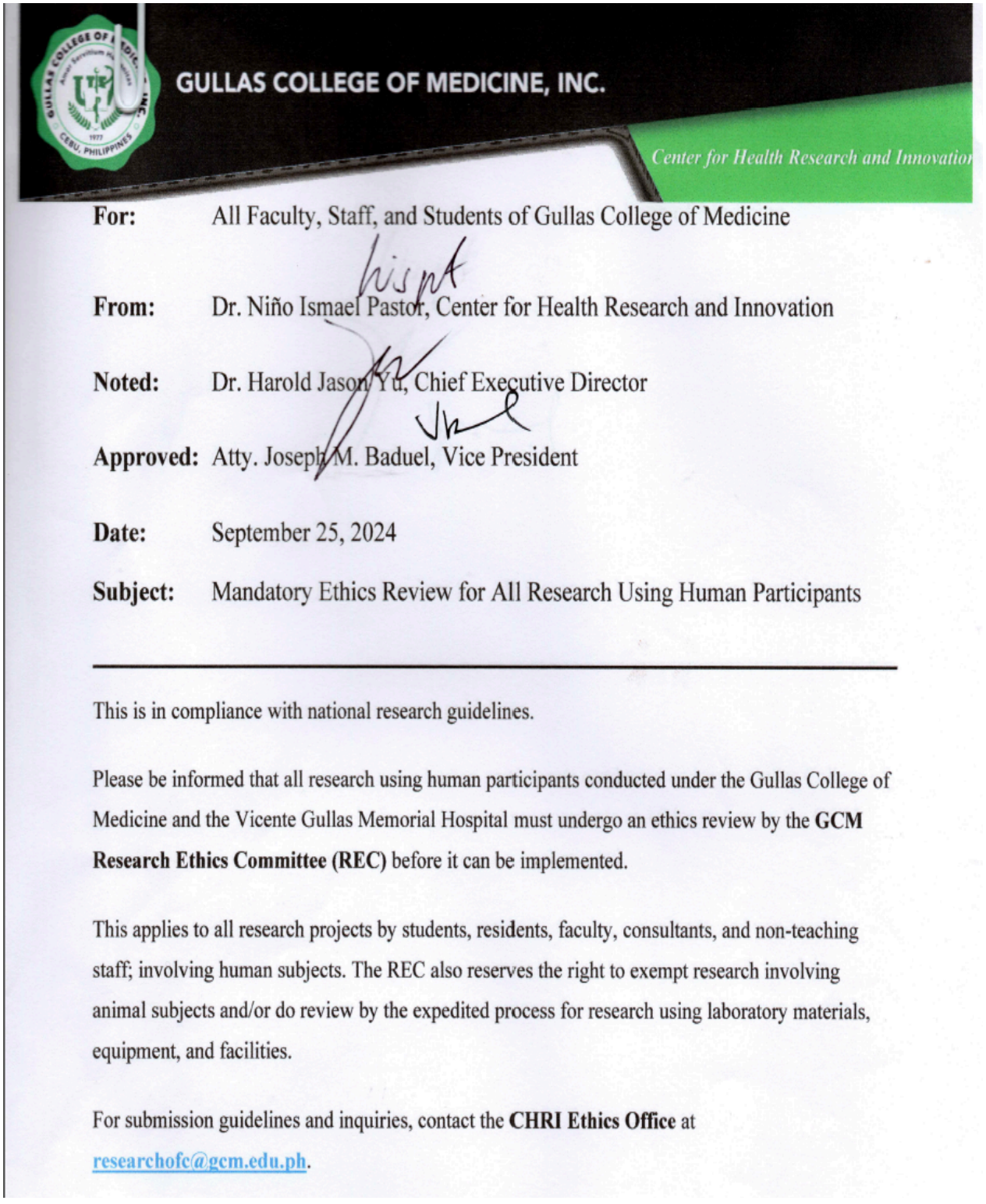
We thank you for your continued support and cooperation.

Figure 2: Memorandum of Relocating of CHRI and REC under the Vice President for Operations

The REC is administratively under the CHRI to save on manpower resources. But the REC shall be independent of any office and is directly under the Office of the Vice-President.

The REC envisions PROTECTING THE SAFETY AND WELL-BEING OF HUMAN PARTICIPANTS in GCM RESEARCH. The REC's mission is to
(1) maintain a fully functional organization, and;
(2) efficiently and independently operate an efficient system of the ethical review process,

The REC will be located on the second floor of the GCM Main Building, its office will be with the CHRI temporarily. It will be transferred to its own office when the Vicente Gullas Memorial Hospital (VGMH) renovation is completed. The VGMH is located within the same compound as
GCM in Sitio Atis, Barangay Banilad, Mandaue City, Cebu.



GULLAS COLLEGE OF MEDICINE, INC.

Center for Health Research and Innovation

For: All Faculty, Staff, and Students of Gullas College of Medicine

From: Dr. Niño Ismael Pastor, Center for Health Research and Innovation

Noted: Dr. Harold Jason Yu, Chief Executive Director

Approved: Atty. Joseph M. Baduel, Vice President

Date: September 25, 2024

Subject: Mandatory Ethics Review for All Research Using Human Participants

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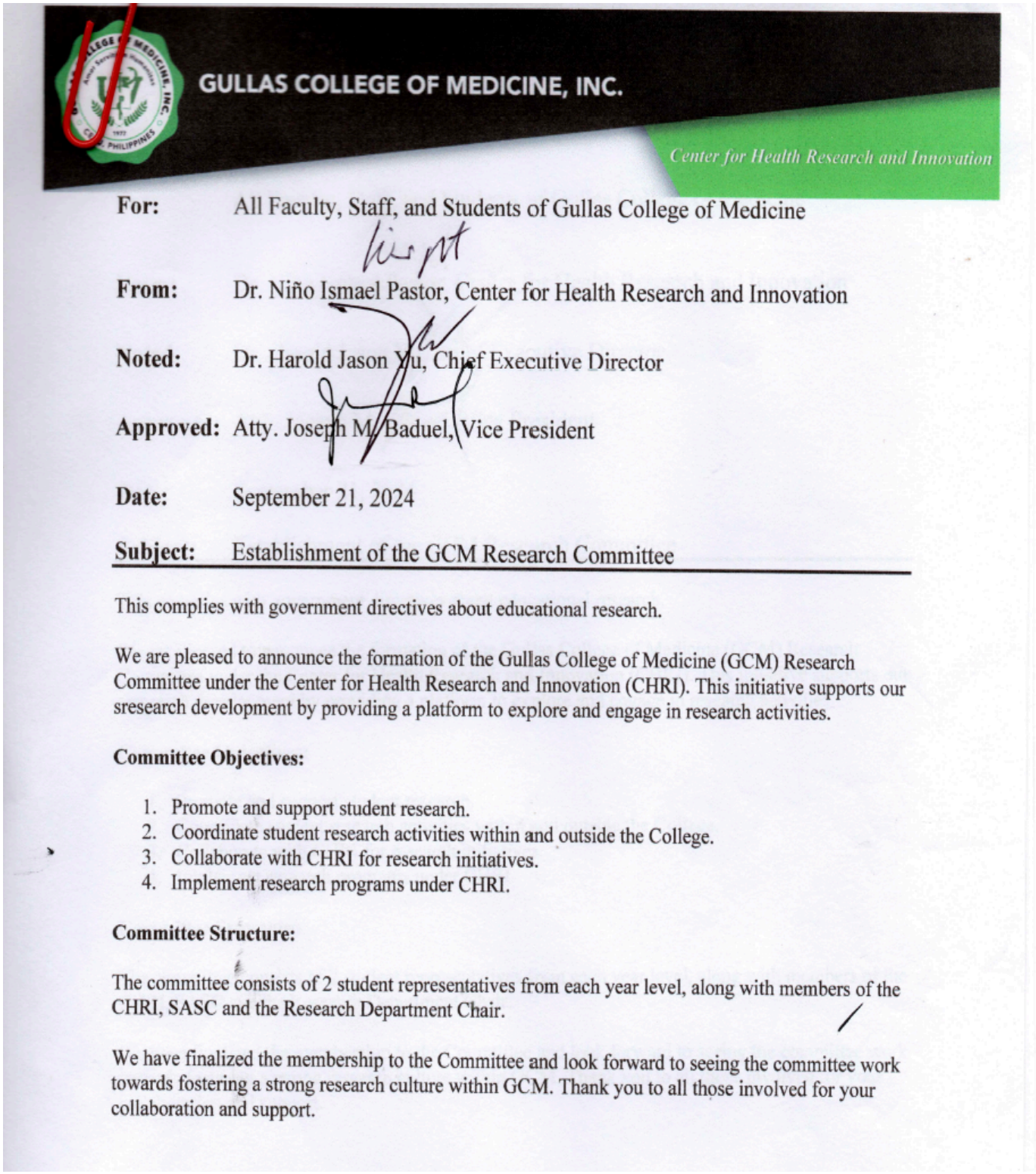
This is in compliance with national research guidelines.

Please be informed that all research using human participants conducted under the Gullas College of Medicine and the Vicente Gullas Memorial Hospital must undergo an ethics review by the **GCM Research Ethics Committee (REC)** before it can be implemented.

This applies to all research projects by students, residents, faculty, consultants, and non-teaching staff; involving human subjects. The REC also reserves the right to exempt research involving animal subjects and/or do review by the expedited process for research using laboratory materials, equipment, and facilities.

For submission guidelines and inquiries, contact the **CHRI Ethics Office** at researchofc@gcm.edu.ph.

Figure 3: Memorandum of Mandatory Ethics Review for All Research Using Human Participants



GULLAS COLLEGE OF MEDICINE, INC.

Center for Health Research and Innovation

For: All Faculty, Staff, and Students of Gullas College of Medicine

From: Dr. Niño Ismael Pastor, Center for Health Research and Innovation

Noted: Dr. Harold Jason Yu, Chief Executive Director

Approved: Atty. Joseph M. Baduel, Vice President

Date: September 21, 2024

Subject: Establishment of the GCM Research Committee

This complies with government directives about educational research.

We are pleased to announce the formation of the Gullas College of Medicine (GCM) Research Committee under the Center for Health Research and Innovation (CHRI). This initiative supports our sresearch development by providing a platform to explore and engage in research activities.

Committee Objectives:

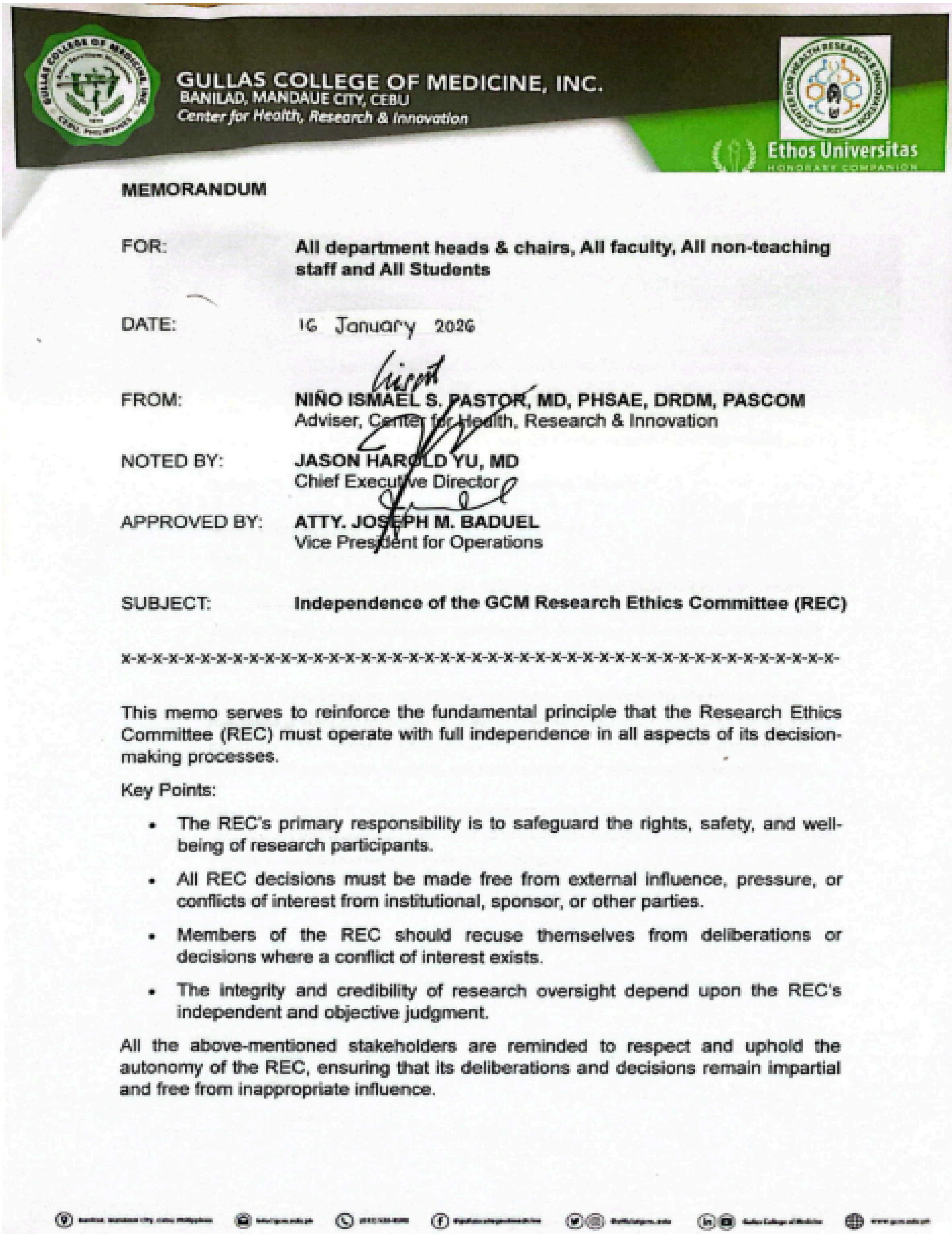
1. Promote and support student research.
2. Coordinate student research activities within and outside the College.
3. Collaborate with CHRI for research initiatives.
4. Implement research programs under CHRI.

Committee Structure:

The committee consists of 2 student representatives from each year level, along with members of the CHRI, SASC and the Research Department Chair.

We have finalized the membership to the Committee and look forward to seeing the committee work towards fostering a strong research culture within GCM. Thank you to all those involved for your collaboration and support.

Figure 4: Memorandum of Establishment of the GCM Research Committee



GULLAS COLLEGE OF MEDICINE, INC.
BANILAD, MANDAUE CITY, CEBU
Center for Health, Research & Innovation

Ethos Universitas
HONORARY COMPANION

MEMORANDUM

FOR: **All department heads & chairs, All faculty, All non-teaching staff and All Students**

DATE: 16 January 2026

FROM: **NIÑO ISMAEL S. PASTOR, MD, PHSAE, DRDM, PASCOM**
Adviser, Center for Health, Research & Innovation

NOTED BY: **JASON HAROLD YU, MD**
Chief Executive Director

APPROVED BY: **ATTY. JOSEPH M. BADUEL**
Vice President for Operations

SUBJECT: **Independence of the GCM Research Ethics Committee (REC)**

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This memo serves to reinforce the fundamental principle that the Research Ethics Committee (REC) must operate with full independence in all aspects of its decision-making processes.

Key Points:

- The REC's primary responsibility is to safeguard the rights, safety, and well-being of research participants.
- All REC decisions must be made free from external influence, pressure, or conflicts of interest from institutional, sponsor, or other parties.
- Members of the REC should recuse themselves from deliberations or decisions where a conflict of interest exists.
- The integrity and credibility of research oversight depend upon the REC's independent and objective judgment.

All the above-mentioned stakeholders are reminded to respect and uphold the autonomy of the REC, ensuring that its deliberations and decisions remain impartial and free from inappropriate influence.

Figure 5: Memorandum of Independence of the GCM Research Ethics Committee (REC)

MEMORANDUM

FOR: **All department heads & chairs, All faculty, All non-teaching staff, and All Students**

DATE: 10 February 2026

FROM: **ATTY. GERALDINE JORDA**
Chairperson, GCM REC

NIÑO ISMAEL S. PASTOR, MD, PHSAE, DRDM, WMA
Adviser, CHRI

NOTED BY: **JASON HAROLD E. YU, MD**
Chief Executive Director

APPROVED BY: **ATTY. JOSEPH M. BADUEL**
Vice President for Operations

SUBJECT: **Investigation Of Suspected Unethical Conduct by Researchers and to Impose Consequences.**

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INTRODUCTION

This memorandum establishes a formal investigation into allegations of research misconduct, specifically related to ALL research conducted by students, faculty, and non-teaching staff at Gullas College of Medicine in Banilad, Mandaue City, Cebu. Research misconduct occurs when researchers invent or falsify data, manipulate data analysis, use articles or parts of them without proper citation, or misrepresent results in research reports. These can be summarized into three categories: falsification, fabrication, and plagiarism (FFP). It constitutes academic fraud. These actions are intentional and carry serious consequences; research misconduct is not a simple mistake or mere disagreement about research. It is a serious ethical issue because it can undermine academic integrity and the credibility of the institution. Additionally, it leads to the wastage of funding and resources that could otherwise be used for alternative research.

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.

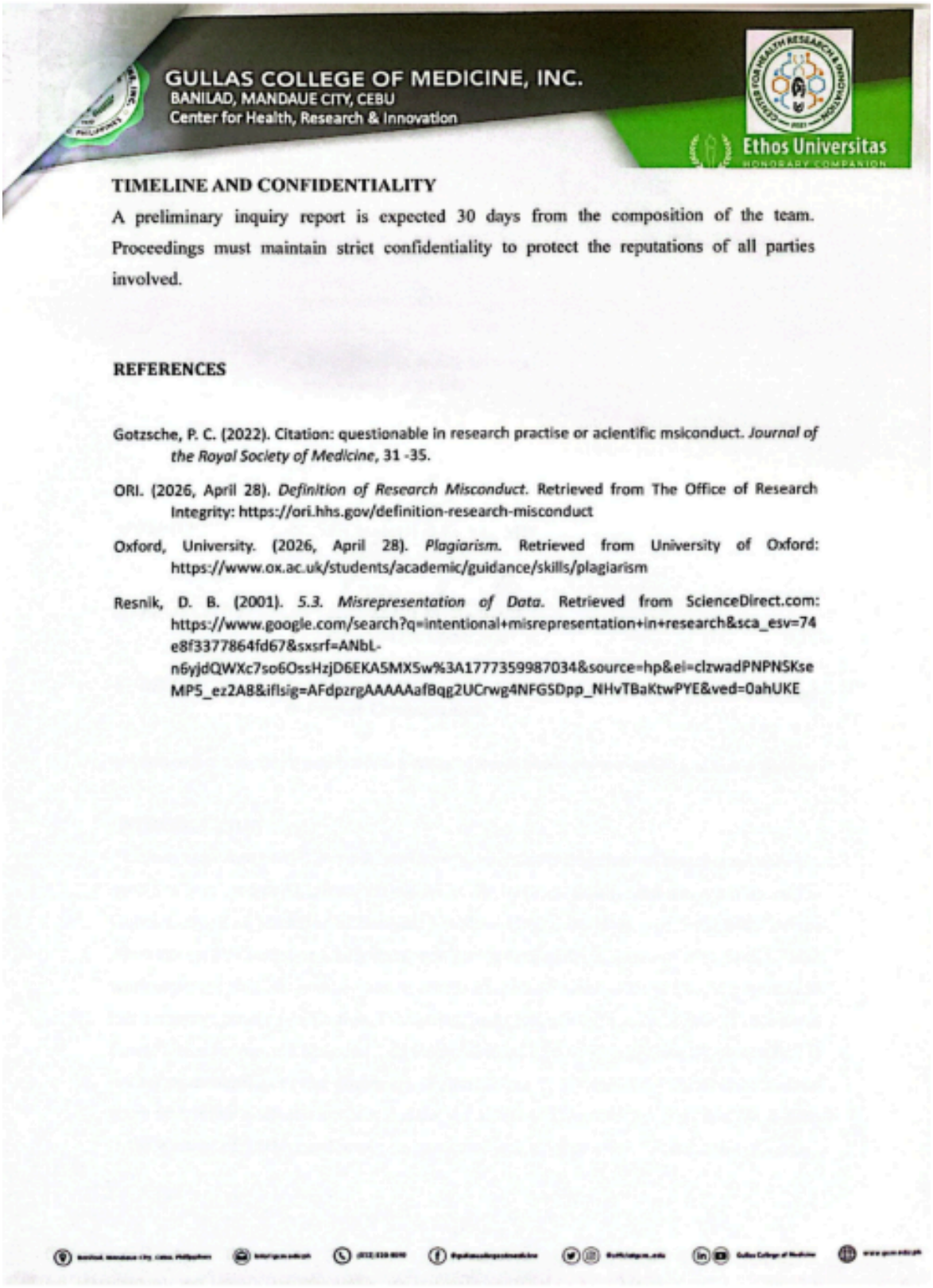

Figure 6: Memorandum to Investigate Unethical Conduct by Researchers and to Impose Consequences

MEMORANDUM

TO:	All GCM Researchers, Principal Investigators, Faculty, Students, and Non-Teaching Staff
DATE:	16 February 2026
FROM:	**ATTY. GERALDINE JORDA** Chairperson, GCM REC
	NIÑO ISMAEL S. PASTOR, MD, PHSAE, DRDM, WMA Adviser, GCMJ CHRI
NOTED BY:	**JASON HAROLD E. YU, MD** Chief Executive Director
APPROVED BY:	**ATTY JOSEPH M. BADUEL** Vice-President for Operations, GCM
SUBJECT:	**Empowerment of the Gullas College of Medicine (GCM) Research Ethics Committee (REC) and/or the Center for Health Research & Innovation (CHRI) to Suspend or Terminate Research Studies**

x-x-x-x-x-x-x-x-x-x-x-x-x-x-x-x-x-x-x-x-x-x-x-x-x-x-x-x-x-x-x-x-x-x-x-x-x-x-x-x-x-x-x-x-x-x-x-x-

INTRODUCTION

The primary mandate of the GCM REC is to protect the rights, safety, and well-being of human research participants. To fulfill this mandate, the REC is authorized to suspend and/or terminate studies that pose unexpected risks or are not conducted in accordance with approved protocols or the REC's ethical standards (PHREB, 2025) . This memorandum formally confers the REC with this authority.

This memo is effective if the research:

- Was not being conducted in accordance with the GCM REC's requirements.
- Was associated with unexpected serious harm to participants.
- Presented unmanageable risks to the safety, health or welfare of participants.
- Engaged in significant non-compliance with institutional, national, or international ethical guidelines.
- Did not conform to CHRI and/or Research Department policies and procedures
-

The GCM REC Chair or the Adviser of the Center for Health Research & Innovation (CHRI) has the authority to impose a temporary suspension or termination of study activities if immediate risks to participant safety are identified, prior to a full board meeting.

OBJECTIVE:

- To protect the health and safety of human participants to GCM research
- To promote the integrity of GCM

DEFINITION OF TERMS

R.E.C. Chairperson – the REC official invited and appointed as the Chair of the REC

Suspension - temporary cessation of some or all activities in a currently approved research Study (Purdue, 2026).

Termination - Determination made by the REC to permanently withdraw approval for some or all activities of a currently approved research study (Purdue, 2026).

REC research integrity team - three members of the REC officially given a mission order by the REC Chairperson to investigate a research that may be suspended or terminated

SCOPE

- All GCM students, faculty, and non-teaching staff are expected to be covered by this policy.
- This memo shall be effective upon signing thereof
- Begins with the creation of an REC integrity team
- Ends with the suspension or termination of a research study

WORKFLOW

- **Detection of research by a REC member or a CHRI panelist that the research:**
  1. Was not being conducted in accordance with the GCM REC's requirements.
  2. Was associated with unexpected serious harm to participants.
  3. Presented unmanageable risks to the safety, health or welfare of participants.
  4. Engaged in significant non-compliance with institutional, national, or international ethical guidelines.
  5. Did not conform to CHRI and/or Research Department policies and procedures
- **Creation of a Research Integrity Team (RIT)** by the REC chairperson or the Center for Health Research & Innovation
- **Investigation** in accordance with the memo on research misconduct
- The RIT **reports** to REC or CHRI as the case maybe
- **Notify** the Principal Investigator (PI) and the institutional official in writing, stating the reasons for the action.
- **Consider Participant Welfare:** Determine actions to protect currently enrolled participants, including continuing care.
- **Require Reporting:** The PI must immediately report the suspension/termination to any relevant sponsors, and/or participants as required.

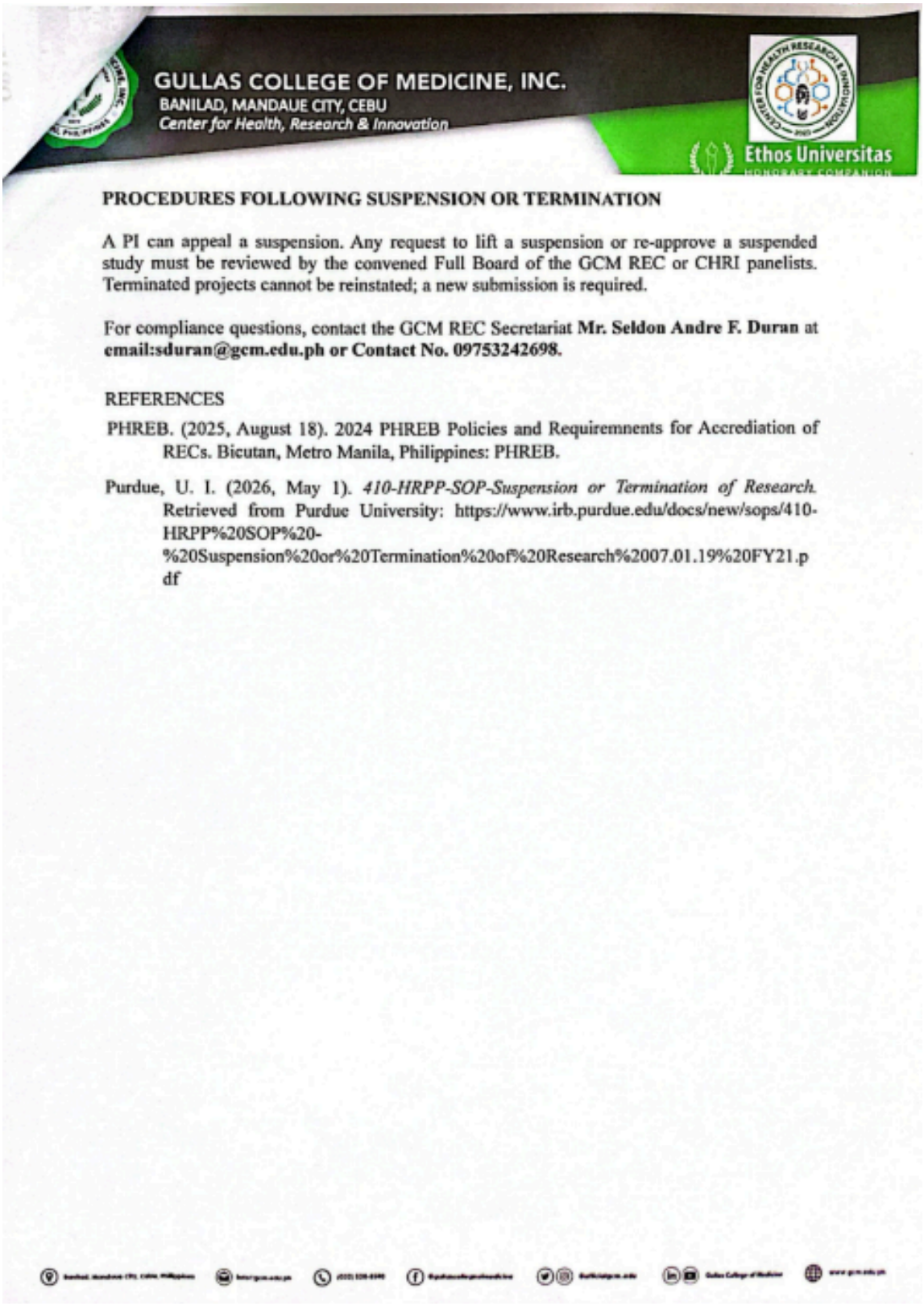

Figure 7: Memorandum of Authority to Terminate or Suspend Studies

Table 1. The REC Members & Independent Consultants

NAME	SPECIALTY	AFFILIATION	REC POSITION	REMARKS
REGULAR MEMBERS (N = 8)				
Geraldine Jorda	Law	Non-GCM	Chair	Scientist
Sonny Redula	Gen Medicine	GCM	Vice-Chair	Scientist
Junisa Rose Fuentes	Management	GCM	Member Secretary	Non-Scientist
Sumiya Fanlo	OB/GYN	GCM	Member	Scientist
Joarni Riveral	Preventive Medicine	GCM	Member	Scientist
Leonel Paolo Rodriguez	Animal Developmental Biology, MS Biology, PhD ongoing	UV, USC	Member	Scientist
Maria Fe Abejar	Registered Psychologist	Non-GCM	Member	Scientist
Celia Canonigo	Barangay Worker	Non-GCM	Member	Non-scientist
ALTERNATE MEMBERS (n = 3)				
Lorna Sitoy	Family Medicine	GCM	Member	Scientist
Carmel Arcanses	Psychometrician	GCM	Member	Non-scientist
Merly Gallardo	Biology	GCM	Member	Non-Scientist
INDEPENDENT CONSULTANTS (N = 11)				
Albim Cabatingan	Management, PhD BA, DPA	UV	IC	Scientist
Ronald Catacte	Biomedical Research, MAN, PhD, ongoing, Nurse	SWU	IC	Scientist
Maricar Canonigo	Biomedical Research, MAN, PhD ongoing, Nurse	SWU	IC	Scientist
Aljoriz Dublin	Education, MBA	UV	IC	Scientist
Rosemarie Camille Cunanan	Pharmacy, MPA, DPA	Non-GCM	IC	Scientist
Julius Mario	Medical Technology, PhD Med Tech	SWU	IC	Scientist

Rosie Mendoza	English, MA Eng, PhD Edu	UV	IC	Scientist
Faith Yee	Internal Medicine	GCM	Member	Scientist
Queen Heneylour Relatorres	Criminal Justice, MA Crim Justice	UV	IC	Scientist
Niño Ismael Pastor	Epidemiology, MAED cert, DRDM	GCM	IC	Scientist
Mara Bernadette Redula	Gen Medicine	GCM	IC	Scientist
Rochelle Go	Pharmacist	Velez Gen Hosp	IC	Scientist
Joanne Camello	Gen Pediatrics	CIM, VGH	IC	Scientist

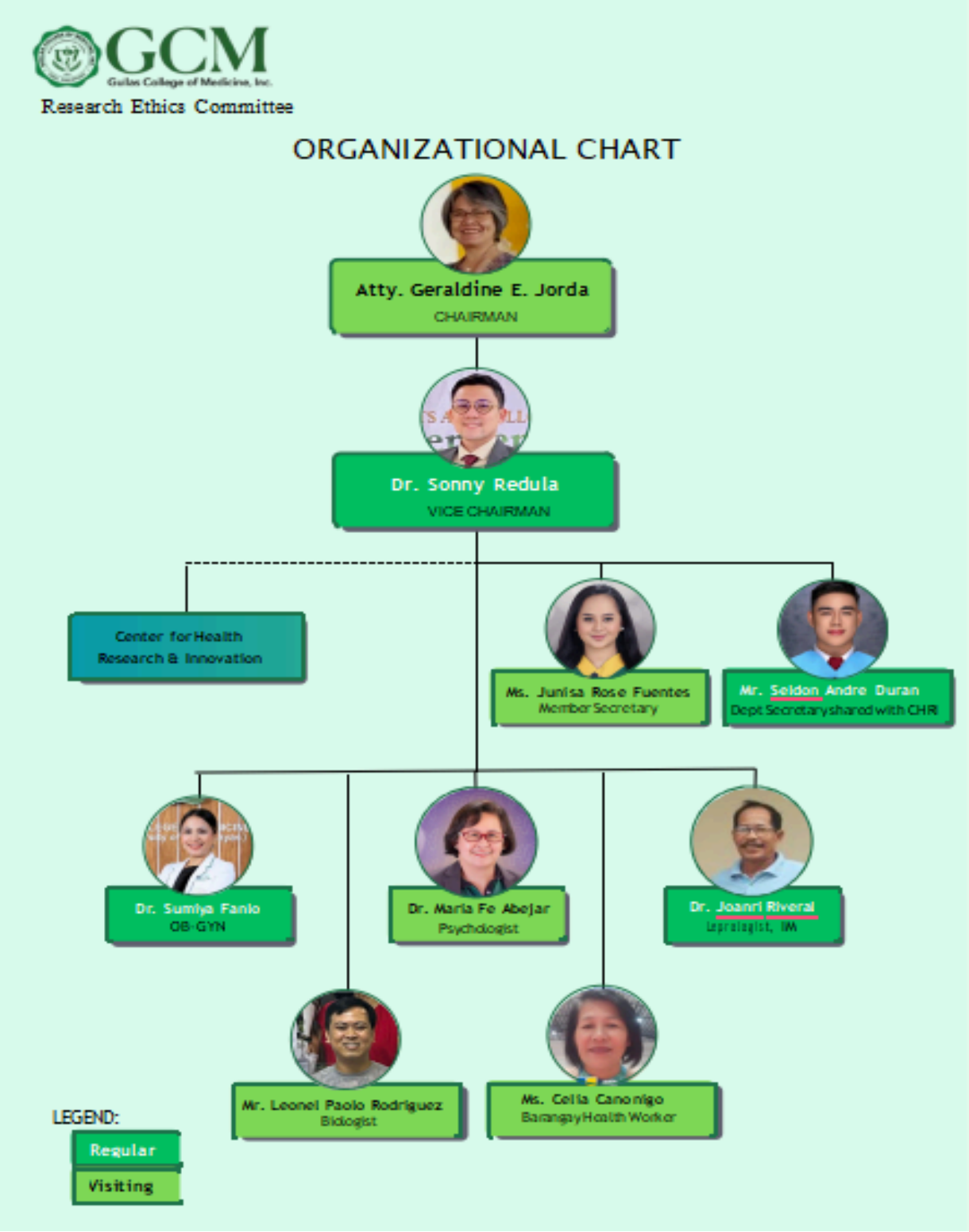

Figure 8: REC Organizational Chart

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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.

GULLAS COLLEGE OF MEDICINE, INC.
BANILAD, MANDAUE CITY, CEBU
Center for Health, Research & Innovation
Ethos Universitas
HONORARY COMPANION

MEMORANDUM

FOR: **All department heads & chairs, All faculty, All non-teaching staff, and All Students**

DATE: 23 January 2026

FROM: **NIÑO ISMAEL S. PASTOR, MD, PHSAE, DRDM, PASCOM**
Adviser, CHRI – GCM

NOTED BY: **JASON HAROLD YU, MD**
Chief Executive Director

APPROVED BY: **ATTY. JOSEPH M. BADUEL**
Vice President for Operations

SUBJECT: **Protection of REC Members from Unjust Removal and Safeguarding Tenure of Research Ethics Committee (REC) Members**

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In compliance with the latest regulation by the Philippine Health Research Ethics Board (PHREB) this memo is issued to protect and safeguard the tenure of the pioneer members of GCMs REC (REC).

- REC members are appointed for a fixed term of office to ensure continuity and independence in oversight.
- Members shall not be removed from their positions before the expiration of their term except for just cause.
- Just cause may include, but is not limited to, misconduct, violation of organizational policies, or inability to fulfill designated duties.
- The removal process must be taken up during an REC administrative meeting that is transparent, fair, and consistent with established organizational procedures.
- Protecting the tenure of REC members is essential to maintaining the committee's independence and the credibility of its decisions.

All stakeholders are expected to respect and uphold these principles, ensuring a fair and secure environment for REC members to perform their duties.

REC members are appointed for a fixed term of office to ensure continuity and independence in oversight.

REC members can terminate or suspend studies also.

GULLAS COLLEGE OF MEDICINE, INC.
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HONORARY COMPANION

MEMORANDUM

FOR: **All department heads & chairs, All faculty, All non-teaching staff, and All Students**

DATE: 10 February 2026

FROM: **ATTY. GERALDINE JORDA**
Chairperson, GCM REC

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APPROVED BY: **ATTY. JOSEPH M. BADUEL**
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SUBJECT: **Investigation Of Suspected Unethical Conduct by Researchers and to Impose Consequences.**

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INTRODUCTION

This memorandum establishes a formal investigation into allegations of research misconduct, specifically related to ALL research conducted by students, faculty, and non-teaching staff at Gullas College of Medicine in Banilad, Mandaue City, Cebu. Research misconduct occurs when researchers invent or falsify data, manipulate data analysis, use articles or parts of them without proper citation, or misrepresent results in research reports. These can be summarized into three categories: falsification, fabrication, and plagiarism (FFP). It constitutes academic fraud. These actions are intentional and carry serious consequences; research misconduct is not a simple mistake or mere disagreement about research. It is a serious ethical issue because it can undermine academic integrity and the credibility of the institution. Additionally, it leads to the wastage of funding and resources that could otherwise be used for alternative research.

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

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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

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SOP NO. 2 - DESIGNATION OF REC OFFICERS

Section 1. Policy Statement.

The REC officers shall consist of a Chairperson, Vice-chairperson, and a Member Secretary. Since this is still the first time that GCM will create a REC, officers will be screened, nominated, and appointed by the Vice-President. This will be a temporary policy until the Vicente Gullas Memorial Hospital, which is being renovated, opens and the term of the pioneer officers expires. An election will be performed after the Terms of the pioneer officers expire. The election will be conducted during a special meeting initially presided over by an outgoing officer.

These pioneer REC officers shall retain their positions for six (6) years to secure a smooth establishment of the new REC. The REC members may change the term of office when the REC is operational (See SOP 27 – Writing & Revising the SOP).

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.

The tenure of these REC officers is protected and safeguarded against termination unless there is just cause to do so. They also have the power to suspend or terminate any project or proposal after due process described in this SOP.

Section 2. Objective.

This SOP intends to ensure that the REC officers are qualified and are selected transparently and fairly in conformity with institutional and related policy and practice.

Section 3. Scope.

This SOP begins by selecting possible officers from the pioneer members. Subsequent officers will be elected by the REC Members after the expiration of the terms of the pioneer officers. The procedure of this SOP ends with the filing and archiving of the appointment documents of the officers.

The duties and responsibilities of the officers are described below.

Research Ethics Committee (REC) Chairperson

The REC Chair occupies a college-related-teaching position serving the College as part of the REC of the GCM.

The REC Chair handles providing leadership for the REC. S / he advocates for the work of the REC (North, 2020). The REC Chair reports to the Vice President and coordinates with the REC Member Secretary and Administrative Secretary for REC activities and concerns.

- General Job Description
    - Guide the REC in deciding a proposal's acute and / or chronic impact/effect to humans and/or animals.
    - Manage the REC office.
    - Supervise the research ethics review process.

- Duties and responsibilities (North, 2020) (PHREB, NATIONAL ETHICAL GUIDELINES FOR RESEARCH INVOLVING HUMAN PARTICIPANTS, 2022):
    - Participate in REC activities:
        - Preside over REC Meeting.
        - Oversee review of protocols.
        - Assign Primary Reviewers of protocols based on expertise and experience.
        - Supervise development and revisions of SOPs.
        - Prepare and submit the annual budget of the REC.
        - Prepare and submit annual report of the REC to the office of the Vice President and to PHREB.
        - Ensure initial and continuing research ethics training of members and Administrative Secretary.
    - Submit on time properly filled out necessary Forms and documents to the REC.
    - Advice / inform the Member Secretary about review-related concerns and suggest ways to address the same concern.
    - Collaborate with colleagues and other stakeholders in promoting and improving good clinical and ethical practices in the conduct of basic and clinical research.

Research Ethics Committee (REC) Vice-Chairperson

The REC Vice-Chair occupies a college-related-teaching position serving the College as part of the REC.

The REC Vice-Chair handles helping the Chair of the REC. S / he advocates for the work of the REC (North, 2020). The REC Vice-Chair reports to the REC Chair and coordinates with the REC Member Secretary and REC Member Secretary for REC activities and concerns.

- General Job Description
    - Performs duties assigned by the Chair.
    - Performs the duties of the REC Chair in his / her absence.
    - Assists in REC activities.
- Duties and responsibilities
    - Participate in REC activities (PHREB, 2020 PHREB SOP, 2020), (North, 2020):
        - Perform tasks assigned by the Chair
        - Participate in the review of research proposals and other related reports when requested.
    - Submit on time properly filled out necessary Forms and documents to the REC Admin Officer
    - Advice / inform the rec Chair about review-related concerns and suggest ways to address the same concern.
    - Collaborate with colleagues and other stakeholders in promoting and improving good clinical and ethical practices in the conduct of basic and clinical research.
    - Perform other tasks prescribed by the REC Chair

Research Ethics Committee (REC) Member Secretary

The REC Member Secretary occupies a college related-teaching position serving the College as part of the REC.

The REC Member Secretary is responsible for assisting the Chair, vice-Chair & members of the REC. S / he advocates for the work of the REC (North, 2020). The REC Member Secretary reports to the REC Chair and coordinates with the members for REC activities and concerns.

- General Job Description
    - Assist the REC Chair
    - Administer the REC office.

- Duties and responsibilities
    - Attend GCM-sponsored accreditation seminars about biosafety, ethical research procedures and practices, good clinical practices, basic research methods, animal care, and/or other research-related topics.
    - Assist the REC Chair assign proposals to reviewers.
    - Be assigned to study and review any GCM research proposal.
    - Perform tasks to aid the Chairperson complete the review process.
    - Participate in REC activities (North, 2020) (PHREB, 2020 PHREB SOP, 2020):
        - Receipt of protocol documents
        - Preparation of protocol files and folders
        - Preparation of draft of communications

- Preparation of draft Agenda and Minutes
- Updating of records
-

- Submit on time properly filled out necessary Forms and documents to the REC.
- Advice / inform the REC Chair about review-related concerns and suggest ways to address the same concern.
- Collaborate with colleagues and other stakeholders in promoting and improving good clinical and ethical practices in the conduct of basic and clinical research.
- Perform other tasks prescribed by the Chair.

Administrative Secretary (AS)

The Administrative Secretary occupies an administrative position serving The College as part of a Research Ethics Committee (REC).

An administrative secretary provides high-level organizational and clerical support to keep the REC office running efficiently. S/he assists the Member Secretary and reports directly to the Member Secretary.

- General Job Description
  - Supports primary health research unit functions
  - Prepare, maintain, and update HRU materials
  - Attend seminars, meetings and HRU related activities as necessary
  - Contribute in many ways to the HRU activities
  - Reports to the HRU Director
  - Acts as GCMs Data Privacy Officer

- Duties and Responsibilities
  - The AS manages general office duties, such as typing documents, filing documents, setting appointments with stakeholders, entering data and other miscellaneous activities and concerns of the REC.
  - The AS also answers questions about the research processes, requirements and documents.
  - S/he also maintains and archives records. S/he coordinates with the REC members and clients and/or clients of the REC.

Ethics Reviewer

The Ethics Reviewer(s) occupies a college-related-teaching position serving the College as part of a Research Ethics Committee (REC) member.

Reviewers will oversee the ethical integrity of any GCM research. They will be assigned to a proposal based on their specialization(s) and the guidelines and policies of the REC. The assignments will be determined by the REC Chairperson. Reviewers will be under the direct supervision of the Chairperson of the REC.

- General Job Description
    - Decide the acute and/or chronic ethical risks, impact, and/or effect on humans and/or animals of a proposal.

- Duties and responsibilities (PHREB, 2020 PHREB SOP, 2020):
    - Attend GCM-sponsored accreditation seminars about biosafety, ethical research procedures and practices, good clinical practices, basic research methods, animal care, and/or other research-related topics.
    - Attend REC meetings consistently.
    - Participate in the ethical review of research proposals and other related reports. The non-scientific member shall give special attention to the Informed Consent Form and process to ensure that these are comprehensible by ordinary persons and are considerate of community values.
    - Participate in the after-review activities, e.g., continuing review, site visits, etc.
    - Declare any conflict of interest (COI) in the review of research proposals.
    - Maintain confidentiality of the documents and deliberations of the REC meetings.
    - Attend continuing ethics education and other related activities
    - Perform other tasks prescribed by the REC Chair

Section 4. Workflow.

ACTIVITY	***RESPONSIBILITY***	**TIMELINE**
Step 1: Convocation of the Organizational and Nominating Meeting	CHRI Adviser, Vice President Subsequent meetings: REC Chair	1 day
Step 2: Screening and Nomination Criteria for Executive Positions	CHRI Adviser, Vice President Subsequent officers: REC member	2 weeks
Step 3: Credential Review and Election Procedures	CHRI Adviser, Vice President for pioneers	1 day

	REC members for subsequent officers	
Step 4: Executive Endorsement for Appointment	CHRI Adviser for pioneers Subsequent officers: REC Chair, Members	1 day
Step 5: Official Executive Appointment	Vice President & Officer Subsequent officers: Member Secretary & President	4 days
Step 6: Archiving, Document Control, and Database Tracking	Member secretary for pioneer officers Administrative Secretary for subsequent officers	1 day
TOTAL		22 DAYS

Section 5. Description of Procedures.

Step 1: Convocation of the Organizational and Nominating Meeting.

Because initial pioneer committee members lack established working relationships, an objective, data-driven approach is required to organize leadership. The Center for Health Research and Innovation (CHRI) Adviser shall retrieve and review the Curriculum Vitae (CV) and professional credentials of all pioneer Research Ethics Committee (REC) members. This preliminary review aims to evaluate each member's institutional qualifications, demonstrated commitment, and capacity for administrative responsibility. Once evaluated, the CHRI Adviser will call an initial organizational meeting.

Upon the expiration of the pioneer officers' terms, the responsibility shifts to the incumbent REC Chair, who shall be responsible for officially calling a special meeting dedicated exclusively to the nomination and election of a new set of officers.

Step 2: Screening and Nomination Criteria for Executive Positions

The selection of candidates for officer positions—applicable to both pioneer and subsequent iterations of committee leadership—must be objectively justified based on the following verified criteria in their CVs:

1. Leadership Experience: Proven track record in previous or current management and administrative positions.
2. Exclusivity of Service: Absence of active concurrent membership in external Research Ethics Committees outside of the Gullas College of Medicine (GCM) to prevent conflicts of interest.
3. Academic Qualifications: Attainment of the highest relevant educational achievement or postgraduate degrees.
4. Research Productivity: Evidence of research publications in peer-reviewed journals within the last five (5) years preceding the selection or nomination.

Executive Search Implementation in nominating/electing officers:

- For Pioneer Officers: The CHRI Adviser will evaluate the pioneer membership pool against the above criteria to independently select the primary candidates for the foundational officer positions (Chair, Vice-Chair, and Member Secretary).
- For Subsequent Officers: The nomination process for future vacancies shall be presided over by the incumbent REC Chair. If the incumbent Chair is being re-nominated, a neutral, designated REC member shall preside over the floor. Once a new Chair is successfully determined, they will immediately assume leadership of the meeting to preside over the nominations for the Vice-Chair and Member Secretary. To ensure institutional continuity, candidates for subsequent officer positions must have served as active members of the REC for a minimum of one (1) year.

Step 3: Credential Review and Election Procedures

Pioneer Officer Selection: The CHRI Adviser will conduct a rigorous final review of the credentials of the selected pioneer members and formally nominate them to their designated executive roles.

Subsequent Officer Elections: Elections for new leadership will take place immediately upon the expiration of the preceding officers' terms. The REC Chair is responsible for calling the electoral assembly. The Administrative Secretary shall distribute a formal **Notice of Meeting** to all active REC members, with a copy furnished to the CHRI Adviser, explicitly stating that an election will be conducted.

The election of subsequent officers must be executed via secret ballot to ensure fairness and confidentiality. Winning candidates are determined by a simple majority vote of the members present (provided a quorum is met). In the event of an exact tie, the deadlock shall be settled immediately via a transparent "toss-coin" procedure or an alternative randomized process mutually agreed upon by the body.

Step 4: Executive Endorsement for Appointment

Following the final selection or election of officers, their names must be officially endorsed to institutional leadership:

- **For Pioneer Officers:** The CHRI Adviser will finalize the shortlist of the selected foundational candidates, complete **Form 2.1 (Endorsement Note)**, and formally route the document to the Vice President.
- **For Subsequent Officers:** Upon the successful conclusion of a general election, the outgoing or re-elected REC Chair shall officially endorse the newly elected officers by completing **Form 21.2 (Endorsement Note)** and forwarding it to the Vice President for executive action.

Step 5: Official Executive Appointment

Upon receipt and verification of the Endorsement Note, the Vice President retains the final authority to sign and issue the official appointment papers. This executive action confirms the placement of the qualified candidates into their respective roles as REC Chair, Vice-Chair, and Member Secretary.

The Vice president will sign the appointment documents of the pioneer and subsequent officers who met the above criteria as Chair, Vice Chair, and Member Secretary.

Step 6: Archiving, Document Control, and Database Tracking

To maintain institutional accountability, data compliance, and robust record-keeping, the appointment documentation must be systematically processed:

- **Physical File Management:** The Member Secretary (for pioneer officers) or the Administrative Secretary (for subsequent officer terms) will take possession of the signed appointment documents and archive them securely in accordance with **SOP 23: Management of Active Files**.
- **Administrative Logging:** The responsible secretary will complete **Form 4.7A (Filing Form Log)** to catalog the physical entry. Each reviewer will be allotted 1 separate independent folder.

Digital Tracking: The digital record of the newly appointed officers must be updated on **Form 1.9 (Administrative Research Tracking System - ARTS)** to maintain accurate, real-time metrics on committee leadership.

Section 6. Forms

Form 2.1 - Endorsement Note
Form 2.2 - Appointment letter for REC Officer
Form 21.2 - Active File Mgt.
Form 1.9 - ARTS

Section 7. History of SOP

Version No.	***Date***	***Authors***	***Main Change***
1	10.2.23	Nino Ismael s. Pastor	1st draft
2	09.16.24	Nino Ismael s. Pastor	2nd draft: Form label, Workflow
3	06.04.26	Nino Ismael s. Pastor	3rd draft: Few contents

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Gullas College of *Medicine* **RESEARCH ETHICS COMMITTEE** Ethos Universitas HONORARY COMPANION		Version No:	Draft
		Date of Approval:	
		Effectivity Date:	

SOP NO. 3 - APPOINTMENT OF INDEPENDENT CONSULTANTS

Section 1. Policy Statement.

Independent consultants whose expertise is not available among the current REC members but is needed in a study under review will be invited. Their role will be to review and clarify the technical aspects of the research proposal, not the ethical component of the research proposal.

Section 2. Objective of the Activity.

This SOP will ensure the appointment of independent consultants following institutional practices and policies. The purpose of independent consultant(s) in the REC is:

a. To assure the quality of the research proposal.
b. To ensure that the independent consultant's expertise is not available among REC members and his/her expertise is needed and;
c. To help the REC identify mitigating measures to reduce the technical impact of the proposal on human participants.

Section 3. Scope.

Appointments of independent consultants shall begin with a review of the proposal by the REC to determine the need for such consultant/s. This is followed by the identification of independent consultants inside or outside GCM who are not REC members. The identified independent consultant is invited to review the research proposal. After he/she accepts the invitation, the name of the independent consultant shall be enlisted in the pool of consultants, and an appointment shall be made. This is the endpoint for the independent consultant appointment.

Section 4. Workflow

ACTIVITY	*RESPONSIBILITY*	**TIMELINE**
Step 1: Identification of the study that requires an independent consultant	Primary Reviewer, Chairperson, Member Secretary	1 working day
Step 2: Identification of the independent consultant	Chairperson	2 working days
Step 3: Invitation of the independent consultant	Member Secretary	1 working day
Step 4: Receipt of the Appointment w Conforme /COI and Data privacy agreement of independent consultant	REC Member Secretary	3 working days
Step 5: Inclusion in the pool of independent consultants.	REC Member Secretary	1 working day
Step 6: Filing of appointment documents. See Form 4.7a (Filing Form Log) and ARTS (Form 1.9)	REC Administrative Secretary	2 working days
TOTAL		10 DAYS

Section 5. Description of Procedures

Step 1: Identification of the study that requires an independent consultant.

During the protocol review workflow, any specialized protocol requiring niche technical, clinical, or socio-cultural expertise that is not currently represented within the active Research Ethics Committee (REC) general membership must be flagged. The Primary Reviewer, Committee Chairperson, or REC Member Secretary possesses the authority to identify these specific protocols. Once a gap in internal expertise is declared, the REC Member Secretary shall explicitly document the exact nature of the scientific, ethical, or technical competency required to properly evaluate the proposal.

Step 2: Identification of the independent technical consultant.

The REC Member Secretary shall formally brief the Chairperson regarding the specific domain expertise needed for the protocol under review. Upon notification, the Chairperson will conduct a comprehensive audit of the internal institutional roster, including active members and alternate specialists across the Gullas College of Medicine (GCM) and Vicente Gullas Memorial Hospital (VGMH).

If a qualified specialist cannot be sourced internally, the search will expand to external affiliate institutions. Once an appropriate expert is identified who can provide the necessary clarity and objective review, the Chairperson will officially select the candidate and instruct the REC Member Secretary to initiate the formal invitation protocol.

Step 3: Invitation of the independent consultant.

Upon receiving authorization from the Chairperson, the REC Member Secretary is responsible for compiling the formal invitation packet. This packet must include:

- **The Formal Letter of Invitation (Form 3.1):** Outlining the scope of the protocol, the specific feedback required, and the expected timelines.
- **The Conforme Form (Form 1.2):** Serving as the candidate's initial mechanism for formal acceptance or refusal.

The Member Secretary shall route the finalized Invitation Letter to the Chairperson for signature before dispatching the complete packet to the prospective consultant.

Step 4: Receipt of the Appointment w Conforme /COI and Data privacy agreement of independent consultant.

The invited expert must formally communicate their willingness to serve by returning an executed copy of the Conforme (Form 1.2). Upon receipt of the affirmative Conforme, the Member Secretary shall immediately prepare the official **Letter of Appointment (Form 3.2)**, which must be signed by the REC Chairperson and transmitted back to the consultant. To protect the integrity of the research and ensure regulatory compliance, the onboarding consultant must review, execute, and return the following regulatory documents prior to accessing any research protocols:

- Conflict-of-Interest (COI) Disclosure Statement (Form 1.5)
- Data Privacy Agreement (DPA) (Form 1.6)
- Comprehensive Curriculum Vitae (CV) via the Institutional Template (Form 1.7)
- Confidentiality and Non-Disclosure Agreement (NDA) (Form 1.8)

Step 5: Inclusion in the pool of consultants.

Once all signed onboarding agreements are successfully verified, the REC Member Secretary shall officially induct the specialist into the committee's active consultant registry. The Member Secretary will encode the consultant's complete professional profile, contact information, and specific areas of technical expertise into the digital **Administrative Research Tracking System (Form 1.9 - ARTS)**. This updates the roster in real time, making the consultant searchable for future protocol distributions.

Step 6: Filing of appointment documents. (See SOP 23 on Managing Active Files).

To ensure absolute compliance with institutional audits and record-keeping regulations, all physical and digital records generated during this process must be systematically archived in accordance with **SOP 23: Management of Active Files**:

- **Physical Records:** The Administrative Secretary will gather the signed Appointment Letters, Conformes, COIs, DPAs, and CVs, and file them securely in the designated REC active storage repository.
- **Document Log Control:** The Administrative Secretary will update **Form 4.7A (Filing Form Log)** to track the physical file placement and perform corresponding system updates on the primary tracking platform (**Form 23.4 - ARTS**) to maintain cross-referenced accuracy. Each independent consultant will have a separate and independent folder.

Roster of Founding Independent Consultants (N = 13)

The following subject-matter experts have been formally vetted, designated, and integrated into the institutional pool of Independent Consultants (IC). They serve as external, non-voting scientific reviewers when specialized protocol evaluations are triggered.

INDEPENDENT CONSULTANTS (N = 11)				
Albim Cabatingan	Management, PhD BA, DPA	UV	IC	Scientist
Ronald Catacte	Biomedical Research, MAN, PhD ongoing, Nurse	SWU	IC	Scientist
Maricar Canonigo	Biomedical Research, MAN, PhD ongoing, Nurse	SWU	IC	Scientist
Aljoriz Dublin	Education,	UV	IC	Scientist

	MBA			
Rosemarie Camille Cunanan	Pharmacy, MPA, DPA	Non-GCM	IC	Scientist
Julius Mario	Medical Technology, PhD Med Tech	SWU	IC	Scientist
Rosie Mendoza	English, MA Eng, PhD Edu	UV	IC	Scientist
Queen Heneylour Relatorres	Criminal Justice, MA Crim Justice	UV	IC	Scientist
Niño Ismael Pastor	Epidemiology, Medical Education DRDM	GCM	IC	Scientist
Mara Bernadette Redula	Gen Medicine	GCM	IC	Scientist
Rochelle Go	Pharmacist	Velez Gen Hosp	IC	Scientist
Joanne Camello	Gen Pediatrics	CIM, VGH	IC	Scientist

Section 6. Forms

Form 3.1 – Letter of Invitation for a Technical Expert
Form 3.2 – Appointment letter independent consultant
Form 1.2 - Conforme
Form1.8 – Confidentiality Agreement
Form 1.5 - Conflict of Interest Declaration Form
Form 1.6 – Data privacy agreement
Form 21.2 – Active File Mgt
Form 1.9 - ARTS

Section 7. History of SOP

Version No.	***Date***	***Authors***	***Main Change***
1	10.6.23	CHRI Director	First draft

2	9.26.24	Faith Yee	Workflow, form labels
3	6.4.26	Nino Ismael Pastor	Form labels, few content

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Section 1. Policy Statement

All research proposals should file an application for an REC review. The application form will be similar for all researchers. Research proponents or investigators do not have the right to determine how their proposal will be reviewed. The REC will determine how the proposal will be reviewed: exempted, expedited, or by full Committee. This SOP No. 4 concerns proposals that may be exempted from an REC review.

Research proposals may be exempted if (1) they do not use humans or animals as test subjects, (2) the proposal poses no more than a minimal risk to human interviewees, and/or (3) all research procedures or methodologies fit the exemption categories stated in this section.

The Belmont Principle requires that human subjects or respondents be given the opportunity to participate or decline to participate in the research. All human subjects or respondents must sign an Informed Consent Form, even if the proposal is exempt from REC review. A copy of this ICF is included with this proposal. This ICF should contain at least the minimum information, which includes the following (NWU, 2023):

- An explanation that they will be interviewed or asked to answer survey questionnaires to participate in a research study.
- The identity and affiliation of the researcher (s).
- A clear description of the study procedures and how data will be used in the future.
- A statement that participation in the research is voluntary.
- Contact information of researchers(s) that participants can ask questions and concerns about the research.

However, researchers must follow the ICF outlined in the SOP forms.

Changes to the proposal do not need to be submitted to the REC after an exemption is granted, as long as the modifications in research procedures and methodologies pose

minimal risks and still fall within the exempted categories that the REC used as the basis for the exemption. However, if the changes do not adhere to the exemption categories cited by the REC, the proponent must notify the REC secretary.

Section 2. Objective of the Activity

The objective of the activity is to describe the policies and procedures for exempting a research proposal from ethics review when the proponent exercises due diligence in drafting it.

Section 3. Scope

The REC may decide to exempt submitted protocols from an ethics review. This SOP explains how to exempt a proposal from the ethics review process. Proposals that will be exempted may fall under the following categories (PHREB, NEGRIHP 2022, 2022):

- Protocols for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests;

- Research that only includes interactions involving survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording), if the following criteria are met:

    - There will be no disclosure of the human participants' responses outside the research that could reasonably put the participants at risk of criminal or civil liability or harm their financial standing, employability, or reputation; and

    - The investigator records the information obtained in such a manner that the identity of the human participant cannot readily be ascertained, directly or through identifiers linked to the participant.

- Protocols that involve the use of publicly available data or information.

Category A. Research involving educational practices that do not impact on the human participant's time, environment, or experience. These practices may focus on teaching methods, the medical curriculum, class management, and learning styles or strategies. Examples (NWU, 2023):

Evaluations of academic tests

Evaluations of medical education programs

Research about curricula or study modules

Evaluation of health programs

The researchers or investigators will be advised of the results of the REC review for exemption after the application is submitted. The REC will also inform the CHRI about their decision regarding the proposal.

Category B. Proposals that only involve interviews or observing human participants involving educational tests (cognitive, diagnostic, aptitude, or achievement), surveys needing responses from participants, or observing human participants who will record (visually or audibly) their behavior. Examples (NWU, 2023):

- Surveying teachers, students, nurses, or doctors about a technique or an outcome
- Interviewing managers about a management style, programs or best practice
- Conducting a focus group about an experience or an opinion of a community program

Category C. Proposals that use safe and harmless behavioral interventions while collecting data from human participants through spoken or written responses and/or audiovisual recordings of the participants who previously signed an informed consent form (ICF), as long as the data collection method is brief, safe, respects data privacy principles, and does not cause harm to the participant. Example:

- Healthy adult subjects are asked to take part in assessments of memory, attention, attitude, behavior, and information processing speed. The procedures are conducted during a single visit, and subjects are encouraged to take breaks when desired (NWU, 2023).

Category D. Proposals that review existing data and / or laboratory results that were or will be collected for non-research (i.e., diagnosis) purposes or from related research studies. The research materials typically are publicly available materials like medical records, or existing repositories of clinical specimens. There is no contact between researchers and human participants. Example:

- A proposal reviewing medical records of patients with certain diseases.

Category E. Proposals that are conducted to evaluate the public health or clinical benefit of procedures, programs, and possible improvements of services under these programs. Example:

- Studies that evaluate the impact of a health or medical education program that reviews the records of accomplishment of said program

- Proposals evaluating the clinical efficacy of a clinical procedure using patient records

Category F. This includes proposals for flavor and food nutritional quality evaluation and consumer acceptance studies. Example:

- Studies on the nutrition of foods without additives.
- Proposals that test a food ingredient at or below the level and for a use found to be safe, or an agricultural chemical or environmental contaminant at or below the level found to be safe, as determined by the Food and Drug Administration or approved by the Department of Environment and Natural Resources or the Department of Agriculture.

The above categories of proposals do not entail more than a minimal risk to human subjects, or human subjects that do not belong to vulnerable groups and where vulnerability issues are absent. Researchers, however, are asked to provide information about the study, and participants sign informed consent forms.

This SOP begins with the assignment of reviewers or independent consultant/s and ends with the inclusion of the review in the agenda of the next meeting."

Section 3. Workflow

In order to exempt the proposal from an ethics review, here are the different steps involved in exempting a proposal from the review, and the people responsible for each of these steps.

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Application (Form 4.0 – Applicatiion for Ethics Review) for a REC review and submission of a proposal (Chp 1,2, &3), ICF, CHRI Notice To Proceed, validity of QQ certificate to REC	Student	1 day
Step 2: Assignment of Reviewers OR Appointment of Independent Consultants w conforme **(Form 3.1 AND/OR Form 4.3)**	Admin Secretary Member Secretary REC Chair	1 day

Step 3: Notification of Reviewers or Independent Consultant/s w conforme (**Form 3.1 and/or Form 4.3)**	Member Secretary	1 day
Step 4: Provision of study documents and evaluation forms**, Form 4.8. Proposal Summary Sheet, and form 4.5 ICF WS, Form 4.4 - REC Review Checklist** to the primary reviewer and other reviewers)	Admin Secreatary	5 days
Step 5: Accomplishment and submission of evaluation forms	Reviewer	7 days
Step 6: : Inclusion of the Review in the Agenda of the next meeting (Form 18.1: Preparing the Meeting Agenda)	Chair and Member Secretary	2 days
Step 7: Finalization of review results	Member Secretary Chair	3 days
Step 8: **: Communication of review results to the researcher** (Form 4.6– Decision letter), Form 4.1 (Exemption) & Form 4.11 (Certificate of Exemption).	Chair and Member Secretary	1 day
Step 9: Filing of documents in the protocol file **(FORM 4.9)**	Member Secretary |Admin Secretary	1 day
	TOTAL	**22 Days**

Sectio 4. Description of Procedures

Step 1: Application (Form 4.0 – Application for Ethics Review) for a REC review and submission of a proposal (Chp 1,2, &3), ICF, CHRI Notice to Proceed, validity of QQ certificate to REC

The ethical review lifecycle begins when a student proponent (or team of student researchers) secures the formal **REC Review Application Form (Form 4.1)**. The proponents must complete the form, affix their signatures, and attach it to their

comprehensive research proposal. This complete application packet is then submitted to the REC Administrative Secretary.

Upon receipt, the Administrative Secretary will log the entry and immediately alert the Member Secretary of the new submission. The Administrative Secretary serves as the clearinghouse, compiling all incoming applications over the course of the week. Every Friday, the Administrative Secretary consolidates these weekly submissions and presents them to the Member Secretary for initial regulatory and technical evaluation.

Step 2: Assignment of Reviewers OR Appointment of Independent Consultants w conforme (Form 3.1 AND/OR Form 4.3)

Following the initial evaluation of the protocol's scope, the Member Secretary will formulate a reviewer assignment plan. The Member Secretary recommends to the REC Chairperson specific accredited reviewers or external independent consultants whose scientific credentials directly align with the protocol's subject matter.

The Chairperson exercises final approval over these assignments, cross-referencing the potential reviewer's files curriculum vitae and active workload against the specialized technical needs of the proposal to ensure an objective, high-quality review.

Step 3: Notification of Reviewers or Independent Consultant/s w conforme (Form 3.1 and/or Form 4.3)

Once the Chairperson approves the assignments, formal communication is initiated to secure the reviewers' services:

- **For Accredited REC Members:** The **Notice to Review (Form 4.3)** is dispatched.
- **For External Specialists:** The **Appointment of Independent Consultant Letter (Form 3.1)** is issued.

The assigned reviewer or consultant must review the request and formally communicate their availability and willingness to assume the review. A binding confirmation of their agreement to evaluate the proposal must be received by the REC office before any confidential study documents are transmitted.

Step 4: Provision of study documents and evaluation forms, Form 4.8. Proposal Summary Sheet, and form 4.5 ICF WS, Form 4.4 - REC Review Checklist to the primary reviewer and other reviewers)

Upon receiving a reviewer's formal acceptance, the Member Secretary coordinates the secure distribution of the evaluation packet. The Member Secretary provides the assigned reviewers or independent consultants with the complete primary documentation and supporting institutional evaluation forms, which include:

- The full Research Proposal / Protocol

- The Certificate of Validity for the utilized research questionnaires
- **Protocol Summary Sheet (Form 4.8)**
- **REC Review Checklist (Form 4.4)**
- **Informed Consent Form Worksheet (ICF WS - Form 4.5)**

Step 5: Accomplishment and submission of evaluation forms.

Reviewers and independent consultants—who have undergone specific institutional training regarding health research ethics and human participant protections—will independently conduct a rigorous assessment of the protocol. Reviewers are allocated a standard period of at least one (1) month from the date of document receipt to thoroughly study the proposal and complete the mandatory evaluation forms.

Upon completing the assessment, the reviewer fills out the **REC Review Checklist (Form 4.4)** and submits it directly to the Member Secretary. The Member Secretary collates these completed checklists and forwards them to the Chairperson. After reviewing the gathered assessments, the Chairperson instructs the Member Secretary to calendar the protocols for the upcoming committee session.

Step 6: Inclusion of the Review in the Agenda of the next meeting (Form 18.1. Preparing the Meeting Agenda**).**

To facilitate a collective deliberation on the evaluated protocols, the Member Secretary consults with the Chairperson to finalize a date and time for the next formal REC review assembly. Once the date is locked, the Member Secretary designs the session layout using **Preparing the Meeting Agenda (Form 18.1)**. This meeting agenda is formally distributed to all active REC members, advising them of the schedule and outlining the specific protocols slated for committee discussion.

Step 7: Finalization of review results.

During the convened REC meeting, the general membership deliberates on the merits, ethical considerations, and reviewers' feedback for each protocol. The Member Secretary documents the proceedings and finalizes the official **Minutes of the Review Meeting**. Based on the collective determinations recorded in the minutes, protocols qualifying for an absolute exemption from a full Committee ethics review will be explicitly identified and categorized.

Step 8: : Communication of review results to the researcher (Form 4.6– Decision letter), Form 4.1 (Exemption) & Form 4.11 (Certificate of Exemption).

Following the finalization of the meeting minutes, the review results must be officially communicated to the student researchers within a strict administrative timeline. The

Member Secretary drafts the appropriate institutional correspondence based on the committee's decision:

- **Standard Decision Letter (Form 4.6):** Issued to communicate regular review outcomes (e.g., Approval, Minor Revisions, Major Revisions, or Disapproval).
- **Exemption Correspondence (Form 4.1 & Form 4.11):** For protocols determined to be exempt from further ethical oversight, the Member Secretary issues a formal **Exemption Letter (Form 4.1)** paired with an official **Certificate of Exemption (Form 4.11)**.

Step 9: Filing of documents in the protocol file (SOP 23 Mgt of Active File.

To maintain institutional compliance, transparency, and strict audit trails, all documents generated during the review lifecycle must be systematically filed. Under the direct supervision of the Member Secretary, the Administrative Secretary will archive all physical and digital records in strict compliance with **SOP 23: Management of Active Files**.

The Administrative Secretary will generate a dedicated **Protocol Folder Index (Form 4.9)** for each new proposal, log the entries into the **Research Management Summary Sheet (RMSS - Form 4.7)**, and record the administrative track within the **Filing Form Log (Form 4.7a)**.

Protocol Review Matrix

Stage	Responsible Officer	Primary Tool / Form Used	Operational Output
Intake & Consolidation	Administrative Secretary	REC Review Application (Form 4.1)	Weekly Consolidated Dossier
Intake & Consolidation	Member Secretary & Chair	Notice to Review (Form 4.3) / Appointment Letter (Form 3.1)	Confirmed Reviewer Matrix
Reviewer Assignment	Member Secretary	Summary Sheet (Form 4.8), Checklist (Form 4.4), ICF WS (Form 4.5)	Complete Evaluation Packet
Dossier Distribution	Assigned Reviewers / ICs	REC Review Checklist (Form 4.4)	Completed Ethical Assessment
Ethical Assessment	Member Secretary	Preparing the Meeting Agenda (Form 18.1)	Distributed Institutional Agenda
Agenda Formatting	Member Secretary	Decision Letter (Form 4.6) / Cert. of Exemption (Form 4.11)	Official Notification to Proponents

Stage	Responsible Officer	Primary Tool / Form Used	Operational Output
Outcome Delivery	Administrative Secretary	Folder Index (Form 4.9), RMSS (Form 4.7), Filing Log (Form 4.7a)	Archived Master Protocol Folder

Section 5. Forms

Form 3.1 Invitation Tech Expert W Conforme
Form 4.0 - Application For Ethics Review
Form 4.1 Exemption
Form 4.3 Notice of Review
Form 4.4 REC Review Checklist,
Form 4.5 ICF WS.
Form 4.6 Decision Letter
Forn 4.7 Research Monitoring Surveillance System
Form 4.7a the Filing Form log.
Form 4.8 Proposal Summary Sheet
Form 4.9 Protocol folder Index
Form 4.7a Filing form (for each proposal)
Form 4.11 – Certificate of Exemption
Form 21.2 Active File Mgt

Section 6. History of SOP

This is the first time SOP 4 was formulated for a proposal that is exempted from an ethical review.

Version No.	Date	Authors	Main Change
1	2023 Dec 6	Nino Ismael Pastor	First draft
2	9.16.24	Nino Ismael Pastor	2nd Draft
3	06.04.20256	Nino Ismael Pastor	3rd Draft

Section 7. References

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SOP NO. 5 - EXPEDITED REC REVIEW

Section 1. Policy Statement

The REC conducts an expedited review for study protocols that (1) do not cause beyond minimal risk to the study participants, (2) do not have vulnerable human participants, and (3) do not generate vulnerability as determined by its chairman before the assignment of reviewers. The students are instructed to apply for an ethical review.

An expedited review is conducted by at least one (1) member of the REC designated by the REC Chair. In an expedited review, the assigned reviewer exercises all the roles & responsibilities of the REC but consults and seeks the advice of the Chair.

Section 2. Objectives of the Activity

Demonstrate due diligence and high standards of protection of human participants in research that (1) do not cause beyond minimal risk to the study participants, (2) do not have vulnerable human participants, and (3) does not generate vulnerability as determined by its chairman before the assignment of reviewers.

Section 3. Scope

The expedited review process begins with the assignment of the reviewer, or independent consultant, and ends with the inclusion of the said study in the next meeting.

Section 4. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Assignment of Reviewers (Form 4.3) or Independent Consultant/s (Form 3.2).	Member Secretary Chair Administrative Secretary	1 day
Step 2 – Notification and reply of Reviewers or Independent Consultant/s	Administrative Secretary	7 days after assignment
Step 3 - Provision of documents and evaluation form to reviewers.	Administrative Secretary	2 days after conforme
Step 4: Accomplishment and submission of evaluation Forms	Reviewers	7 days after receiving document
Step 5: Finalization and approval of review results	Chair	

Step 6: Communication of review results to the researcher (SOP 21 – Communicating REC decisions)	Chair & Administrative Secretary	1 day
Step 7: Filing of documents in the protocol file **(Form 4.9) and Form 4.7a (Filing Folder Log)**	Administrative Secretary	1 day
Step 8: Inclusion of the Review in the Agenda of the next meeting (SOP 17 – Preparing the Meeting Agenda)	Chair and Administrative Secretary	1 days
TOTAL		21 days

Section 5. Description of Procedures

Step 1: Assignment of Reviewers (Form 4.3) or Independent Consultant/s (Form 3.2).

The ethics review lifecycle is initiated upon the submission of a comprehensive protocol package by the primary investigator(s):

- **Initial Submissions:** Proponents must complete and execute the **Application for Ethics Review (Form 4.0)** and attach the corresponding **Informed Consent Form (ICF) Template (Form 4.2 or 4.2a, or 4.2b, 4.2c)**.
- **Resubmissions:** For protocols requiring re-evaluation, the researcher must execute the **Resubmission Form (Form 7.1)** and append all altered or supporting documentation.

Within twenty-four (24) hours of administrative receipt, the Member Secretary shall evaluate the scope of the study. If the protocol meets the institutional criteria for minimal risk, the Member Secretary will formally recommend an expedited review path to the REC Chairperson via rapid communication channels (phone or secure text message).

The Chairperson must review the recommendation and concur within that same working day, identifying one (1) Primary Reviewer based on matching scientific and clinical credentials. If internal committee expertise is absent, the Chairperson shall invoke **SOP 3 (Appointment of Independent Consultants)**, instructing the Member Secretary to issue the **Invitation for a Technical Expert with Conforme (Form 3.2)**.

Once the reviewer is selected, the Chairperson instructs the Administrative Secretary to generate the **Notice of Review (Form 4.3)**. The Administrative Secretary may provide an advance notification to the reviewer via phone or text message; however, the formal, signed Conforme block on Form 4.3 must be returned to the REC office to log into the **Protocol Folder Index (Form 4.9)** and register the entry within the **Research Management Summary Sheet (RMSS) Database (Form 4.7), and the Filing Form log (Form 4.l7a)**.

Step 2 – Notification and reply of Reviewers or Independent Consultant/s:

To prevent administrative bottlenecks, strict communication windows are enforced:

- **Formal Written Conforme:** The invited primary reviewer or independent consultant must sign and return the official Conforme block of Form 4.3 to the Administrative Secretary within three (3) calendar days of receipt, and under no circumstances later than seven (7) calendar days following the institutional intake of the study.
- **Alternative Telecommunication:** The reviewer may provide an expedited verbal or digital commitment (via phone call or SMS) to the Administrative Secretary within the same three-to-seven-day operational window to ensure immediate protocol tracking.

Step 3 - Provision of documents and evaluation form to reviewers.

Upon receiving the signed Conforme, the Administrative Secretary will assemble the complete evaluation packet. This package contains the primary study documents alongside specific institutional tracking and assessment sheets, including:

- The full Research Protocol / Proposal
- Official approval documentation from the Technical Service Panel
- **REC Review Checklist (Form 4.4)**
- **Proposal Summary Sheet (Form 4.8)**
- The appropriate Informed Consent template variant **(Form 4.2, 4.2a, 4.2b, or 4.2c)**
- **Informed Consent Form Evaluation Worksheet (Form 4.5)**

For **Resubmissions** undergoing expedited processing, the Administrative Secretary will retrieve the historical master file and compile the **Resubmission Form (Form 7.1)**, the previous ethics review report, and the revised protocol sections highlighting changes.

Material Distribution Timelines:

- **Physical Media:** The Administrative Secretary shall ensure that complete physical hard copies of the dossier are delivered to the primary reviewer via official courier/messenger no later than ten (10) calendar days from the initial application or resubmission date.
- **Digital Media:** To expedite evaluation, soft copies of the protocol packet must be transmitted securely via email to the primary reviewer (and, when contextual

demands dictate, to select REC members) within five (5) to nine (9) calendar days from institutional receipt.

Step 4 -Accomplishment and Submission of Evaluation Forms.

The designated reviewer or independent consultant shall perform a comprehensive, independent ethical evaluation of the study materials.

- **General Expedited Submission Window:** The completed **REC Review Checklist (Form 4.4)** and **ICF Evaluation Worksheet (Form 4.5)** must be executed and returned to the Administrative Secretary via secure email or secure hand-delivery within seventeen (17) calendar days of receiving the packet.
- **Session Deadlines:** For standard expedited protocols, completed evaluations must be submitted on or before the scheduled monthly meeting held on the **third (3rd) Saturday of the month**.
- **Full Committee Contingency Window:** If a protocol is redirected from an expedited path toward a Full Committee Review, the finalized evaluation forms must be submitted at least **seven (7) calendar days prior** to the regular general assembly to ensure proper packet replication.

Step 5 - Finalization and approval of the review results.

The Administrative Secretary collects all individual evaluation checklists from the primary reviewers and routes them to the Member Secretary. Within seventeen (17) calendar days from the initial intake of the protocol or resubmission, the Member Secretary will consolidate, align, and finalize the unified evaluation report and submit it to the REC Chairperson.

The Chairperson conducts an executive review of the compilation to issue an initial determination. These approved evaluations are then prepared for formal presentment at the upcoming monthly REC general assembly.

Critical Increase of Ethical Concern: If any active committee member raises material ethical, technical, or procedural concerns regarding a protocol presented under the expedited track during the general assembly, that protocol shall be immediately stripped of its expedited status and rescheduled for a comprehensive Full Committee Review at the next regular meeting.

Step 6 - Communication of review results to the researcher: (See SOP 21-Communicating REC Decisions).

The Administrative Secretary will translate the committee's final determination into the official **Decision Letter (Form 4.6)** and route it to the Chairperson for signature.

- **Expedited Approval Distribution:** If a protocol achieves expedited approval, the signed Decision Letter must be transmitted to the researcher via email or hand-carried delivery within one (1) working day of executive approval.
- **Conditional Outcomes (Minor/Major Modifications):** If the committee demands modifications, a formal notification letter incorporating the consolidated reviewer recommendations, queries, and critiques will be dispatched to the researcher.
- **Disapproval Outlay:** If an expedited protocol faces a recommendation for disapproval, it is automatically escalated and placed onto the agenda of the upcoming full Committee meeting for final collective adjudication.

Proponent Response Framework:

The researcher is granted a window of **five (5) to ten (10) working days** to address the committee's findings (the exact due date is determined by the Chairperson based on the structural complexity of the requested changes). The researcher must submit the modified protocol documents alongside an itemized point-by-point response matrix back to the REC office.

Step 7: Filing of documents in the protocol file (**Form 4.9), RMSS (Form 4.7) and Form 4.7a (Filing Folder Log)**

To maintain a flawless audit trail, all documentation generated throughout the review process must be filed systematically under the guidelines of **SOP 19 / SOP 23 (Management of Active Files)**:

- **Folder Initialization:** Each new proposal is assigned a unique institutional protocol folder. The Administrative Secretary will record the protocol's movement within the **RMSS Database (Form 4.7)** and the physical **Filing Folder Log (Form 4.7a)**.
- **Informed Consent Waivers:** If the REC determines that a protocol qualifies for an operational exemption from human participant consent, the Principal Investigator must execute **Form 4.10 (Waiver of Informed Consent)**, which is then appended to the master file.
- **Final Administrative Logging:** Upon reaching a terminal administrative state (Final Approval, Disapproval, or Formal Withdrawal), the Administrative Secretary will record the closing actions in the **Protocol Folder Index (Form 4.9)**, update

the **Filing Form Log (Form 4.7a)**, and finalize the entry within the central **RMSS Database (Form 4.7)**.

Step 8 - Inclusion of the Review in the Agenda of the next REC regular meeting: **See SOP 17 (Preparing the Meeting Agenda)**

In strict compliance with **SOP 17 (Preparing the Meeting Agenda)**, transparency must be maintained between tracks. All protocols that successfully receive final approval via the expedited review mechanism cannot remain isolated; they must be formally integrated into the agenda of the next regular REC full Committee meeting for reporting, validation, and official entry into the permanent institutional minutes.

Section 6. Forms

Form 3.1 – Invitation Tech Expert with Conforme
Form 4.0 – Application for Ethics Review
Form 4.2 – ICF Template
Form 4.2a – ICF for children less 18 yrs
Form 4.2b – ICF for clinical studies
Form 4.2c - ICF for qualitative studies
Form 4. 3 – Notice of Review
Form 4.4 – REC Review Checklist
Form 4.5 – ICF Eval Worksheet
Form 4.6 – Decision Letter
Form 4.7 – RMSS Database
Form 4.7a- Filing Form
Form 4.8 – Proposal Summary Sheet
Form 4.9 – Protocol Folder Index
Form 4.10 - Waiver of Informed Consent
Form 7.1 – Resubmission Form

Section 7. History of SOP

This the first time that this SOP is being prepared. The approval of the Vice President of GCM will be obtained as soon as all the SOPs are completed.

Version No.	***Date***	***Authors***	***Main Change***
1	12.07.2023	Niño Ismael Pastor	*First draft*
2	9.16.24	Faith Yee	Workflow, Forms & Form labels
3	6.4.26	Nino Ismael Pastor	Form labels, Workflow

Section 8. References

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SOP NO. 6 - FULL COMMITTEE REC REVIEW

Section 1. Policy Statement

This SOP applies to the review and approval of proposals and amendments to proposals that (1) pose beyond minimal risk to participants, (2) use study participants belonging to vulnerable groups, and/or (3) create vulnerability to human participants. Major revisions in a submitted proposal or its informed consent are also included. Primary reviewers will be required to conduct the review processes. A full review ensures compliance with the technical and ethical standards for research on human participants, their identifiable data, and materials.

Section 2. Objective of the Activity

To describe the REC's procedures when conducting a full Committee meeting.

Section 3. Scope

This SOP begins with the researcher filing for an initial, resubmission, or any post-approval concern needing an ethical review. Primary reviewers or independent consultants will then be assigned. It ends with the filing of research documents in the protocol folder, updating the Protocol Folder Index (Form 4.9) and Form 4.7 (RMSS DATABASE).

Section 4 - Workflow

Listed below are the steps involved in conducting a FULL COMMITTEE review, which begins after the researcher(s) submit(s) an initial, resubmission, or post-approval request needing an ethics review.

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Assignment of primary reviewers (Form 4.3) or Independent Consultant/s (Form 3.1 Invitation tech exert w conforme)	Member Secretary Chair	2 days from receipt of submission
Step 2: Notification of primary reviewers or Independent Consultants	Member Secretary	

Step 3: Provision of protocol and protocol-related documents and assessment Forms to reviewers	Administrative Secretary	2 days
Step 4: Presentation of review findings and recommendations during a committee meeting (SOP 19. Conduct of Meeting)	Primary Reviewers	1 day: every 3rd Saturday of the month
Step 5: Documentation of Committee deliberation and action (Form 20.1 - Minutes of the meeting)	Member Secretary Administrative Secretary	6 days
Step 6: Communication of Committee Action to the researcher (Form 4.6 – Decision letter template)	Chair, Member Secretary, and Administrative Secretary	9 days after the monthly REC meeting
Step 7 - Step 7: Filing of protocol-related documents and Updating of the Protocol Database (Form 4.7), RMSS (Form 4.7) and filing Form Log (Form 4.7a) (See SOP 19 – Management of Active Files).	Administrative Secretary	
TOTAL		20 days

Section 5. Description of Procedures

Step 1: Assignment of primary reviewers (Form 4.3) or Independent Consultant/s (Form 3.1 Invitation tech exert w conforme)

The formal ethical review lifecycle for protocols requiring comprehensive evaluation is initiated upon the investigator's submission of necessary documentation to the REC office:

- Initial Protocols: Requiring the execution of the Application for Ethics Review (Form 4.1).
- Protocol Amendments/Revisions: Requiring the Resubmission Form (Form 7.1).
- Post-Approval Amendments: Tracking deviations, renewals, or adverse events demanding structural review.

Upon administrative intake, the Member Secretary shall evaluate the submission to determine if the study presents more than minimal risk to human participants, thereby requiring a Full Committee review. The Member Secretary formally presents this assessment to the REC Chairperson.

Upon concurrence, the Chairperson officially authorizes the Full Committee track and assigns at least one (1) Primary Reviewer—or an external Independent Consultant pursuant to SOP 3 (Appointment of Independent Consultants)—whose specialized scientific, medical, or socio-cultural credentials directly align with the proposal's subject matter. For legacy or post-approval protocols, the Chairperson identifies the historically

assigned Primary Reviewer to maintain continuity of oversight and instructs the Member Secretary to initiate notification protocols.

Step 2 - Notification of and acceptance by primary reviewers and/or Independent Consultants:

To maintain strict adherence to institutional review timelines, the Member Secretary must rapidly transmit the protocol to the assigned evaluators:

- Document Generation: Within two (2) calendar days of receiving the submission, the Member Secretary shall fill out the Notice of Review (Form 4.3) along with the accompanying Conforme (Form 1.2).
- The Response Window: The designated Primary Reviewer or independent technical expert must review the assignment and return the executed Conforme block within two (2) calendar days of receipt. The Conforme (Form 1.2) represents a formal commitment to evaluate the protocol thoroughly and confirms the absence of any conflicting interests.

Step 3 - Provision of protocol and protocol-related documents and assessment Forms to primary reviewers/independent consultants.

Immediately upon receiving the signed Conforme from the reviewer, the Administrative Secretary assumes responsibility for assembling and distributing the complete protocol evaluation documents. This standardized packet must include:

- The primary Research Proposal and all appended investigator profiles
- REC Review Checklist (Form 4.4)
- Informed Consent Form Evaluation Worksheet (Form 4.5)
- Proposal Summary Sheet (Form 4.8)
- *For resubmissions or modifications:* The Resubmission Form (Form 7.1) alongside previous committee notes.

Distribution Modalities & Timelines:

- Primary Reviewer Packet: The Administrative Secretary shall print, package, and hand-carry complete physical hard copies of the dossier directly to the designated Primary Reviewer.
- General Membership Packet: Concurrently, secure soft copies of the protocol packet must be compiled and distributed via secure electronic channels to all other active REC Committee members to facilitate independent pre-meeting evaluations.
- Regulatory Deadline: The complete distribution workflow—both physical and digital—must be concluded within seven (7) calendar days of initial application intake**.**

Step 4: Presentation of review findings and recommendations during a committee meeting (SOP 19. Conduct of Meeting)

The assigned Primary Reviewer must perform an independent, comprehensive evaluation of the protocol's ethical and scientific merits prior to the convened assembly. All general committee members are expected to review their digital packets to participate meaningfully in floor deliberations.

The Primary Reviewer must formalize their critiques, questions, and recommendations using the provided institutional evaluation worksheets and submit these findings to the Chairperson at least three (3) days prior to the meeting, or precisely on the third Wednesday of the month.

The general committee will officially convene to debate, vote on, and settle the protocol's status on the third Saturday of the month.

In the event that an assigned Primary Reviewer or Independent Consultant faces an emergency and cannot attend the scheduled session, the Chairperson exercises executive prerogative to assume the role of Primary Reviewer. This ensures that the review proceeds smoothly without compromising institutional timelines or leaving the protocol in an unaddressed bottleneck.

Step 5 - Documentation of Committee deliberation and action Meeting (SOP 20 – Preparing the Minutes of the Meeting).

During the official session, the committee's cross-disciplinary discussions must focus heavily on core ethical pillars: informed consent process validity, vulnerable population protections, data confidentiality matrices, and, where applicable, institutional biosafety guidelines and animal welfare protocols.

The Member Secretary is responsible for recording all Committee actions, motions, and collective arguments to generate the official document under SOP 20 (Preparing the Minutes of the Meeting).

To maintain clear systemic boundaries, the Administrative Secretary will compile an independent registry of all protocols that achieved approval through the parallel expedited track during the prior month. The Member Secretary will formally present this list during the Full Committee meeting to ensure that it is recorded in the permanent institutional minutes.

Step 6: Communication of Committee Action to the researcher (Form 4.6 – Decision letter template)

Following the adjournment of the review session, the Member Secretary translates the raw session notes into a clean administrative draft for the Chairperson's review. The Chairperson will

review the notes, summarize the complex ethical issues or data clarifications raised during the floor debates, and call for an explicit vote on each pending resolution.

The definitive outcomes, explicit provisos, and specific reviewer critiques are transposed into the formal Decision Letter (Form 4.6). This letter must be signed by the Chairperson and dispatched to the primary investigator via secure email or courier within seven (7) calendar days post-meeting. The committee must issue one of the following four standardized operational actions:

1. Approval: The protocol is cleared, and an ethical clearance certificate is issued.
2. Minor Modifications: The protocol requires simple, non-structural clarifications, which may be vetted via an expedited review path upon resubmission.
3. Major Modifications: The protocol exhibits material ethical or scientific gaps and must be revised by the researcher and routed back to a Full Committee meeting for re-evaluation.
4. Disapproval: The protocol is rejected due to severe ethical violations or insurmountable structural flaws.

Any protocol receiving a recommendation for disapproval or requiring major overhauls will automatically be placed on the action agenda for the subsequent monthly REC session.

Step 7: Filing of protocol-related documents and Updating of the Protocol Database (Form 4.7), RMSS (Form 4.7) and filing Form Log (Form 4.7a) (See SOP 19 – Management of Active Files).

To satisfy national regulatory bodies and internal audit controls, all documentation generated through this lifecycle must be preserved securely in accordance with SOP 19 / SOP 23 (Management of Active Files). The Administrative Secretary shall execute the following archiving protocols:

- Physical File Management: Gather all signed application sheets, completed checklists, meeting notes, and copy sets of the final Decision Letter, and file them within a uniquely serialized protocol folder.
- Log Control Updates: Fill out the physical Protocol Folder Index (Form 4.9) and register the transaction within the Filing Form Log (Form 4.7a).
- Digital Registry Synch: Log the terminal action, meeting dates, voting outcomes, and expiration data within the Research Management **Summary Sheet (RMSS) Database (Form 4.7) to maintain real-time tracking metrics.**

Section 6. Forms

Form 1.2 – Conforme
Form 3.1 – Invitation Tech Expert
Form 4.1 – Application for Ethics Review

Form 4.4 – REC Review Checklist
Form 4.5 – ICF Eval Worksheet
Form 4.6 - Decision Letter Template
Form 4.7 – RMSS DATABASE
Form 4.7a – Filing Form log
Form 4.8 – Proposal Summary Sheet
Form 6.1 – Protocol folder Index
Form 7.1 – Resubmission

Section 7. History of SOP

Version No.	***Date***	***Authors***	***Main Change***
1	4.22.2024	NINO ISMAEL S. PASTOR	Draft
2	10.04.2024	Faith Yee	Contents, Forms, and Forms label
3			

Section 8. References

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

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

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

Section 1. Policy Statement

GCM research investigators must submit pertinent documents to the REC on or before **the 2nd Wednesday of every month**, together with an application for ethical review (Form 4.0). Only complete submissions will be accepted from GCM or Vicente Gullas Memorial Hospital (VGMH) faculty, students, non-teaching staff, residents, and/or consultants.

The REC shall determine whether the proposal will be exempted, expedited, or need a full Committee ethical review based on the NEGRIHR 2022 Guidelines (PHREB, NATIONAL ETHICAL GUIDELINES FOR RESEARCH INVOLVING HUMAN PARTICIPANTS, 2022). The REC shall also determine if amendments to the approved proposal need to be exempted, expedited, or need a full Committee ethical review. Accepted proposals, post-approval requests, or concerns will be addressed during a regular REC meeting on the 3rd Saturday of each month.

The REC may delegate the decision to exempt a protocol from review to a REC member for efficiency and to save time. However, subsequent amendments to a protocol that was exempted from review shall be submitted for a preliminary evaluation to determine whether the revised protocol can still be “exempted from review.

Section 3. Objective of the Activity

Ensure the quality and longevity of the research documents submitted initially, covering completeness, receipt, distribution, evaluation, archiving, and obsolescence.

Section 3. Scope

This SOP begins with the receipt of study documents for initial review:

1. The Proposal (Chapters 1, 2 & 3)
2. Form 4.0 -Application for ethics review
3. Form 4.2 – ICF incorporated in the Proposal
4. Form 4.8 – Proposal Summary Sheet
5. Form 4.10 – Waiver of ICF
4. CVs of authors incorporated in the Proposal
6. Certificate Questionnaire Validity
7. CHRI Notice to Proceed

This protocol information and documents are entered in the database, protocol folder index, and ends with obsolescence of the documents.

Section 4. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Receipt of submitted research documents for initial review and determination of completeness.	Administrative Secretary	1 day
Step 2: Acceptance & entry into the Protocol Folder Index (Form 4.9) and RMSS DATABASE (Form 4.7) **and Filing Form Log (Form 4.7a).**	Administrative Secretary	2 days post-receipt
Step 3: Coding	Administrative Secretary	
Step 4: Determination of the Type of Review • Exemption from Review (SOP 4) Exemption • Expedited Review (SOP 5) • Full Review (SOP 6)	Chair Member Secretary	3 days post-receipt
Step 5: Preparation of a protocol folder	Administrative Secretary	5 days post receipt
Step 6: Entry into the database RMSS DATABASE (Form 4.7) and the Protocol Folder Index (Form 4.9)	Administrative Secretary	

Section 5. Description of Procedures

Step 1 - Receipt of study documents for initial review and determination of completeness of submission:

The Research Ethics Committee (REC) Secretariat operates under strict institutional hours: Monday through Friday from 8:00 AM to 5:00 PM, and Saturdays from 8:00 AM to 12:00 Noon. The Administrative Secretary is the designated officer authorized to receive all protocol submissions during these windows.

Investigators must submit their complete application dossier in two formats: matching physical hard copies and secure electronic soft copies. The Administrative Secretary shall meticulously audit the submission package against the Application for Ethics Review (Form 4.1) to verify the presence of the following documentation:

Required Principal Investigator (PI) Submission Dossier:

1. Complete Research Proposal: Chapters 1, 2, and 3 (Introduction, Literature Review, and Methodology).
2. Application for Ethics Review Form (Form 4.1).

3. Informed Consent Form (ICF) Template (Form 4.2): Fully integrated within the proposal text or appended explicitly.
4. Proposal Summary Sheet (Form 4.8).
5. Application for Waiver of Informed Consent (Form 4.10): *Required only if the investigator is requesting an exemption from consent protocols.*
6. Curriculum Vitae (CV) of All Authors: Integrated or appended to demonstrate clinical/academic competency.
7. Certificate of Questionnaire Validity: Documented proof of psychometric or instrument validation.
8. Center for Health Research and Innovation (CHRI) Notice to Proceed.

Regulatory Framework for Informed Consent Waivers:

In strict accordance with the PHREB National Ethical Guidelines for Research Involving Human Participants (2022), the requirement for an Informed Consent Process may be waived or altered by the investigator, subject to explicit, prior evaluation and approval by the REC, under the following specific research contexts:

- Archival and Retrospective Research: Studies restricted entirely to secondary data or publicly available documents where tracking down individual participants to secure consent is practically impossible or logistically unfeasible.
- Naturalistic Covert Observation: Research observing public behaviors in natural environments where explicit consent would compromise the validity of the data, provided the investigator satisfies all four of the following criteria:
    1. A rigorous scientific and ethical justification demonstrating that the research cannot be conducted using an overt method.
    2. A comprehensive data-use plan detailing exactly how observed metrics will be processed.
    3. An absolute assurance that the observation presents zero to minimal risk of harm or distress to the observed individuals.
    4. Robust, pre-existing structural mechanisms to guarantee total confidentiality and anonymity (e.g., recording data using unlinked codes so that observed individuals are entirely unidentifiable).
- Comprehensive Waiver/Amendment Criteria: Some or all elements of informed consent may be waived or amended only if the REC confirms that: the research involves no more than minimal risk to participants; the waiver or alteration will not adversely affect the rights and welfare of the participants; and the research could not practicably be carried out without the waiver or alteration.

Actions Arising from Receiving a Protocol:

- Incomplete Submissions: If any required element is missing or improperly executed, the Administrative Secretary will refuse the submission, issue an immediate deficiency notice to the proponent, and detail the exact documents needed for compliance. The Secretariat must verify that Form 4.1 is fully

completed, signed, and dated, and that an official receipt proving payment of the institutional ethics review fee is attached.

- Complete Submissions: If the dossier passes the completeness screening, the Administrative Secretary will formally accept the package, apply an institutional date-and-time received stamp onto the face of Form 4.0, and return a stamped duplicate copy to the PI or the submitting representative as official proof of intake.

Step 2: Acceptance & entry into the Protocol Folder Index (Form 4.9) and RMSS DATABASE (Form 4.7) and Filing Form Log (Form 4.7a).

Once a submission is verified as complete, the Administrative Secretary initiates the onboarding process into the active tracking ecosystem under the guidelines of SOP 23 (Management of Active Files). The Administrative Secretary shall attach a new Protocol Folder Index (Form 4.9) securely onto the inside front cover of a dedicated, color-coded binding folder specific to the tracking track. Concurrently, the secretary will log the complete baseline metrics of the protocol into the digital Research Management Summary Sheet (RMSS) Database (Form 4.7) and Filing Form Log (Form 4.7a).

Step 3 - Coding:

To ensure data tracking and absolute compliance, every accepted submission must be assigned an immutable, unique alpha-numeric Protocol ID Code. This tracking code is unique to the file and cannot be recycled or assigned to another protocol.

Coding Architecture:

The standard structural format follows a clear date-sequence matrix: [Year] - [Month/Day Block Code] - [Chronological Record Number]

- The chronological record number runs in strict succession from 001 to n for the current calendar year.
- *Examples of active sequences:* 2026-502-001, 2026-502-002, up to 2026-502-n.

Expanded Descriptive Nomenclature:

For formal institutional communications, Committee presentations, and tracking, the core protocol code is lengthened to incorporate the principal investigator's surname and the central research keyword to maximize scanning:

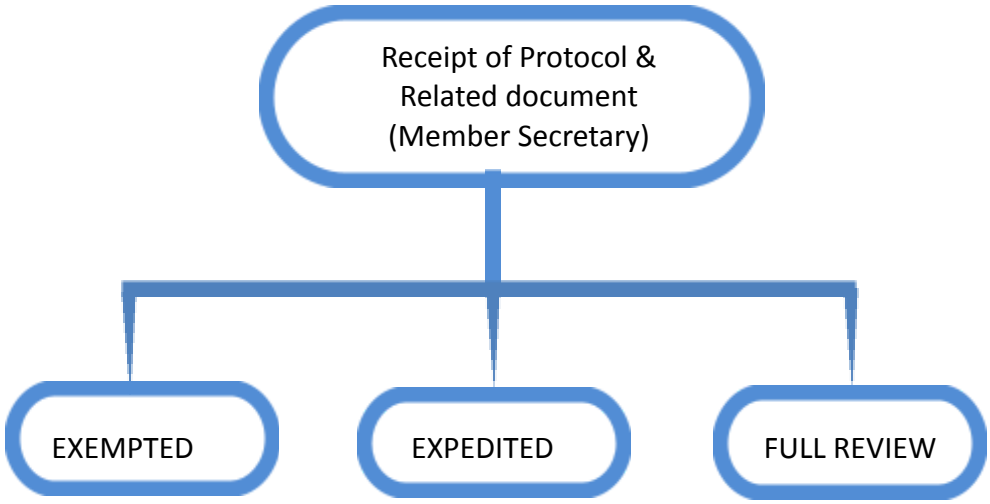
Format Example: REC Code 2026-502-001: Delacruz–HIV

Both the REC office and the Principal Investigator must display this exact Protocol ID Code across all subsequent resubmissions, amendments, clearance letters, and official institutional correspondences.

Step 4: Determination of the Type of Review: Exemption from Review (SOP 4) Exemption, Expedited Review (SOP 5), or Full Review (SOP 6).

Following receipt of a protocol and coding, the Member Secretary performs a primary technical appraisal of the protocol to determine its risk classification. The Member Secretary determines whether the study qualifies for an Exemption from Review, an Expedited Review, or must undergo a Full Committee Review. This assessment is routed to the Chairperson as a formal recommendation. The Chairperson reviews the recommendation and assigns a Primary Reviewer or Independent Consultant matching the study's profile.

The three operational review tracks are strictly governed by the PHREB National Ethical Guidelines for Research Involving Human Participants (2022):



No risk beyond minimal;	Minimal risk protocols;	Vulnerable populations;
Institutional evaluations;	Patient chart reviews;	Vulnerability created;
Publicly available data.	Non-sensitive surveys.	Beyond minimal risk.

Exemption from Ethical Review (SOP 3)

The Chairperson may grant an absolute exemption from further ethical oversight if the study poses no risk beyond minimal human risk, matching the following criteria:

- Protocols designed strictly for institutional quality evaluation, public program assessments, public health surveillance, educational evaluation initiatives, and consumer acceptability metrics.

- Research utilizing survey tools, structured interviews, or public behavioral observations (including audio/video recordings), provided that:
    1. There is no possibility of disclosing participant identities outside the research framework that could expose them to criminal/civil liability, financial loss, employability damage, or reputational ruin.
    2. The data is gathered in a completely anonymized manner, preventing the tracking of identity through direct or linked identifiers.
- Protocols relying exclusively on open-source, de-identified, or publicly available databases.

Administrative Action: If an exemption is officially approved, the Chairperson directs the Administrative Secretary to execute the notification protocol and deliver the formal Certificate of Exemption (Form 4.1) to the investigator.

Expedited Review (SOP 4)

An expedited review track is authorized by the Chairperson for protocols that present no more than minimal risk to human participants. Typical protocols include:

- Standard minimal-risk clinical or behavioral protocols.
- Retrospective patient chart reviews.
- Sociological or epidemiological surveys focusing on non-sensitive, non-stigmatizing subject matter.
- Research utilizing strictly anonymized or unlinked laboratory pathology specimens, archived data sets, or stored biological tissues.

Administrative Action: The Member Secretary takes charge of the protocol file and executes all procedures detailed in SOP 4 (Expedited Review).

Full Committee Review (SOP 5)

A comprehensive Full Committee Review is mandatory whenever one or more of the following risk indicators are identified:

- The human participant pool involves vulnerable populations (e.g., minors, pregnant women, prisoners, indigenous groups, cognitively impaired individuals, or economically/educationally disadvantaged communities).
- Situations where vulnerability is structurally manufactured or exacerbated by the study design itself.
- The protocol involves physical, psychological, legal, or social risks that project clearly beyond minimal risk.

Administrative Action: The Member Secretary immediately flags the study for the next Committee meeting and executes all protocols under SOP 5 (Full Committee Review).

Step 5 - Preparation of a Protocol Folder.

Once the review track is finalized, the Administrative Secretary builds the physical master asset folder for the study. The secretary writes the new Protocol ID Code on the binding spine and attaches the Protocol Folder Index (Form 4.9) directly to the inside front cover.

This tracking sheet serves as the primary ledger for the protocol file; any future post-approval submissions, amendments, annual reports, or adverse events must be recorded on Form 4.9 to ensure a clean internal audit trail.

Step 6: Entry into the database RMSS DATABASE (Form 4.7), Filing Form Log (Form 4.7a), and the Protocol Folder Index (Form 4.9).

The final phase of the initial workflow requires multi-system data entry to prevent data gaps. The Administrative Secretary shall cross-reference and execute simultaneous data entry across three document-control systems:

1. The Protocol Folder Index (Form 4.9): Initialed and updated to reflect the completion of the intake file setup.
2. The Filing Form Log (Form 4.7a): Completed to register the physical placement and folder location within the secure archive room.
3. The RMSS Database (Form 4.7): Updated electronically with all core metrics (PI name, title, date received, assigned tracking code, and review pathway determination) to maintain up-to-date tracking of the committee's active portfolio.

Section 6. Forms:

Form 1.5 - Conflict of Interest Declaration Form
Form 1.6 - Data Privacy
Form 4.0 – Application for an ethics review
Form 4.1 - Exemption
Form 4.2 - Informed Consent Form (incorporated into the Proposal)
Form 4.3 – Notice of Review
Form 4.7 - RMSS DATABASE
Form 4.7a – Filing Form log
Form 4.8 - Proposal Summary Sheet
Form 4.9 - Protocol Folder Index

Section 7. History of SOP

Version No.	***Date***	***Authors***	***Main Change***
1	2024 April 22	NINO ISMAEL S. PASTOR	*First draft*
2	*2024 October 08*	Sonny Redula	Second draft post-WS
3	*2026 June 5*	Nino Ismael Pastor	Form labels, Content

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Gullas College of *Medicine* **RESEARCH ETHICS COMMITTEE**	Version No:	Draft
	Date of Approval:	
	Effectivity Date:	

SOP NO. 8 - MANAGEMENT OF RESUBMISSION

Section 1. Policy Statement

Protocols with minor or major modifications recommended by an initial REC review need to be resubmitted four weeks after receiving a decision letter for the research. The resubmitted protocol must comply with the recommended modifications. Minor modifications will undergo expedited reviews, while major modifications will require a full Committee.

Section 2. Objective of the Activity

The objective of this activity is to control the resubmission application processes and documents to ensure that the researcher addresses the required modifications before approval of the protocol.

Section 3. Scope

This SOP starts with the receipt of a resubmission application and attached documents and ends with the entry of the resubmission documents into the RMS DATABASE and related databases.

Section 4. **Workflow**

ACTIVITY	***RESPONSIBLE PERSONS***	***TIMELINE***
Step 1: Reception and Recording in the Protocol Folder Index (Form 4.9), Filing Form (Form 4.7a), and Form 4.7 (RMSS DATABASE)	Administrative Secretary	1 day
Step 2: Evaluation by the Chair and Notification of Reviewers	Member Secretary Chair	7 days post-receipt
Step 3: Review of the Resubmission • Expedited Review (SOP 4, "Expedited Review") • Full Review (SOP 5 Full Review")	Assigned Reviewers Admin Secretary Member Secretary	1 day 3rd Saturday of the month
Step 4: Communication of Decision. **(See SOP 21– Communicating REC Decisions).**	Secretary	7 days post-meeting

Step 5: Filing of Documents in the Protocol File Index (Form 4.9), update of the Filing Form log (Form 4.7a), and RMSS DATABASE (Form 4.7)	Administrative Secretary	10 days post-meeting
	TOTAL	19 days

Section 4. Description of Procedures

Step 1: Reception and Recording in the Protocol Folder Index (Form 4.9), Filing Form (Form 4.7a), and Form 4.7 (RMSS DATABASE)

The proponent submits a Resubmission form (Form 7.1) along with the pertinent documents to the Administrative Secretary. The Administrative Secretary checks that the resubmission form and pertinent documents are complete. S/he checks the REC Code, records the resubmission in the correct Protocol Folder Index (Form 4.9) of the proposal, and updates the Filing Form (Form 4.7a) and the RMSS DATABASE (Form 4.7). The **Administrative Secretary retrieves** the first Decision Letter (Form 4.6) of the initial protocol and informs the Member Secretary about the resubmission and its nature.

Step 2- Evaluation by the Chair and Notification of Reviewers.

The Member Secretary evaluates the resubmitted documents at his/her level and recommends to the Chair the type of review for the resubmission. The Chair considers the recommendations and, if s/he concurs, asks the Administrative Secretary to contact the Primary Reviewer (for minor revisions) or include the resubmission in the provisional agenda of the next REC meeting (for major revisions).

The reviewer is informed of the resubmission of the minor modifications, and the researcher's response, and given a copy of the documents.

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Step 3: Review of the Resubmission: Expedited Review (SOP 4, "Expedited Review")
Full Review (SOP 5 Full Review").

The assigned reviewers shall review the resubmitted documents, make comments, and record his/her recommendation/comments in the Resubmission Form (Form 4.7a). The report is submitted to the Administrative Secretary, who shall inform the Chair.

If the modification(s) was major, the Administrative Secretary shall inform the Member Secretary to include the resubmission and Forms needed in a full Committee meeting for the next REC meeting. The Member Secretary shall inform the Chair.

Step 4 - Communication of Decision (See SOP 21– Communicating REC Decisions).

If the resubmitted proposal underwent an expedited review, the Chair instructs the Member Secretary to prepare a decision letter (Form 4.6) about the resubmission and sign it.

If the resubmitted proposal was approved through a Full Committee review, refer to SOP 21– Communicating REC Decisions.

Step 5: Filing of Documents in the Protocol File Index (Form 4.9), update of the Filing Form log (Form 4.7a), and RMSS DATABASE (Form 4.7)
All the pertinent documents related to the resubmission (revised protocol, assessment Forms, excerpts of minutes, approval letter,) will be collected by the Admin Secretary and enter the relevant resubmission information in the RMSS (Form 4.7), Filling Form log (Form 4.7a) and update the proposal folder. Form 6.1(Protocol folder Index).

Section 6. Forms:

Form 7.1 – Resubmission
Form 4.9 – Protocol Folder Index
Form 4.4 – REC review checklist
Form 4.7 – RMSS DATABASE
Form 4.6 – Decision Letter Template

Section 7. History of SOP

Version No.	***Date***	***Authors***	***Main Change***
1	*2024 April 28*	*NINO ISMAEL S. PASTOR*	1st draft
2	*2024 October 09*	Sonny Redula	Content, Forms, Form labels
3	*05 June 2026*	Nino Ismael Pastor	Form labels, few content

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

Section 1. Policy Statement

The REC shall require the submission of progress reports at least one month before the study ends or if the level of risk of the study requires it ((PHREB, 2020 PHREB SOP, 2020).

The study will be deemed at risk' if the research:

- is experiencing progress difficulties
- fails to meet agreed research goals
- fails to meet requirements at the first attempt
- fails to submit their research output by the expected submission date or end of the grace period
- caused adverse reactions compromised the safety of the participants (see SOP 11A – Review of RNE Reports; SOP 11B – Review of RSAE & SUSAR Report)

The frequency of progress reports of protocols at risk will be determined by the REC.

Progress will be deemed as unsatisfactory if the proponent:

- fails in their second attempt
- fails for a second time to meet the requirements of any research milestone

In this case, early termination of the research may be necessary to protect the safety of the participants.

Section 2. Objective of the Activity

This procedure describes the Progress Reporting process, which protects the safety and wellness of study participants and Confirms Database that the study is performed in accordance with the approved protocol.

Section 3. Scope

This SOP begins with the acceptance of the progress report, updating the RMSS DATABASE (Form 4.7), Filing form long (Form 4.7a) and ends by updating the protocol folder index (Form 4.9), updating the RMSS DATABASE (Form 4.7), and Filing form long (Form 4.7a).

Section 4. Workflow

ACTIVITY	***RESPONSIBILITY***	***TIMELINE***
Step 1: Receipt and entry of the progress report (Form 8.1) into the protocol folder, updating the protocol folder index, (Form 4.9), Filing Form log (Form 4.7a) and RMSS DATABASE (Form 4.7).	Administrative Secretary	2 days
Step 2: Retrieval of pertinent protocol file	Administrative Secretary	
Step 3: Notification of Chair and Primary Reviewers	Member Secretary Chair	7 days post-receipt
Step 4: Meeting (SOP 17 - Preparing the Meeting Agenda, SOP 4 – Expedited review, SOP 5 – Full Committee Review)	Chair and Primary Reviewers	1 day 3rd Saturday of the month
Step 5: Communication of committee action (Form 4.6 - Decision letter template)	Administrative Secretary Chair	7 days post-meeting
Step 6: Filing the progress report and decision letter (Form 4.6) and updating the protocol database. (Form 6.1) – Protocol Index File; & RMSS DATABASE (Form 4.7)	Administrative Secretary	10 days post-meeting
	TOTAL	20 DAYS

Section 5. Description of Procedures

Step 1: Receipt and entry of the progress report (Form 8.1) into the protocol folder, updating the protocol folder index, (Form 4.9), Filing Form log (Form 4.7a) and RMSS DATABASE (Form 4.7).

To ensure uninterrupted ethical clearance, the Research Ethics Committee (REC) maintains strict monitoring overactive research portfolios.

The Administrative Secretary shall monitor the expiration milestones of all active protocols and formally issue a reminder to the Principal Investigator (PI) exactly one (1) month prior to the scheduled conclusion or annual anniversary of the research. This notification instructs the PI to submit a comprehensive progress report.

Upon submission by the PI, the Administrative Secretary receives the formal Progress Report Form (Form 8.1). The secretary performs an immediate intake audit to ensure the form is fully accomplished, signed, and dated.

Once verified, the Administrative Secretary logs the exact intake metrics across the committee's internal systems to maintain a clean tracking history:

1. The Protocol Folder Index (Form 4.9): The physical log attached to the inside cover of the protocol's master folder is updated with the date of report receipt.
2. The Filing Form Log (Form 4.7a): Document movement is logged to note that the folder is active and undergoing continuing review.
3. The RMSS Database (Form 4.7): The central electronic registry is updated to change the protocol's operational metric flag to "Progress Report Submitted – Under Review."

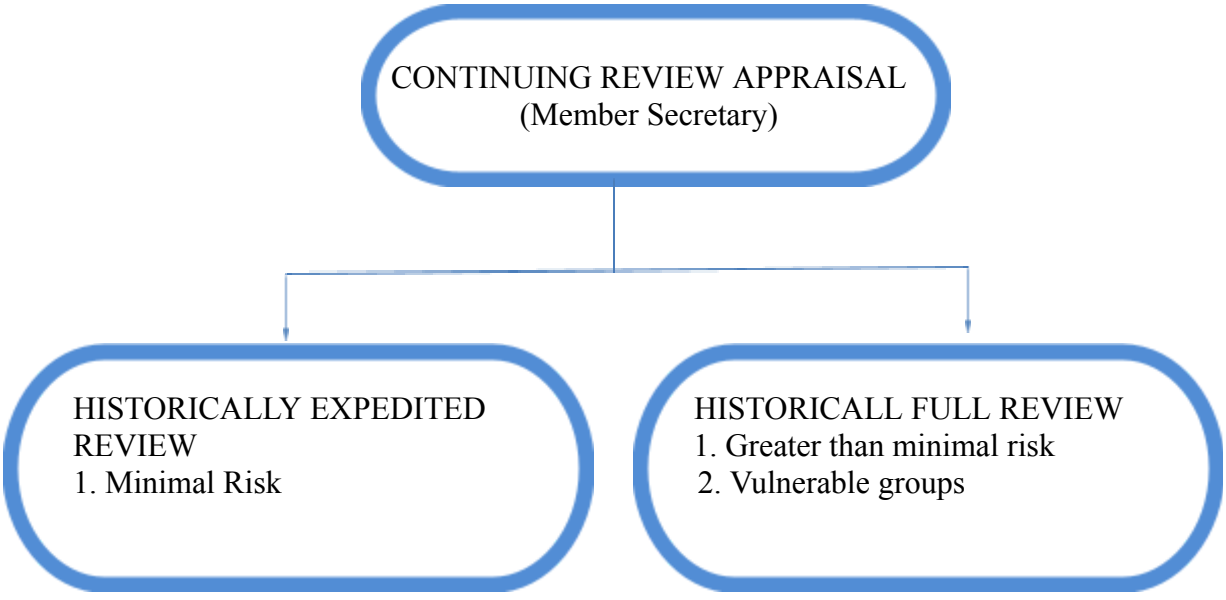
Step 2 - Retrieval of pertinent protocol file:

To facilitate a contextual and accurate review, the Administrative Secretary shall locate and retrieve the physical master protocol file(s) corresponding to the resubmitted progress report from the secure archive repository.

This retrieved historical dossier—which contains the initial proposal, previous decision letters, approved consent forms, and any prior amendments—is compiled alongside the new Form 8.1. The complete reference package is then forwarded directly to the Member Secretary for initial evaluation.

Step 3 - Notification of Chair and Primary Reviewers:

Upon receiving the compiled continuing review packet, the Member Secretary conducts an initial technical appraisal of the progress report. The review track for continuing oversight is strictly determined by the protocol's historical risk classification and approval history:



2. Simple data collection

EXPEDITED CONTINUING REVIEW	FULL COMMITTEE CONTINUING REVIEW
Assigned to a Primary Reviewer via Notice to Review (Form 4.3).	Placed on the Full Committee Agenda for open floor deliberation.

If the protocol was initially approved via the expedited track and maintains a minimal-risk profile with no reported adverse events, it qualifies for an expedited continuing review. If the protocol originally required full Committee oversight, or if the progress report indicates new participant risks, structural deviations, or unresolved ethical issues, it must be routed to the Full Committee.

The Member Secretary must complete the technical evaluation and brief the Chairperson within seven (7) calendar days post-receipt of the progress report. The Chairperson then issues a formal Notice to Review (Form 4.3) to the historically assigned Primary Reviewers, tracking their confirmation and setting the protocol on the committee's operational calendar.

Step 4: Meeting (SOP 17 - Preparing the Meeting Agenda, SOP 4 – Expedited review,
SOP 5 – Full Committee Review)

The evaluation of the progress report is governed by its assigned review track, adhering strictly to SOP 17 (Preparing the Meeting Agenda), SOP 4 (Expedited Review), or SOP 5 (Full Committee Review):

- The Review Process: The assigned Primary Reviewers independently evaluate Form 8.1 against the historical master file to ensure the study is progressing according to the approved ethical parameters. They check for issues such as slow recruitment numbers, unapproved modifications, or newly surfacing participant risks.
- Floor Discussions: The reviewers present their comments, evaluations, and final recommendations during the scheduled monthly REC session. The committee discusses any flagged issues and votes to determine whether to extend the ethical clearance, demand modifications, or suspend the study.
- Minutes & Documentation: The Member Secretary records the floor debates, motions, and official votes to draft the comprehensive Minutes of the Meeting. Under the direct supervision of the Member Secretary, the Administrative Secretary is instructed to draft the corresponding institutional decision letter based on these finalized minutes.

Step 5: Communication of committee action (Form 4.6 - Decision letter template)

Following the closure of the review session and the validation of the minutes, the Administrative Secretary transposes the committee's final determination into the official Decision Letter (Form 4.6). The completed draft is routed directly to the Chairperson for review and signature.

The Chairperson evaluates the drafted text against the finalized meeting minutes. Upon verification, the Chairperson signs the document to formalize the committee's action (e.g., Continuing Approval Granted, Revisions Required, or Study Suspended).
The REC office must ensure that the signed Decision Letter is formally dispatched and delivered to the Principal Investigator within a strict deadline of seven (7) calendar days post-meeting.

Step 6: Filing the progress report and decision letter (Form 4.6) and updating the protocol database. (Form 6.1) – Protocol Index File; & RMSS DATABASE (Form 4.7)

To maintain a clean institutional audit trail and satisfy national regulatory standards, all physical and digital records generated during this continuing review cycle must be systematically archived.

The Administrative Secretary gathers the executed Progress Report (Form 8.1), the completed reviewer checklists, relevant excerpts of the meeting minutes, and a copy of the signed final Decision Letter (Form 4.6) and integrates them securely into the protocol's physical master folder.

The Administrative Secretary will perform the following final document control updates to close out the transaction cycle:

1. The Protocol Folder Index (Form 4.9): The physical ledger bound to the inside cover of the master folder is updated to log the receipt of the progress report and the date the corresponding decision letter was issued.
2. The Filing Form Log (Form 4.7a): Updated to confirm the physical return and storage location of the master folder within the secure archive room.
3. The RMSS Database (Form 4.7): The central digital database is synchronized in real time, changing the protocol's status line from "Under Review" to "Approved & Active" (with the new ethical clearance extension date recorded) or "Terminated/Closed" depending on the final action of the Committee.

Section 6. Forms

Form 4.3 - Notice to Review
Form 4.6 - Decision letter
Form 4.7 - RMSS DATABASE
Form 4.7a – Filing Form log
Form 4.9 - Protocol Folder index
form 8.1- Progress Report Form

Section 7. History

Version No.	***Date***	***Authors***	***Main Change***
1	5.2.2024	Nino Ismael S. Pastor	1st DRAFT
2	10.10.24	Nino Ismael S. Pastor	Content, Form Labels
3	06.05.26	Nino Ismael S. Pastor	Content, Form Labels

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

SOP NO. 10 - REVIEW OF AMENDMENTS

Section 1. Policy Statement

The REC must approve changes in the protocol procedures, titles, forms, and materials of an approved proposal from the proponent.

Section 2. Objective of the Activity

The purpose of this SOP is to describe REC review procedures of amendments to ensure that such amendments do not impact on the safety and welfare of the participants.

Section 3. Scope

This SOP begins with the receipt of an application for amendments and ends with its entry to the RMSS DATABASE (Form 4.7), Filing Form log (Form 4.7a), and Protocol Folder Index (Form 4.9).

Section 4. Workflow

ACTIVITY	**RESPONSIBILITY**	**TIMELINE**
Step 1: Receipt and evaluation of the Amendment form (Form 10.1 - Amendment Form). Entry Form 10.1 to the Protocol Folder Index (Form 4.9), RMSS (Form 4.7) and Filing Folder Log (Form 4.7a)	Administrative Secretary	1 day
Step 2: Retrieval of pertinent protocol file	Administrative Secretary	
Step 3: Notification of Chair and Primary Reviewer (Form 4.3, Notice of Review)	Administrative Secretary Member Secretary Chair Reviewers	7 days post-receipt
Step 4: Review of amendments & determination of the need and type of review: expedited (SOP 4 on Expedited Review) or full review (SOP 5 on Full Review)	Chair and Primary Reviewer	10 days post-receipt

Step 5: Discuss in the REC meeting	Chair and Primary Reviewer	1 day every 3rd Saturday of month
Step 6: Communication of committee action (Form 4.6 - Decision Letter Template)	Member Secretary Administrative Secretary	7 days post-meeting
Step 7: Filing of Amendments and decision letter in the correct protocol folder and updating the RMSS database (Form 4.7), Filing Form log (Formk4.7a), and the Protocol Folder Index (Form 4.9).	Administrative Secretary	
	TOTAL	19 days

Section 5. Description of Procedures

Step 1: Receipt and evaluation of the Amendment form (Form 10.1 - Amendment Form). Entry Form 10.1 to the Protocol Folder Index (Form 4.9), RMSS (Form 4.7) and Filing Folder Log (Form 4.7a)

The amendment lifecycle is initiated when a Principal Investigator (PI) seeks to modify an already approved research protocol. The investigator must accomplish and submit the formal **Protocol Amendment Form (Form 10.1)** alongside all modified study components (such as revised protocols, updated informed consent scripts, or newly translated recruitment ads).

The Administrative Secretary serves as the primary receiving officer and must immediately perform a completeness screening on the submitted packet. S/he notes the following items**:**

- **The Completeness Audit:** The Administrative Secretary verifies that all sections of Form 10.1 are completely filled out, signed, and dated, and that all modified documents are attached with changes clearly marked (e.g., via track changes or a side-by-side comparison matrix).
- **Deficiency Routing:** If the submission package is missing crucial components or lacks clear justification, the Administrative Secretary will reject the application at the desk and return it to the PI with an itemized deficiency notice.

Step 2 - Retrieval of pertinent protocol file:

Once the amendment application passes the initial completeness screening, the Administrative Secretary formally accepts the dossier. The secretary locates the study's physical master folder within the secure archive repository and begins integrating the new paperwork into the active document-control tracking system under **SOP 23 - Management of Active Files)**. S/he update**s the following:**

1. **The Protocol Folder Index (Form 4.9):** The physical ledger bound to the inside cover of the master folder is updated to log the receipt and description of the modification request.
2. **The Filing Form Log (Form 4.7a):** Document movement is recorded to flag that the file has been pulled from deep storage and is actively under review.
3. **The RMSS Database (Form 4.7):** The central electronic database is synchronized in real time, shifting the protocol's active status flag to "Amendment Submitted – Pending Review."

The Administrative Secretary withdraws the historical approval documents and previous versions of the protocol from the folder, attaches the new Amendment Form (Form 10.1) securely to the top of the history stack, and passes the compiled reference package to the Member Secretary.

Step 3 - Notification of Chair and Primary Reviewer (Form 4.3, Notice of Review).

The Member Secretary reviews the compiled amendment dossier to assess its operational background. Within a strict deadline of **seven (7) calendar days post-receipt** of the submission, the Member Secretary briefs the Chairperson and the historically assigned Primary Reviewer(s) regarding the scope of the requested modifications.

The Administrative Secretary then generates and dispatches a formal **Notice to Review (Form 4.3)** along with the amendment dossier to the assigned primary evaluators to initiate the technical assessment phase.

Step 4: Review of amendments & determination of the need and type of review: expedited (SOP 4 on Expedited Review) or full review (SOP 5 on Full Review)

The Primary Reviewer independently evaluates the modifications to determine if they alter the study's overall risk-benefit ratio. The reviewer routes a technical review track recommendation to the Chairperson, who exercises final authority over the review pathway.

Modifications that do not impact participant safety, study design, or data integrity (e.g., minor typographic corrections, administrative contact detail changes, personnel updates or basic logistical updates) are routed via the expedited path. The Primary Reviewer evaluates the file independently under **SOP 4 (Expedited Review)** and returns their final decision directly to the Chair.

Modifications that materially change the protocol's core methodology, title changes, introduce new safety risks, or alter participant interactions must undergo full Committee re-evaluation under **SOP 5 (Full Committee Review)**.

The Chairperson signs off on the final tracking track and instructs the Administrative Secretary to either process the expedited approval papers or calendar the protocol for the next general Committee session.

Step 5. **Discuss in the REC meeting.**

If an amendment is classified as a major modification, it must be placed on the agenda of the next regular REC session for open floor debate.

In compliance with the **PHREB National Ethical Guidelines (2022)**, modifications that trigger a mandatory Full Committee Review include, but are not limited to:

- Material changes to the core study design, statistical frameworks, or research objectives.
- Title changes after REC approval
- The introduction of new or increased physical, social, or psychological risks to participants.
- Changes in drug choices, dosages, administration routes, or clinical interventions.
- Any modifications to the pre-approved participant inclusion or exclusion criteria.
- The introduction of new vulnerable populations into an active study that is classified as greater than minimal risk.
- *Contextual/Borderline Cases:* Depending on their complexity and impact on participant welfare, items such as localized translations of approved consent forms, changes to recruitment methods, the removal or transfer of study sites, clarifications of study procedures, or the enrollment of a single participant under a sponsor-approved eligibility variance may also be flagged by the Chair for full Committee discussion.

Following formal floor deliberations and a collective vote, the committee will issue one of four explicit determinations:

1. **Approved:** The amendment is cleared as written and updated ethical clearance parameters are established.
2. **Additional Justification/Information Required:** The amendment is deferred until the PI provides satisfactory written clarifications or data to justify the structural changes.
3. **Re-consent Required:** The amendment is approved conditional upon the requirement that all currently enrolled participants are re-consented using an updated, approved Informed Consent Form reflecting the new modifications.
4. **Disapproved:** The amendment is rejected due to safety concerns or structural flaws. The investigator must continue using the previously approved version of the protocol.

Step 6: Communication of committee action (Form 4.6 - Decision Letter Template)

Following the review (either via the expedited track or after the validation of the Full Committee meeting minutes), the Member Secretary drafts the formal institutional notification using the **Decision Letter Template (Form 4.6)**. The draft must reflect the precise conclusions, conditions, or mandates issued by the committee.

The completed letter is routed to the Chairperson for final review and signature. The Chairperson signs the Decision Letter, explicitly checking the box corresponding to the Committee's action: **Approved**, **Additional Justification Required**, **Re-consent Required**, or **Disapproved**. The REC office must ensure this official signed notification is dispatched and delivered to the Principal Investigator within **seven (7) calendar days following the committee session**.

Step 7: Filing of Amendments and decision letter in the correct protocol folder and updating the RMSS database (Form 4.7), Filing Form log (Formk4.7a), and the Protocol Folder Index (Form 4.9).

To satisfy regulatory audits and preserve a flawless institutional history, all physical and digital materials generated during the amendment lifecycle must be systematically archived.

The Administrative Secretary retrieves all deployed review sets and integrates the executed Amendment Form (Form 10.1), completed reviewer checklists, relevant meeting minutes excerpts, and a copy of the final signed Decision Letter (Form 4.6) into the protocol's physical master folder.

The Administrative Secretary will execute the following document control updates to finalize the transaction cycle:

1. **The Protocol Folder Index (Form 4.9):** The physical ledger bound to the inside cover of the master folder is meticulously updated to record the exact date of final amendment action and the document version changes.
2. **The Filing Form Log (Form 4.7a):** Updated to confirm the secure return and filing location of the updated folder within the active archive repository.
3. **The RMSS Database (Form 4.7):** The central electronic database is updated in real time, shifting the status from "Pending Review" back to "Approved & Active," while appending an administrative suffix to the database line to track the newly approved protocol version number.

Section 6. Forms

Form 10.1 – Amendment Form
Form 4.9 – Protocol Folder Index
Form 4.7 – RMSS Database
Form 4.6 - Decision letter
Form 4.3 - Notice to Review

Section 7. History

Version No.	***Date***	***Authors***	***Main Change***
1	5.2.24	NINO ISMAEL S. PASTOR	*Draft*
2	10.11.24	Maricar Canonigo	Contents, Form labels
3			

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Gullas College of *Medicine* **RESEARCH ETHICS COMMITTEE**	Ethos Universitas HONORARY COMPANION	Version No:	Draft
		Date of Approval:	
		Effectivity Date:	

SOP NO. 11 - REVIEW OF PROTOCOL NONCOMPLIANCE/DEVIATION/ VIOLATION

Section 1. Policy Statement

Researchers are to take special extra precautions to avoid deviating from approved research.
The REC requires researchers to report protocol deviations within a week of detecting the protocol violation/deviation. Major protocol violations undergo a full review.

Section 2. Objective(s)

This SOP explains how the REC will manage noncompliance, violations or deviations in previously approved protocols. This is to safeguard the safety and welfare of human study participants and maintain the credibility the REC and integrity of data.

Section 3. Scope

This SOP begins with the receipt and documentation of the report of protocol violations and deviations in the Protocol Folder Index (Form 6.1). It ends with the filing of all related documents in the correct protocol folder and updating them in the RMSS Database (Form 4.7).

Section 4. Workflow

ACTIVITY	**RESPONSIBILITY**	**TIMELINE**
Step 1: Delivery, Receipt, and documentation of report of protocol noncompliance, violations and deviations in the Protocol Folder Index (Form 4.9)	Administrative Secretary	1 day
Step 2: Recovery of appropriate protocol file	Administrative Secretary	
Step 3: Notice to Chair and primary reviewers (Form 4.3 - Notice of Review).	Member Secretary	3 days post-receipt
Step 4: Determination of the type of review: expedited Review (SOP 4), full review (SOP 5)	Primary Reviewer Chair	10 days post-receipt
Step 5: Including the report in the next regular REC meeting (SOP 17 – Preparing the Meeting Agenda	Member Secretary	

Step 6: Communication of decision to the Principal Investigator/researcher (Form 4.6 – Decision Letter)	Member Secretary and Chair	7 days post REC meeting
Step 7: Filing of all related documents into the correct protocol folder and update the Protocol Folder Index (Form 4.9), Filing Form log (Form 4.7a), and RMSS Database (Form 4.7)	Administrative Secretary	
	TOTAL	21 days

Section 5. Description of Procedures

Step 1: Delivery, Receipt, and documentation of report of protocol noncompliance, violations and deviations (Form 10.1 – Deviation or violation form) in the Protocol Folder Index (Form 4.9)

The proponent, stakeholder, or participant formally submits Form 11.1 (Protocol Noncompliance, Deviation, or Violation Form) to the Administrative Secretariat. Upon receipt, the Administrative Secretary is responsible for immediately logging the submission into the Research Management Support System (RMSS) Database (Form 4.7) and documenting it in the Filing Form Log (Form 4.7a). To ensure complete traceability, the Administrative Secretary must also update the Protocol Folder Index (Form 4.9) corresponding to that specific protocol, noting the addition of Form 10.1 (Deviation or Violation Form) to the dossier.

Step 2: Recovery of appropriate protocol file

To facilitate the upcoming review, the Administrative Secretary locates and retrieves the officially approved protocol file along with all relevant historical and supporting documents from the archives. During this retrieval process, the Administrative Secretary cross-checks the file to identify the originally assigned primary reviewers. This information is compiled and presented as a reference to guide the Member Secretary and the Chair in determining the most appropriate personnel for the current review.

Step 3: Notice to Chair and primary reviewers (Form 4.3 – Notice of Review).

- The Member Secretary reviews the retrieved pertinent documents and formally refers the protocol noncompliance, deviation, or violation report to the Chair. Following an initial assessment, the Chair signs and issues a formal **Notice of Review (Form 4.3)**. This notice, along with the complete dossier of retrieved materials, is then officially dispatched to the designated primary reviewer(s) to initiate the evaluation process.

Step 4: **Determination of the type of review: expedited (SOP 4), full review (SOP 5):**

Based on the severity and risk level of the reported noncompliance, violation, or deviation, the Chair, in consultation with the primary reviewers, determines the appropriate review pathway. The protocol will either be routed for an **Expedited Review (pursuant to SOP 5)** or a **Full Committee Review (pursuant to SOP 6)**. Once the

pathway is established, the assigned primary reviewer(s) thoroughly evaluate the submission and synthesize their findings into a formal evaluation report, which will be slated for discussion during the subsequent Research Ethics Committee (REC) session.

Step 5: Including the report in the next regular REC meeting (SOP 17 – Preparing the Meeting Agenda.

Following the completion of the initial evaluation, the Chair instructs the Member Secretary to integrate the matter into the agenda of the next regular REC meeting, adhering to **SOP 17 (Preparing the Meeting Agenda)**. The Member Secretary drafts the meeting agenda, ensuring that full-review cases are listed as standard agenda items, while expedited cases are included via the primary reviewer's finalized decision report. During the session, the Member Secretary is responsible for recording detailed minutes, specifically capturing the committee's deliberations, official consensus, or final decision regarding the report.

Step 6: Communication of decision to the Principal Investigator/researcher (Form 4.6 – Decision Letter).

Based on the approved minutes of a Full Committee Review or the signed report from an Expedited Review, the Member Secretary drafts a formal **Decision Letter (Form 4.6)** addressed to the Principal Investigator or researcher. Depending on the committee's findings, the official directive may encompass one or a combination of the following actions:

1. A mandate for the submission of additional clarifying information.
2. A requirement to submit a formal Corrective and Preventive Action (CAPA) plan.
3. An invitation to attend a clarificatory interview with the committee.
4. A requirement to submit an official protocol amendment.
5. The scheduling of an unscheduled institutional site visit.
6. The immediate suspension of participant recruitment.
7. The formal withdrawal of the protocol's ethical clearance.

Once signed, the Administrative Secretary transmits the final Decision Letter to the proponent or stakeholder and collects all relevant correspondence for institutional tracking.

Step 7: Filing of all related documents back to the correct protocol folder and update of the protocol database (Form 4.7 – RMSS Database), Filing Form Log (Form 4.7a) and the Protocol Folder Index (Form 4.9)

Upon the conclusion of the review cycle, the Administrative Secretary collects all generated paperwork—including the initial deviation/violation report, primary reviewer evaluations, meeting minutes, and the issued **Decision Letter (Form 4.6)**. These documents are securely filed back into their correct physical or digital protocol folder. Finally, the Administrative Secretary executes a comprehensive system update across all

tracking platforms, finalizing entries in the **RMSS Database (Form 4.7)**, the **Filing Form Log (Form 4.7a)**, and the **Protocol Folder Index (Form 4.9 / Form 6.1)** to ensure the protocol's administrative lifecycle is accurately closed.

Section 6. Forms

Form 4.3 - Notice to Review
Form 4.6 – Decision Letter
Form 4.7 – RMSS Database
Form 4.7a – Filing Form log
Form 4.9 - Protocol Folder Index
Form 11.1 – Deviation or violation form

Section 7. History

Version No.	***Date***	***Authors***	***Main Change***
1	05/03/2024	*NINO ISMAEL S. PASTOR*	*First draft*
2	10/11/2024	Dr. Rosemarie Camille Cunanan	Contents, form labels
3	06/05/26	Nino Ismael Pastor	Form labels, few content

Section 8. References

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SOP NO. 11A - REVIEW OF REPORTABLE NEGATIVE EVENTS (RNE) REPORT

Section 1. Policy Statement

A Report of a negative event (RNE) is a formal, mandatory report submitted by a Principal Investigator (PI) to a Research Ethics Committee (REC) of the GCM, detailing any unexpected, untoward, or harmful incident that occurred during the conduct of a research study. The GCM REC requires the submission of an RNE not later than three (3) days after it has come to the attention of the PI. The REC shall conduct an emergency meeting based on the harm or risk it involved.

Section 2. Objective of the Activity

RNE reviews are performed to protect the safety and welfare of human participants, safeguard and promote the integrity of the research team. and to document accurately the RNE.

Section 3. Scope

This SOP begins with the receipt of submission of an RNE report, and documentation in the Protocol Folder Index (Form 6.1) of the proposal and ends in the filing of all related documents into the protocol folder index (Form 6.1) and the RMSS DATABASE (For 4.7).

Section 4. Workflow

ACTIVITY	**RESPONSIBILITY**	**TIMELINE**
Step 1: Receipt of an RNE report (Form 11A.1) and documentation of submission of the RNE report in the protocol folder index (Form 6.1), Filing Form (Form 4.7a), and the (Form 4.7) RMS DATABASE.	Administrative Secretary	1 day
Step 2: Retrieval of pertinent protocol file	Administrative Secretary	
Step 3: Notification of Chair	Member Secretary	3 days post-receipt
Step 4: Call for a Special Meeting	Chair	
Step 5: Deliberation on the RNE	REC members	1-day emergency meeting

Step 6: Communication (Form 4.6, Decision Letter), of REC action (SOP 21- Communication of REC Decisions) to the PI/researcher, sponsor, and/or to the Institutional authority.	Member Secretary Chair	7 days post-meeting
Step 7: Filing of all related documents (SOP 23 - Management of Active Files) and updating of the Protocol Index Folder (Form 4.9), Filing Form log (Form 4.7a) RMS database (Form 4.7)	Administrative Secretary	10 days post-meeting
	TOTAL	

Sept 5. Description

Step 1: Receipt of an RNE report (Form 11A.1) and documentation of submission of the RNE report in the protocol folder index (Form 6.1), Filing Form (Form 4.7a), and the (Form 4.7) RMS DATABASE.

The Principal Investigator (PI) or authorized research representative submits the accomplished **Form 11A.1 (Report of a Reported Negative Event [RNE])** to the Research Ethics Committee (REC) Secretariat. Upon delivery, the Administrative Secretary formally receives the document and conducts an immediate compliance check regarding submission timelines.

The Administrative Secretary cross-references the date of the negative event against the date of submission to verify compliance with the mandatory **three-day (3-day) institutional cut-off period**. If the report is submitted beyond this strict window, the Administrative Secretary flags the noncompliance and formally escalates the delay to the Member Secretary for tracking and potential disciplinary action.

To maintain absolute traceability, the Administrative Secretary logs the submission across all official tracking platforms by:

1. Entering the receipt details into the **Research Management Support System (RMSS) Database (Form 4.7)**.
2. Registering the entry in the **REC Filing Form Log (Form 4.7a)**.
3. Updating the physical and digital **Protocol Folder Index (Form 6.1)** allocated to that specific research study.

Step 2: Retrieval of pertinent protocol file

Following database documentation, the Administrative Secretary extracts the complete historical archive of the approved protocol from the secure repository. This step requires compiling the primary protocol, previous amendments, safety logs, and participant consent templates. Concurrently, the Administrative Secretary reviews past committee minutes to identify the originally assigned primary reviewers for this specific protocol. Once the complete dossier is assembled and the primary reviewers are identified, the materials are formally turned over to the Member Secretary to facilitate an expedited preliminary risk assessment.

Step 3: Notification of Chair

The Member Secretary conducts an immediate review of the RNE report along with the retrieved protocol history to evaluate the severity of the event and its impact on participant safety. The Member Secretary then formally briefs the REC Chair regarding the critical nature of the situation. Based on the perceived level of risk, vulnerability of participants, or systemic implications of the reported negative event, the Member Secretary provides a recommendation to the Chair regarding whether the gravity of the RNE warrants the invocation of an extraordinary emergency session.

Step 4: Call for a Special Meeting

Upon evaluating the brief, the REC Chair officially directs the Member Secretary to convoke a Special Emergency Meeting. The Member Secretary constructs the formal session agenda using **Form 18.1 (Meeting Agenda Template)**, explicitly placing the critical RNE review at the forefront of business. This drafted agenda is routed to the Chair for final approval and signature.

Depending on the context of the event, the Member Secretary, under the guidance of the Chair, issues formal invitations to the Principal Investigator, core research team members, institutional experts, or relevant community stakeholders, requiring them to attend the initial phase of the session to provide eyewitness testimonies, technical clarifications, or context-specific data.

Step 5: Deliberation on the RNE

The special emergency meeting is called to order by the Chair, requiring a designated quorum of REC members. The session proceeds via a strictly structured dual-phase adjudication process:

- **Phase I: Fact-Finding and Hearing:** The Chair presents a comprehensive summary of the RNE report. The committee then interviews the invited PI, research team, or stakeholders. The collective body thoroughly evaluates the specific negative event(s) affecting the participants or research staff, evaluates the immediate effectiveness of any mitigating interventions deployed by the study team, analyzes the depth of community assistance required, and assesses the overall structural impact of the event on the integrity of the research.
- **Phase II: Executive Session and Voting:** Following the fact-finding phase, the Chair officially excuses the PI, research team, and external stakeholders from the room. The REC members enter a closed executive session to deliberate on the ethical and safety implications. The committee must vote to execute one or a combination of the following regulatory actions:
    - Recommend the immediate suspension of all study procedures until the negative event is thoroughly resolved or mitigated.
    - Issue a total withdrawal of ethical clearance, effectively terminating the research study.

- Mandate the immediate submission of a comprehensive Corrective and Preventive Action (CAPA) plan to mitigate future risk or harm.
- Require a mandatory, formal amendment to the protocol design, inclusion criteria, or informed consent documents.
- Uphold the original ethical clearance without modifications, provided the risk has been successfully neutralized.

The Member Secretary carefully records the official minutes of the session, capturing the rationale behind the votes and the definitive decision. Immediately following adjournment, the Member Secretary drafts a formal **Decision Letter (Form 4.6)** reflecting the committee's mandates and submits it to the Chair for final sign-off.

Step 6: Communication of REC action to the PI/researcher, sponsor, (Form 4.6, Decision Letter Template), (See SOP 21-Communication of REC Decisions), and/or to the Institutional authority.

Once the **Decision Letter (Form 4.6)** is scrutinized and signed by the REC Chair, the Member Secretary coordinates its immediate dissemination in strict compliance with **SOP 21 (Communication of REC Decisions)**. The Member Secretary ensures that certified copies of the official directives are securely dispatched to the Principal Investigator, the funding sponsor, and, if required by institutional risk guidelines, escalated directly to the Vice top-tier Institutional Authority or regulatory bodies overseeing research compliance.

Step 7: Filing of all related documents (SOP 23, Management of Active Files) and Update of the protocol folder index (Form 6.1) and the RMSS DATABASE (Form 4.7).

Following the dispatch of the regulatory mandates, the Administrative Secretary re-collects all physical and digital documentation generated throughout this emergency review cycle—including the initial RNE report (Form 11A.1), primary reviewer notes, signed emergency meeting minutes, and the issued Decision Letter (Form 4.6). Adhering to the administrative standards outlined in **SOP 23 (Management of Active Files)**, the Administrative Secretary permanently archives these files within the master protocol folder and synchronizes the records across all tracking platforms by executing final updates in the **Protocol Folder Index (Form 4.9)**, the **REC Filing Form Log (Form 4.7a)**, and the main **RMSS Database (Form 4.7)**.

Section 6. Forms

Form 4.6 – Decision letter
Form 4.7 – RMSS database
Form 4.7a – Filing form Log
Form 4.9 – Protocol Folder Index
Form 11A.1 Report of RNE

Section 7. History of SOP

Version No.	***Date***	***Authors***	***Main Change***
1	6.27.24	NINO ISMAEL S. PASTOR	DRAFT
2	10.15.24	Ronald Catacte	Form labels contents
3	06.05.26	NINO ISMAEL S. PASTOR	Form labels, few content

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Gullas College of *Medicine* **RESEARCH ETHICS COMMITTEE** Ethos Universitas HONORARY COMPANION		Version No:	Draft
		Date of Approval:	
		Effectivity Date:	

SOP NO. 11B - REVIEW OF SERIOUS ADVERSE EVENTS

Section 1. Policy Statement

Approved Clinical trials may cause serious risks or hazards to human participants. The investigator must exert effort to monitor these suspected or unsuspected adverse reactions. Sponsors of these approved clinical trials must also cooperate with the investigator(s) to minimize or prevent these risks or hazards.

The REC shall require submitting PI/Sponsors to report Serious Adverse Events (SAEs) and Suspected, Unexpected, Serious Adverse Reactions (SUSARs) within 7 days after the event has come to the researcher's attention. The Primary reviewer will evaluate these events whose recommendation(s) shall be submitted to the REC for deliberation and final action.

Section 2. Objective of the Activity

Reviewing SAE's and SUSARs are done to safeguard human participants' safety and welfare by properly documenting, monitoring and evaluating SARs and SUSARs and recommending how to mitigate them.

Section 3. Scope

This SOP begins with the receipt of report of SAEs and SUSARs, and documentation in the protocol folder index (Form 6.1). It ends with the filing of all related documents and update of the protocol database (Form 4.7 – RMSS database).

Section 4. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1 - Receipt of submission of the report of SAEs and SUSARs (Form 11B.1) in the logbook .	Administrative Secretary	1 day
Step 2: Retrieval of pertinent protocol file	Administrative Secretary	
Step 3: Notification of Chair	Member Secretary Chair	
Step 4: Review of the SAE or SUSAR report	Primary Reviewer	3 days post-receipt

Step 5: Inclusion of report in the provisional agenda of the special REC meeting	Member Secretary Chair	
Step 6: Deliberations during the special meeting	Chair REC members	1-day special meeting
Step 7: Communication of REC action to the Principal Investigator/researcher (See SOP 21– Communicating REC Decision)	Member Secretary Chair	7 days post-meeting
Step 8: Filing of all related documents (See SOP 23 - Management of Active Files) and update the RMSS database (Form 4.7), Filing form Log (Form 4.7a), and the Protocol Folder Index (Form 4.9).	Administrative Secretary	10 days post-meeting
	TOTAL	**22 days**

Section 5. Description of Procedures

Step 1 - Receipt of submission of the report of SAEs and SUSARs (Form 11B.1) in the logbook.

The Principal Investigator (PI) or clinical research team formally submits the accomplished **Form 11B.1 (Serious Adverse Event [SAE] / Suspected Unexpected Serious Adverse Reaction [SUSAR] Report Form)** to the Research Ethics Committee (REC) Secretariat. Upon arrival, the Administrative Secretary executes an immediate regulatory timeline audit:

- The Administrative Secretary cross-references the date of the investigator's initial awareness of the SAE/SUSAR against the exact date of receipt to determine compliance with the mandatory **seven-day (7-day) institutional reporting threshold**. The Administrative Secretary flags the submission's chronological compliance status and immediately briefs the Member Secretary regarding whether the report was received early, exactly within, or past the critical 7-day cut-off window.
- To establish an uncompromised audit trail, the Administrative Secretary officially logs the transaction across the following data-management systems:
    1. Enters the submission metadata into the **Research Management Support System (RMSS) Database (Form 4.7)**.
    2. Logs the document transfer in the **REC Filing Form Log (Form 4.7a)**.
    3. Formally updates the **Protocol Folder Index (Form 4.9)** designated for that specific research protocol.

Step 2 - Retrieval of pertinent protocol file:

Following initial system logging, the Administrative Secretary accesses the secure archives to retrieve the master protocol folder and all matching historical records for the study in question. This comprehensive dossier must include the primary approved protocol, recent investigator brochures, participant safety logs, and informed consent forms. Concurrently, the Administrative Secretary identifies the original primary

reviewers assigned to this protocol. The entire unified dossier, along with the newly received **Form 11B.1**, is then formally transmitted to the Member Secretary to undergo an immediate administrative screening.

Step 3 - Notification of Chair:

Upon reviewing the assembled safety dossier, the Member Secretary immediately escalates the SAE/SUSAR alert to the REC Chair using a multi-channel communication approach (including secure institutional email, telephonic voice calls, and SMS text notifications) to ensure prompt awareness. The Member Secretary forwards the electronic copy of the dossier to the Chair.

Upon evaluating the preliminary risk, the Chair issues a double directive to the Member Secretary:

1. Formally contact the designated primary reviewer(s) and securely dispatch the complete SAE/SUSAR report and historical dossier for urgent assessment.
2. Convoke a **Special Emergency REC Meeting**, which must be scheduled and executed strictly within **three (3) calendar days** from the initial institutional receipt of the safety report.

Step 4 – Review of the SAE/SUSAR report:

The assigned primary reviewer(s) execute an expedited, rigorous scientific and ethical evaluation of the reported event. The reviewer analyzes the event against the historical safety data of the investigational product, evaluating the causality, severity, and overall threat profile posed to the ongoing safety of human participants. Following this independent evaluation, the primary reviewer details their clinical-ethical findings by completing **Form 11B.2 (SAE/SUSAR Assessment Report)** and signs off before returning the document to the Member Secretary for committee integration

Step 5. Inclusion of report in the provisional agenda of the special REC meeting Call for a special meeting:

Upon receiving the primary reviewer's assessment, the Member Secretary integrates the critical safety review into the institutional agenda. Adhering strictly to the guidelines defined in **SOP 17 (Preparing the Meeting Agenda)**, the Member Secretary drafts a provisional agenda dedicated to this extraordinary Full Committee session. This agenda is presented to the REC Chair for official authorization and signature. Once signed, the Member Secretary distributes the authorized meeting agenda, along with copies of **Form 11B.1** and the reviewer's **Form 11B.2**, to all standing REC Committee members to facilitate pre-meeting brief reviews.

Step 6 – Deliberations during the special REC meeting:

The REC Committee convenes the Special Meeting under a strict quorum. The Chair introduces the case, and the Committee enters intense deliberations, closely scrutinizing

the primary reviewer's **SAE/SUSAR Assessment Report (Form 11B.2)**. The committee systematically evaluates whether the event alters the risk-benefit ratio of the study and votes to implement an official regulatory action. The final Committee directive may include, but is not limited to, the following outcomes:

- **No Further Action Required:** The safety event is deemed expected, successfully mitigated, or unlinked to the intervention.
- **Continuous Monitoring:** The study remains active but requires localized oversight and heightened safety reporting.
- **Mandate a Site Visit:** The Committee orders an unscheduled post-approval monitoring site visit to audit compliance on-site.
- **Information/Action Required:** The Committee requests additional laboratory metrics, investigator clarifications, or a formal revision of the Informed Consent Form (ICF).
- **Suspension of Recruitment:** Active participant enrollment is frozen immediately pending further safety investigations, though currently enrolled participants may continue treatment if safe.
- **Termination of the Study:** Complete and immediate withdrawal of ethical clearance, bringing all research activities to a permanent halt due to unmitigated safety hazards.

Following the final vote, the Member Secretary records the detailed minutes of the session and synthesizes the final Committee consensus into a comprehensive draft of the **Decision Letter (Form 4.6)**.

Step 7: Communication of REC action to the Principal Investigator/researcher (See SOP 21– Communicating REC Decision).

The Member Secretary finalizes the **Decision Letter (Form 4.6)**, ensuring it contains explicit legal, ethical, and procedural mandates reflecting the committee's decision. The finalized letter is routed to the REC Chair for review, validation, and official signature. Once signed, the Member Secretary processes and dispatches the document to the Principal Investigator, institutional sponsors, and relevant regulatory bodies in strict compliance with the protocols established under **SOP 21 (Communicating REC Decisions)**.

Step 8: Filing of all related documents (See SOP 23 - Management of Active Files) and update the RMSS database (Form 4.7), Filing form Log (Form 4.7a), and the Protocol Folder Index (Form 4.9).

Upon completion of the communication cycle, the Administrative Secretary re-collects all physical and digital documentation generated throughout the emergency review process (including the initial safety report, primary reviewer notes, signed emergency minutes, and the issued Decision Letter). Operating under the administrative guidelines of **SOP 23 (Management of Active Files)**, the Administrative Secretary permanently archives these documents within the master protocol folder. To finalize the administrative

lifecycle, the entries are recorded in the **REC Filing Form Log (Form 4.7a)**, the main **RMSS Database (Form 4.7)** is updated, and the physical **Protocol Folder Index (Form 4.9)** is synchronized to guarantee flawless record integrity.

Section 6. Forms

Form 4.6 - Decision Letter
Form 4.7 - RMSS database
Form 4.9 - Protocol Folder Index
Form 11B.2 – SAE/SUSAR Assessment Report

Section 7. History of SOP

Version No.	***Date***	***Authors***	***Main Change***
1	06/05/2024	*NINO ISMAEL S. PASTOR*	*First draft*
2	10.15.24	Dr. Julius Mario	Form labels Contents
3	06.06.26	Nino Ismael Pastor	Form labels, few content

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SOP NO. 12 - APPLICATION FOR CONTINUING REVIEW

Section 1. Policy Statement

Approved protocols need to be continuously reviewed 6 months before the completion of the study. The review process may be expedited or full Committee depending upon the initial approval of the proposal.

Section 2. Objective of the Activity

This activity safeguards the safety and welfare of the participants ensuring that the study was conducted in compliance with the approved proposal. It will also check whether and whether the data they generated is protected beyond its approval till the end of the study.

Section 3. Scope

This SOP describes how the REC should manage an application for Continuing Review (Form 12.1) before a study is terminated. It begins with the application by the proponent for a continuing review and ends with the entry of documents into the protocol folder index (Form 6.1) and the Research Monitoring Surveillance System database (Form 4.7).

Section 4. Workflow

ACTIVITY	***RESPONSIBILITY***	***TIMELINE***
Step 1: Receipt of the application for Continuing Review (Form 12.1) and entry of the application in the Protocol folder Index (Form 4.9) and into the Research Monitoring System (RMSS) database (For 4.7), and the Filing Form Log (Form 4.l7a).	Administrative Secretary	1 day
Step 2: Retrieval of pertinent protocol files	Administrative Secretary	
Step 3: Notification of Chair and Primary Reviewers	Member Secretary	3 days post-receipt
Step 4: Determination of the type of review: expedited (SOP 5 Expedited Review) or full review (SOP 6 Full Review)	Member Secretary Chair	
Step 5: Deliberations on the continuing review	Chair REC reviewers	1 day

		Every 3rd Saturday of the month
Step 6: Communication of REC Decision (SOP 21) (Form 4.6 Decision Letter)	Member Secretary Chair Admin Secretary	7 days post-meeting
Step 7: Filing documents in the appropriate protocol folder, updating the protocol folder index (Form 4.9), Filing Form 4.7a) and RMSS database (Form 4.7),	Administrative Secretary	10 days post-meeting
	TOTAL	22 days

Section 5. Description of Procedures

Step 1: Receipt of the application for Continuing Review (Form 12.1) and entry of the application in the Protocol folder Index (Form 4.9) and into the Research Monitoring System (RMSS) database (For 4.7), and the Filing Form Log (Form 4.l7a).

The Principal Investigator (PI) or authorized research representative formally submits **Form 12.1 (Application for Continuing Review Form)** to the Research Ethics Committee (REC) Secretariat prior to the expiration of the current ethical clearance. Upon delivery, the Administrative Secretary executes an immediate administrative audit:

- **Completeness and Accuracy Check:** The Administrative Secretary meticulously scrutinizes the application to verify that all mandatory fields are thoroughly accomplished, necessary signatures are present, and required cumulative summaries are attached. If the file is incomplete or inaccurate, it is returned to the investigator with an itemized deficiency note.
- **Multi-Platform Intake Logging:** Once verified as complete, the Administrative Secretary officially logs the submission across the institutional tracking ecosystem by:
    1. Entering the intake metadata into the **Research Management Support System (RMSS) Database (Form 4.7)**.
    2. Recording the transaction in the **REC Filing Form Log (Form 4.7a)**.
    3. Formally updating the master **Protocol Folder Index (Form 4.9)** designated for that specific research study.

Step 2: Retrieval of pertinent protocol files.

Following successful logging, the Administrative Secretary accesses the secure archives to retrieve the master protocol folder and compiles all matching files generated during the preceding period of the protocol's ethical clearance. This assembled dossier must include:

- The originally approved protocol and recent amendments.
- Cumulative progress reports and subject enrollment logs.
- All **Protocol Deviation/Violation Reports (Form 11.1)**.
- All **SAE/SUSAR Reports (Form 11B.1)** and **Reported Negative Events (RNEs - Form 11A.1)**.

- Historical committee decisions, noting specifically the methodology of the initial review (Expedited vs. Full Committee Review).

The Administrative Secretary formally briefs the Member Secretary regarding the arrival of the application and transfers the fully synthesized file dossier to their desk for preliminary administrative assessment.

Step 3: Notification of Chair and Primary Reviewers.

The Member Secretary reviews the assembled dossier to ensure all historical notes from the validation period match the investigator's continuing review summaries. Following this internal evaluation, the Member Secretary coordinates with the Secretariat to formally package and transmit the complete Continuing Review application—along with the compiled historical safety data—to the REC Chair and the designated primary reviewer(s) who were originally assigned to oversee the lifecycle of the study.

Step 4: Determination of type of review: expedited (SOP 5 Expedited Review) or full review (SOP 6 Full Review).

The REC Chair, in formal consultation with the Member Secretary and the primary reviewer(s), establishes the appropriate regulatory review pathway. The determination of the review typology is strictly tied to the initial risk determination and prior review framework of the master protocol:

- **Expedited Review Pathway (SOP 5):** Protocols that were initially approved via an expedited track and have maintained a low-risk profile may undergo an expedited Continuing Review.
- **Full Committee Review Pathway (SOP 6):** Protocols that initially required full Committee oversight, or low-risk protocols that have experienced significant safety developments (such as unresolved SAEs, SUSARs, or critical protocol violations), are mandated to undergo a Full Committee Review.

The assigned primary reviewer(s) thoroughly study the application against the historical data to evaluate ongoing participant safety, study relevance, and ethical compliance. The reviewer(s) synthesize their findings into a formal assessment report, which is signed and submitted to the Member Secretary for committee integration.

Step 5. Deliberations on the Continuing Review:

The Member Secretary integrates the primary reviewer’s assessment report into the agenda for the next scheduled REC meeting. During the session, the REC Committee members deliberate on the findings to evaluate if the risk-benefit ratio has shifted and determine whether the study continues to meet ethical benchmarks. The committee votes to implement a definitive regulatory action, which may include, but is not limited to, the following outcomes:

- **No Further Action Required:** The protocol is granted a renewal of its ethical clearance for another defined period (typically 12 months) without modifications.
- **Continuous Monitoring:** Enhanced oversight is mandated, which may include more frequent interval progress reporting.
- **Prepare for a Site Visit:** The Committee orders an unscheduled post-approval monitoring site visit to visually verify compliance.
- **Further Information/Action Required:** Ethical clearance is conditional, pending the submission of clarifying data or revisions.
- **Suspension of Recruitment:** Active subject enrollment is frozen immediately due to pending safety or administrative concerns, while currently enrolled subjects are managed safely.
- **Termination of the Study:** The immediate and total withdrawal of ethical clearance, resulting in the permanent cessation of all research activities due to unmitigated safety hazards or systemic noncompliance.

The Member Secretary precisely documents the deliberations within the official meeting minutes and drafts a formal **Decision Letter (Form 4.6)** mirroring the Committee's mandates.

Step 6: Communication of REC Decision (SOP 21) (Form 4.6 Decision Letter)

The Member Secretary finalizes the **Decision Letter (Form 4.6)** based on the signed expedited report or the approved Full Committee meeting minutes. The letter is routed to the REC Chair for final validation and official signature. Once signed, the Secretariat processes the document and coordinates its formal transmission to the Principal Investigator, institutional sponsors, and relevant institutional authorities in strict compliance with the communication guidelines established under **SOP 21**.

Step 7: Filing documents in the appropriate protocol folder, updating the protocol folder index (Form 4.9), Filing Form 4.7a) and RMSS database (Form 4.7).

Upon the conclusion of the communication cycle, the Administrative Secretary re-collects all physical and digital documentation generated throughout the continuing review process—including the initial application (Form 12.1), primary reviewer notes, signed meeting minutes, and a copy of the issued Decision Letter (Form 4.6). The Administrative Secretary permanently archives these files within the master protocol folder and executes final synchronizations across all data management platforms by updating the entry status within the **REC Filing Form Log (Form 4.7a)**, the main **RMSS Database (Form 4.7)**, and the physical **Protocol Folder Index (Form 4.9)** to guarantee impeccable regulatory record integrity.

Section 6. FORMS

Form 4.7 – RMSS database
Form 4.6 – Decision letter template

Form 4.9 – Protocol Folder Index
Form 12.1 – Application for Continuing Review

Section 7. History

Version No.	Date	Authors	Main Change
1	11 June 2024	NINO ISMAEL S. PASTOR	1sat Draft
2	16 October 2024	Ms. Maricar Canonigo	Form labels Content
3	05 June 2026	Nino Ismael Pastor	Form Labels Few Content

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Gullas College of *Medicine* **RESEARCH ETHICS COMMITTEE**	Ethos Universitas HONORARY COMPANION	Version No:	Draft
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		Effectivity Date:	

SOP NO. 13 - REVIEW OF THE FINAL REPORT

Section 1. Policy Statement

The REC requires a final report not later than 8 weeks after the end of the study. Final reports shall undergo either expedited or full review.

Section 2. Objective of the Activity

The final report ensures that the implementation of the study complies with the approved protocol. It shall also check if the study promoted the safety and welfare of the study participants and if the data and information it generated were protected until the study was completed.

Section 3. Scope

This SOP describes the steps in managing and evaluating the final report(s) from the Principal Investigator(s) at least 8 weeks after the end of their study. The first step is the reception of the final report(s) form (Form 13.1) and ends when the report and related documents have been entered into the Protocol Folder Index (Form 4.9) and the RMSS database (Form 4.7) and the Filing Form Log (Form 4.7a) are updated.

Section 4. Workflow

ACTIVITY	**RESPONSIBILITY**	**TIMELINE**
Step 1: Receipt of final report (Form 13.1) and entry into the Protocol Folder Index (Form 6.1), Filing Form log (Form 4.7a) and the RMSS database (Form 4.7) And the Filing Form Log (Form 43.l7a).	Administrative Secretary	1 day
Step 2: Retrieval of pertinent protocol file	Administrative Secretary	
Step 3: Notification of Chair and Primary Reviewer	Member Secretary Chair	3 days post-receipt
Step 4: Expedited (SOP 4) or Full review (SOP 5)	Chair, REC Members	1 day Every 3rd Saturday of the month
Step 5: Communication of committee action (SOP 21-Communication) in an REC Decisions letter (Form 4.6)	Member Secretary Chair	7 days post-meeting

Step 6: Filing the Final Report (Form 13.1) and related documents into the correct protocol folder and update of the protocol folder index (Form 4.9) and the (Form 4.7) RMSS DATABASE and the Filing Form Log (Form 4.7a).	Administrative Secretary	10 days post-meeting
	TOTAL	22 days

Section 5. Description of Procedures

Step 1: Receipt of final report (Form 13.1) and entry into the Protocol Folder Index (Form 6.1), Filing Form log (Form 4.7a) and the RMSS database (Form 4.7) And the Filling Form Log (Form 43.l7a).

The Principal Investigator (PI) formally downloads or obtains Form 13.1 (Final Report Form) from the Research Ethics Committee (REC). After ensuring all sections are thoroughly accomplished and signed, the PI submits the final report dossier to the REC Secretariat. Upon delivery, the Administrative Secretary executes an immediate administrative intake audit:

The Administrative Secretary evaluates the final report to ensure all necessary study closure metrics, cumulative enrollment data, protocol deviation summaries, and safety overviews are complete. Incomplete submissions are rejected immediately and returned to the PI with an itemized deficiency notice.

Once the submission passes the completeness check, the Administrative Secretary officially logs and registers the transaction across the following data-management systems to preserve an uncompromised audit trail:

- Logs the transaction metadata into the Research Management Support System (RMSS) Database (Form 4.7).
- Records the precise intake entry in the REC Filing Form Log (Form 4.7a).
- Updates the master physical and digital Protocol Folder Index (Form 6.1) allocated to that specific study.

Step 2: Retrieval of pertinent protocol file.

Following successful entry logging, the Administrative Secretary accesses the secure institutional archives to extract the complete historical file of the research protocol. The secretary compiles a comprehensive close-out dossier, which must include: the originally approved baseline protocol, the latest authorized version of the Informed Consent Form (ICF), cumulative progress reports, safety logs, and all past committee decision letters. Once compiled, the Administrative Secretary securely transfers this unified historical folder along with the newly received Form 13.1 to the Member Secretary for preliminary administrative assessment

Step 3: Notification of Chair and Primary Reviewer

The Member Secretary evaluates the newly submitted final report against the study's historical dossier to confirm systemic alignment. During this process, the Member Secretary identifies the original primary reviewer(s) who managed the lifecycle of the protocol.

The Member Secretary drafts a formal Notice to Review (Form 4.3) and endorses the complete package to the REC Chair for executive authorization. Upon receiving the Chair's approval and explicit instructions, the Member Secretary formally dispatches the Notice to Review, the Final Report (Form 13.1), and all matching historical protocol documents to the designated primary reviewer(s). The primary reviewer evaluates the close-out materials against the study's history and synthesizes their findings into a comprehensive evaluation report, which is signed and submitted back to the REC Secretariat.

Step 4: Expedited (SOP 5) or Full review (SOP 6)

The methodology for evaluating the final close-out report is strictly determined by the risk classification and initial review framework utilized during the protocol's lifecycle:

- Expedited Review Pathway (SOP 5): Protocols that were initially categorized as low-risk and processed via an expedited track will undergo an expedited close-out evaluation by the primary reviewer(s) and the Chair.

- Full Committee Review Pathway (SOP 6): Protocols that initially required full Committee oversight are mandated to undergo full committee deliberations.

For full Committee items, the Member Secretary integrates the final report and the primary reviewer's evaluation findings into the provisional agenda. Operating under institutional guidelines, the Member Secretary drafts the Notice of Meeting (Form 17.1) and the Provisional Agenda (Form 18.1), routing them to the Chair for signature before distributing them to all standing REC Committee members.

During deliberations, the committee evaluates whether the study objectives were ethically achieved and votes to issue one of the following definitive regulatory decisions:

The final report is officially approved, and the study is formally registered as closed in good standing.

The final close-out is deferred pending the submission of specific clarifying data, metrics, or investigator statements.

Further Action Required: The Committee mandates explicit operational steps (e.g., participant notifications, post-study data monitoring, or safety interventions) that the PI must fulfill before formal closure is granted.

Step 5: Communication of committee action (SOP 21 Communication REC Decisions) in a Decision letter (Form 4.6)

Following the conclusion of the review cycle, the Member Secretary meticulously finalizes the Minutes of the Meeting (Form 20.1), capturing the exact consensus, rationale, and voting metrics of the committee. The completed minutes are routed to the REC Chair for validation and official sign-off. Once the minutes are signed, the Member Secretary drafts a formal Decision Letter (Form 4.6) that precisely mirrors the committee's mandates. The letter is reviewed, approved, and signed by the REC Chair, and the Secretariat coordinates its immediate electronic or physical transmission to the Principal Investigator in strict accordance with SOP 21 (Communicating REC Decisions).

Step 6: Filing the Final Report (Form 13.1) and related documents into the correct protocol folder and update of the protocol folder index (Form 4.9) and the (Form 4.7) RMSS DATABASE and the Filing Form Log (Form 4.7a).

Upon completion of the communication cycle, the Administrative Secretary re-collects the entire physical and digital paper trail from the Member Secretary. This includes the finalized Final Report (Form 13.1), the primary reviewer's evaluation notes, the signed meeting minutes, and a duplicate copy of the officially issued Decision Letter (Form 4.6). The Administrative Secretary securely returns these items to their designated master protocol folder. To officially conclude the administrative lifecycle of the research study, the secretary executes a final system-wide synchronization by updating the Protocol Folder Index (Form 4.9), recording the close-out in the REC Filing Form Log (Form 4.7a), and updating the status entry inside the master RMSS Database (Form 4.7) to label the study as officially completed.

Section 6. FORMS

Form 4.3 – Notice to Review
Form 4.6 – Decision letter
Form 4.7 – RMSS database
Form 4.7a – Filing Form log
Form 4.9 – Protocol Folder Index
Form 13.1 – Final Report Form
Form 18.1 – Meeting Agenda
Form 20.1 – Minutes of the Meeting

Section 7. History

Version No.	***Date***	***Authors***	***Main Change***
1	*11 June 2024*	*NINO ISMAEL S. PASTOR*	DRAFT

2	16 October 2024	*NINO ISMAEL S. PASTOR*	Form labels Contents
3	05 June 2026		

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

Section 1. Policy Statement

The researcher(s) or sponsor may, for various reasons (poor enrollment, high incidence of SAE/SUSARs, funding), decide to terminate the research before it is completed.

The REC may also choose to terminate the study before it is completed when the safety of the participant(s) cannot be further assured or is doubtful, OR because of any of the following

- The research was not being conducted in accordance with the GCM REC's requirements.
- The research was associated with unexpected serious harm to participants.
- It presented unmanageable risks to the safety, health, or welfare of participants.
- It engaged in significant non-compliance with institutional, national, or international ethical guidelines.
- It did not conform to institutional policies and procedures

The GCM REC Chair has the authority to impose a temporary suspension or termination of study activities if immediate risks to participant safety are identified, prior to a full Committee meeting.

Section 2. Objective of the Activity

A review of an early termination of the study aims to ensure the safety and welfare of the human participants and that the decision made by the REC adheres to the principle of fairness. It is also aimed at promoting the integrity of GCM

In either case, a full Committee review for an early termination of the study will be conducted.

Section 3. Scope

This explains how the REC will handle the suspension or early termination of a protocol before the scheduled end of the study. This SOP begins with the researcher(s) or sponsor submitting a report (Form 14,1) for early study termination, or with a REC member identifying situations or conditions outlined in

the policy and concludes with the REC's decision to suspend or terminate the study.

Section 4. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Researcher(s) or sponsor obtains a blank form for an Early Termination report, fills it up, and submits it to the |REC	Researcher or sponsor	1 day
Step 2: Receipt of the early termination report and entry into the RMSS database (Form 4.7), the Filing Form Log (Form 4.7a) and Form 4.9 (Protocol Folder Index)	Administrative Secretary	
Step 3: Retrieval of pertinent protocol file	Administrative Secretary	
Step 4: Notification of Chair and Primary Reviewers	Member Secretary	3 days post-receipt
Step 5. Creation of a Research Integrity Team	REC Chair	7 days
Step 6: Full review (SOP on Full Review (SOP 6)	Primary Reviewers and Members	1 day Every 3rd Saturday of the month
Step 7: Communication of committee action (Form 4.6, a Decision letter template) and update of the protocol folder index (Form 4.9). Filing Folder Log (Form 4.7a) and RMSS DATABASE	Chair Member Secretary Administrative Secretary	10 days post-meeting
	TOTAL	22 days

Section 5. Description of Procedures

Step 1: Researcher(s) or sponsor obtains a blank template for an Early Termination report, fills it up, and submits it to the |REC.

The researcher(s), REC member, or sponsor will obtain and fill up Form 14.1 (Early Termination Report Form), and submit it to the REC.

Step 2: Receipt of the early termination report (Form 14.1) and entry into the RMSS database (Form 4.7), record entry in the Filing Form log (Form 4.7a), and Form 4.9 (Protocol Folder Index).

The Administrative Secretary receives the application, checks its completeness, and documents the submission in the Protocol Folder Index (Form 6.1), records the entry in the Filing Form (Form 4.7a) and the RMSS Database (Form 4.7).

Step 3: Retrieval of pertinent protocol file.

The Administrative Secretary shall retrieve the protocol from the Active Files to collate the documents of the protocol and to determine the identity of primary reviewers. S/he submits them to the Member Secretary.

Step 4: Notification of Chair and Primary Reviewers.

The Member Secretary evaluates the submission in the context of the documents and notifies the Chair and awaits further instruction. The Chair instructs the Member Secretary to issue a Notice to Review (Form 4.3) to the concerned Primary Reviewer and include the submission for a full Committee review in the next regular REC meeting. The Primary Reviewer prepares and submits his/her evaluation of the requested termination to the REC

- **Step 5: Creation of a Research Integrity Team (RIT).**

The REC chairperson or the Center for Health Research & Innovation creates a Research Integrity Team (RIT). The team investigates the report. The RIT **reports** to REC on the next REC meeting or during an emergency meeting as the case maybe.

- **Step 6: Full review (SOP on Full Review (SOP 6).**

The Member Secretary prepares the reports, and Agenda to be presented in the REC meeting.

The review should ensure the implication of the early termination on the rights, safety, and welfare of the study participants, in the form of a set of procedures. The procedures may include adapting specific provisions for continued access to protective mechanisms and information by the study participants.

Step 7: Communication of committee action (Form 4.6, a Decision letter template) and update of the protocol folder index (Form 4.9). Filing Folder Log (Form 4.7a) and RMSS DATABASE

The Member Secretary will make the minutes of the meeting (SOP 20 – Preparing the Minutes of the Meeting) take note of the decision and/or discussion during the Committee meeting, draft a Decision letter (Form 4.6) and send it to the Chair for signature and when signed send it to the PI or sponsor.

Section 6. Forms

Form 4.3 – Notice to Review
Form 4.6 - Decision Letter Template
Form 4.7 – RMSS database
Form 4.7a – Filing Form log
Form 6.1 – Protocol folder Index
Form 14.1 - Early Termination Report Form

Form 20.1 – Minutes of the Meeting

Section 7. History

Version No.	***Date***	***Authors***	***Main Change***
1	11 June 2024	NINO ISMAEL S. PASTOR	Draft
2	17 Oct 2024	Ronald Catacte	Form labels Content
3	05 June 2026	Nino Ismael Pastor	Form labels Few content

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SOP NO. 15 - MANAGEMENT OF APPEALS

Section 1. Policy Statement

Appeals from PI, researcher(s), sponsor(s), or other stakeholders may also be filed against the REC decisions about the protocol and its documentation. Appeals will be discussed during a full Committee meeting.

The REC shall consider these appeals. Appeals shall be considered BY THE REC during full Committee meetings and a decision communicated to the appellant within four weeks of the full Committee meeting. Appeal must be filed with the REC chair within 30 days of the decision of the REC. It should state the grounds upon which the appeal is filed.

Section 2. Objective of the Activity

The objective of appealing is to ensure a transparent, fair, and comprehensive review of the appeal against a REC decision.

Section 3. Scope

This SOP starts with the receipt of the appeal request and ends with updating the Research Monitoring System Database (Form 4.l7) and the Protocol Folder index (Form 6.1).

Section 4. Workflow

ACTIVITY	**RESPONSIBILITY**	**TIMELINE**
Step 1: Receipt of an appeal & updating the Protocol Folder Index (Form 4.9), RMSS (Form 4.7) & the Filing Folder Log (Form 4.7a)	Administrative Secretary	1 day
Step 2: Retrieval of pertinent protocol file	Administrative Secretary	
Step 3: Notification of Chair and Primary Reviewer(s).	Member Secretary	3 days post-receipt
Step 4: Inclusion in the Agenda of the next regular (or emergency) meeting.	Member Secretary Chair	

Step 5: Discussion of and deliberation on the appeal during a full Committee meeting	Chair and REC Members	1 day Every 3rd Saturday of the month
Step 6: Communication of committee action (SOP 21 Communicating REC Decision)	Member Secretary Chair	7 days post-meeting
Step 7: Filing of documents & updating the Protocol Folder Index (Form 4.9), RMSS (Form 4.7) & the Filing Folder Log (Form 4.7a)	Administrative Secretary	10 days post-meeting
	TOTAL	22 days

Section 5. Description of Procedures

Step 1: Receipt of an appeal & updating the Protocol Folder Index (Form 4.9), RMSS (Form 4.7) & the Filing Folder Log (Form 4.7a)

The Administrative Secretary officially receives the formal letter of appeal submitted by the principal investigator or sponsor. Upon receipt, the Administrative Secretary conducts a preliminary administrative review to verify that the appeal package is complete and contains all necessary evidentiary information (London, 2018). The submission must explicitly include the following components:

- **Target of Appeal:** A clear identification of the specific Research Ethics Committee (REC) decision(s) or clauses that the proponent wishes to appeal.
- **Justification and Grounds:** A detailed, written justification outlining the specific ethical, scientific, or administrative grounds for each point of contention.
- **Official Correspondence:** A copy of the original, formal REC decision letter that prompted the appeal.
- **Historical Review Comments:** Copies of the official comments, stipulations, or queries previously provided by the Committee during the initial REC review process.
- **Prior Communications:** Documentation of any and all prior correspondence regarding the disputed protocol or previous appeal attempts held with the Member Secretary, Committee Chair, or individual committee members.
- **Supporting Documentation:** Any additional literature, revised protocol sections, expert opinions, or secondary documents that serve to validate and support the proponent's appeal.

If the appeal package meets all the completeness criteria outlined above, the Administrative Secretary formally accepts the submission. S/he then logs the pertinent details of the appeal into the **Protocol Folder Index (Form 4.9) of that proposal**, logs the physical entry in the **Filing Folder Log (Form 4.7a)**, and updates the digital records within the **RMSS Database (Form 4.7)** to ensure full institutional traceability. If the submission is incomplete, the investigator is notified to provide the Administrative

Secretary officially receives the formal letter of appeal submitted by the missing components before further processing

Step 2: Retrieval of pertinent protocol file.

Once the appeal is logged, the Administrative Secretary securely retrieves the complete archival file corresponding to the protocol under question. This documentary assembly ensures that all historical context is available for the review. The gathered dossier must include:

- The initially submitted research protocol (along with any subsequently approved amendments).
- The exact Informed Consent Form (ICF) versions tied to the decision.
- All relevant research tools, questionnaires, data collection forms, and related investigator brochures.

The Administrative Secretary physically or digitally attaches these baseline reference materials to the newly received appeal letter. This comprehensive dossier is then systematically forwarded to the Member Secretary for initial executive screening.

Step 3: Notification of Chair and Primary Reviewer(s).

Upon receiving the compiled dossier, the Member Secretary immediately notifies the Committee Chair and awaits executive directives. The Chair performs a preliminary evaluation of the appeal's grounds to determine the appropriate course of action. S/he then instructs the member secretary to prepare an Appeal Evaluation Report (For 15.1) and attach to the dossier.

Following this evaluation, the Chair identifies and assigns the protocol to the original Primary Reviewer(s) who oversaw the initial protocol decision, ensuring continuity of expertise. The Chair then instructs the Member Secretary to distribute the appeal dossier to these designated reviewers. Concurrently, the Chair directs the Member Secretary to slate the appeal onto the provisional agenda of the next regularly scheduled Full Committee meeting, or to convene an extraordinary emergency meeting if the timeline or nature of the study dictates urgency.

Upon receiving the dossier, the Primary Reviewer(s) conduct a rigorous re-evaluation of the protocol against the grounds raised in the appeal, subsequently drafting a formal evaluation report to be presented to the REC.

Step 4: Inclusion in the Agenda of the next regular (or emergency) meeting.

Acting on the explicit directives of the Chair, the Member Secretary officially embeds the protocol appeal as an active item on the institutional agenda (Form 18.1) for the upcoming regular or emergency Full Committee meeting (See SOP 17, 18 & 19).

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Once scheduled, the Member Secretary sends a formal meeting notice (Form 4.3 notice top Review) to the principal investigator/proponent. This communication instructs the researcher to be on standby or present during the designated time slot of the meeting, ensuring their availability to address any real-time inquiries or provide crucial clarifications requested by the board

Step 5: Discussion of and deliberation on the appeal during a full Committee meeting.

The Chair opens the meeting in accordance with SOP 16. Then the Primary Reviewer is called to summarize the historical trajectory of the protocol, highlighting the specific ethical or technical issues that sparked the initial decision and contrasting them against the current arguments raised in the appeal. The Committee Chair opens the floor for general panel discussion and takes leadership over the deliberation process. If the panel requires deeper insights, the Member Secretary calls the principal investigator into the meeting room for a formal clarificatory interview. The researcher is given the opportunity to clarify ambiguities or defend their scientific/ethical stance. Once the clarificatory interview concludes, the researcher is politely asked to step out of the room. The Committee enters an executive session to finalize deliberations in absolute privacy. The panel strives to reach a consensus regarding the merits of the case. The Committee officially votes to determine whether to accept the appeal in its entirety, accept only specific elements of the appeal, or uphold the original REC decision.

The Member Secretary records the proceedings in the Minutes of a Meeting (Form 20.1).

Step 6: Communication of committee action (SOP 21 – Communicating REC Decisions).

Associated Forms: Notice of Panel Action / Draft Decision Letter (Form 4.6)

Following the finalization of the committee's collective decision, the Chair synthesizes the core decision points, ethical rationales, and mandatory requirements. The Member Secretary records the proceedings in the Minutes of a Meeting (Form 20.1). The Chair then instructs the Member Secretary to translate these points into a formal **Draft Decision Letter (Form 4.6)**. The Member Secretary drafts the letter, ensuring all administrative and ethical justifications are precisely articulated. This draft is submitted to the Committee Chair for meticulous final review, administrative approval, and official signature. Once signed and sealed, the final decision letter is dispatched to the appellant/proponent via secure institutional channels, adhering strictly to standard communication timelines.

Step 7: Filing of documents & updating the Protocol Folder Index (Form 4.9), RMSS (Form 4.7) & the Filing Folder Log (Form 4.7a).

Associated Forms: Protocol Folder Index (Form 4.9), Research Management Support System (RMSS Database - Form 4.7), Filing Folder Log (Form 4.7a)

Upon the conclusion of the appeal cycle, the Administrative Secretary collects all physical and digital artifacts generated throughout the process—including the appeal letter, supporting attachments, primary reviewer evaluation reports, relevant meeting minutes excerpts, and the signed final decision letter. S/he systematically files these documents into the investigator's dedicated protocol folder to maintain an uninterrupted audit trail. Finally, to ensure institutional data integrity, the secretary logs the completion of the action by making a final entry in the **Filing Folder Log (Form 4.7a)** and completely updating both the **Protocol Folder Index (Form 4.9)** for the specific protocol and the centralized **RMSS Database (Form 4.7)** to reflect the newly adjudicated status of the protocol.

Section 6. Forms

Form 4.6 – Decision letter
Form 4.7 – RMSS database
Form 4.7a -Filing Form
Form 4.9 – Protocol Index File
For 18. 1 - Meeting Agenda Template
Form 20.1 – Minutes of the Meeting

Section 7. History

Version No.	***Date***	***Authors***	***Main Change***
1	11 June 2024	NINO ISMAEL S. PASTOR	1st Draft
2	17 Oct 2024	Dr. Julius Mario	Form labels content
3		NINO ISMAEL S. PASTOR	Form labels content

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

SOP NO. 16 - SITE VISITS

Section 1. Policy Statement

The site(s) of high-risk studies, studies with significant deviation reports, studies with non-receipt of required after-approval reports from the REC, multiple study sites conducted by a researcher and/or studies with participant/family/stakeholder complaints need to be visited.

Section 2. Objective of the Activity

Site visits enable the REC to monitor compliance with approved protocols, and the ICF process to protect and promote participants' dignity, rights, and well-being.

Section 3. Scope

This SOP begins with the identification of the site to be visited and ends with the filing of Site-Visit Reports (Form 16.1) in the protocol folder index (Form 4.9), recording the entry into the Filing Form log (Form 4.7a), and updating of the RMSS DATABASE.

Section 4. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Selection of site to visit	Any REC Member(s)	1 day Every 3rd Saturday of the Month or Special meeting
Step 2: Creation of Site Visit Team	Chair	
Step 3: Notification of researcher	Member Secretary Chair	14 days post-meeting
Step 4: Conduct of site visit	Site Visit Team members	7 days post-notification
Step 5: Draft of report and presentation of report during meeting and discussion for recommendations	Site Visit Team (members)	7 days post-visit
Step 6: Transmittal of Final Report and Recommendations to the Researcher/Investigator	Chair/ Member Secretary	

Step 7: Filing of Site-Visit Reports in the protocol folder index (Form 4.9), and update of the RMSS DATABASE (For 4.7) and the Filing Form Log (Form 4.7a).	*Administrative Secretary*	10 days post-visit
	TOTAL	39 days

Section 5. Description of Procedures

Step 1: Selection of site to visit

Study sites are strategically identified and selected for routine or targeted inspections during the formal ethical review of ongoing research proposals. The Research Ethics Committee (REC) employs a risk-based approach to trigger a site visit. A site inspection will be mandated if a study meets one or more of the following criteria:

- High-Risk Research: Protocols involving vulnerable populations, novel investigational products, invasive procedures, or high-level clinical interventions.
- Protocol Deviations: Studies with documented histories of significant or frequent protocol deviation and non-compliance reports.
- Reporting Delinquency: Ongoing failure to submit mandatory, post-approval follow-up reports required by the REC (e.g., progress reports, final reports).
- Principal Investigator (PI) Workload: Researchers simultaneously overseeing multiple active study sites or an exceptionally high volume of concurrent protocols.
- Participant or Family Grievances: Formal or informal complaints lodged by study participants, their immediate family members, or legal representatives.
- Community Concerns: Issues, complaints, or negative feedback raised by local community members, leaders, or stakeholders at the study site.
- Overwhelming Sample Sizes: Protocols tracking exceptionally large participant cohorts that increase the statistical margin for administrative or ethical oversight errors.
- Critical Safety Events: Studies experiencing a cluster of Serious Adverse Events (SAEs), Suspected Unexpected Serious Adverse Reactions (SUSARs), or Related Negative Events (RNEs).
- Continuing Review Failure: Absolute failure by the PI to submit mandatory continuing review requirements ahead of protocol expiration timelines.

Step 2: Creation of Site Visit Team
Associated Forms: Site Visit Briefing Dossier

When a directive for a site inspection is formally passed during an ethics review meeting, the REC panel elects specialized members to form the dedicated Site Visit Team.

The Committee Chair formally appoints a Team Leader, a role preferentially assigned to the protocol's original Primary Reviewer to maintain continuity of oversight. The Team Leader is then tasked with selecting at least two additional qualified committee members to round out the inspection unit. S/he also prepares the Site Visit Report (Form 16.1).

Prior to deployment, the entire REC panel reviews the baseline protocol to align on the focus of the inspection. The chosen Site Visit Team members then undergo a thorough familiarization process with all historical study data, previous stipulations, and critical compliance files to ensure an informed, targeted investigation.

Step 3: Notification of researcher

The Member Secretary is responsible for drafting and dispatching a formal letter of notification to the principal investigator exactly two (2) weeks prior to the scheduled inspection date. This notification is delivered via secure institutional email or verified postal mail. The communication must clearly explicitly include:

- The exact ethical or administrative justification triggering the site visit.
- A formal request outlining any additional documents or updated logs that the PI must prepare for inspection.
- The names and designations of the REC panel members constituting the Site Visit Team.
- Logistics, scheduling windows, and relevant travel or entry arrangements established for the team.

Step 4: Conduct of site visit

The Administrative Secretary serves as the administrative backbone, organizing and compiling all internal REC records alongside the investigator's file versions to be used on-site. Once at the research facility, the Site Visit Team collaborates with the PI to perform a thorough review of the infrastructure and records. The inspection evaluates the following dimensions:

- Protocol Version Control: Verification that the study site is actively utilizing and executing the absolute latest version of the REC-approved protocol.

- Informed Consent Management: Auditing signed informed consent documents to confirm that the site is administering the most recently approved, unexpired version to active participants.

- Post-Approval Document Trail: Verifying that all modifications, amendments, and updates were submitted to and formally approved by the REC prior to field implementation.

- Data Security and Participant Privacy: Auditing physical and digital infrastructure to ensure data confidentiality, double-locked cabinet storage, password protection, and adherence to privacy regulations.

- Facility Sufficiency: Assessing the physical site facilities to confirm they remain safe, adequate, and well-equipped to support the parameters of the research.

- Participant Welfare Assessment: Making an overarching ethical determination regarding the absolute protection of the rights, safety, physical, and mental welfare of human participants currently enrolled in the trial.

Step 5: Draft of report and presentation of the report during meeting and discussion for recommendations

During the visit, team members record individual findings using the Site Visit Report (Form 16.1). Following the inspection, the Team Leader collates these distinct forms into a synchronized, single consensus report and officially submits it to the Committee Chair.

The Team Leader transforms this consensus report into a comprehensive overall draft within one (1) week of the visit. The Team Leader then presents these findings to the Full Committee panel during the next regularly scheduled meeting or an emergency session if urgent safety concerns were discovered.

The panel deliberates on the findings to reach a consensus decision, establishing formal, binding recommendations that align strictly with REC-approved ethical guidelines and institutional protocols.

Step 6: Transmittal of Final Report and Recommendations to the Researcher/Investigator.

Following the committee's final deliberations, the Member Secretary documents the exact proceedings within the official meeting minutes and creates a formal summary of the REC's findings and binding recommendations.

The Member Secretary adapts these points into a formal Decision Letter (Form 4.6). The Committee Chair reviews, approves, and signs this final transmittal letter. The finalized

document is then sent to the PI through secure communication channels in strict compliance with SOP 21: Communicating REC Decisions, providing clear directives and deadlines for any required corrective and preventive action (CAPA) plans.

Step 7: Filing of Site-Visit Reports in the protocol folder index (Form 4.9), and update of the RMSS DATABASE (For 4.7) and the Filing Form Log (Form 4.7a).

To close out the site visit cycle, the Administrative Secretary gathers all related materials, including the individual and synthesized copies of the Site Visit Report (Form 16.1), meeting minutes excerpts, and the signed final decision letter.

The Administrative Secretary permanently files these physical and digital records into the investigator's primary protocol folder to maintain an uncompromised audit trail.

Finally, the secretary reflects the completion of the action by logging the entry into the physical Filing Folder Log (Form 4.7a) and updating the tracking indexes within both the Protocol Folder Index (Form 4.9) and the institutional RMSS Database (Form 4.7).

Section 6. Forms

Form 4.6 – Decision Letter
Form 4.7 – RMSS database
Form 4.7a – Filing form log
Form 4.9 – Protocol Folder Index
Form 15.1 – Site Visit Report

Section 7. History of SOP

Version No.	***Date***	***Authors***	***Main Change***
1	6.27.24	NINO ISMAEL S. PASTOR	DRAFT
2	10.17.24	NINO ISMAEL S. PASTOR	Form labels Content
3	06.11.26	Nino Ismael Pastor	Form labels Few content

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SOP NO. 17 - PREPARING FOR A MEETING

Section 1. Policy Statement

The REC shall regularly meet every 3rd Saturday afternoon of each month. The Chair may call Emergency or special meetings. These meetings shall be held in the 2F conference room of the Center for Health Research and Innovation or upon notice otherwise.

Section 2. Objective of the Activity

This SOP explains the processes for preparing an orderly, efficient REC meeting.

Section 3. Scope

This SOP begins with the drafting a provisional agenda and ends with the notification and attendance of REC Members,

Section 4. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Preparation of the agenda (Form 18.1- Provisional Agenda)	Member Secretary	1 day Every 2nd Friday of the month
Step 2: Assembly of materials and documents needed for the meeting	Administrative Secretary Member Secretary	1 day Every 3rd Monday of the month
Step 3: Coordinate with the Facility Maintenance Division for the venue, IT for AV equipment, and finance for snacks and meals.	Administrative Secretary	
Step 4: Notification of REC Members and confirmation of attendance	Administrative Secretary	4 days before 3rd Saturday of the month
	TOTAL	6 days

Section 5. Description of Procedures

Step 1: Preparation of the agenda (Form 18.1- Provisional Agenda)

Associated Forms: Provisional Meeting Agenda Template (Form 18.1), Master Agenda Log (Form 17.1)

On the second (2nd) Friday of each calendar month, the Member Secretary formally initiates the meeting preparation cycle by determining the core items to be slated for the upcoming Research Ethics Committee (REC) session. The Member Secretary reviews ongoing protocols, outstanding appeals, overdue continuing reviews, and pending initial submissions to draft the initial lineup. Following this preliminary assessment, the Member Secretary consults with the Committee Chair to integrate any institutional updates, policy directives, or emergency matters into the schedule. Once approved by the Chair, the provisional agenda is systematically finalized using the Provisional Meeting Agenda Template (Form 18.1). The Administrative Secretary then takes this finalized template and officially encodes all listed line items, protocol tracking numbers, and presenter names into the master Notice of Meeting (Form 17.1) to maintain central traceability.

Step 2: Assembly of materials and documents needed for the meeting.

On the third (3rd) Monday of each calendar month, the Administrative Secretary executes the absolute cut-off for data collection, gathering all physical and digital documentation required for the upcoming panel deliberations. The finalized meeting dossier must be systematically structured to include:

- Official Agenda: The finalized meeting agenda (Form 18.1) outlining the timeline and sequence of the proceedings.
- Historical Minutes: Comprehensive minutes of the immediately preceding REC meeting for board review and formal approval.
- Attendance Tracking: A blank institutional attendance sheet prepared for physical or digital signatures on the day of the session.
- Protocol Submissions: At least two (2) complete hard-copy dossiers alongside a verified electronic copy of all study protocols submitted on or before the strict deadline.
- Member Folders: Custom, individual documentation folders compiled for each attending board member containing their designated reviewer assignments.
- Administrative Documentation: Miscellaneous institutional communications, oversight policy memos, or external regulatory correspondence (retained in both hard-copy and electronic soft-copy formats).

For sessions conducted online, the Administrative Secretary must securely transmit all electronic document packets to the respective panel members via institutional email at least four (4) calendar days prior to the scheduled meeting. Concurrently, the secure video-conferencing access links must be generated and distributed within this exact four-day window.
Special or Emergency Sessions: Deadlines and documentation timelines for extraordinary or emergency meetings remain completely flexible and will be adapted on a case-by-case basis as dictated by the urgency of the ethical matter under review.

Step 3: Coordination with the Facility Maintenance Division for venue, IT for AV equipment & Finance for snacks and meals.

Associated Forms: Facility Booking Requests, Catering/Purchase Orders

On the third (3rd) Monday of each calendar month, the Administrative Secretary coordinates with necessary institutional support services to guarantee that all infrastructural demands for the upcoming session are met. The secretary initiates formal requests to the following departments:

- Facility Maintenance Division: To reserve the designated physical committee room, ensure optimal room configuration, and confirm climate control functionality.

- Information Technology (IT) Department: To request and lock in required audiovisual equipment, multimedia projectors, microphones, and stable video-conferencing connectivity for remote participants.

- Finance and Dietary Division: To file formal requisition orders for appropriate snacks, beverages, and meals allocated for panel members based on the projected duration of the meeting.

Step 4: Notification of REC Members and confirmation of attendance.

To ensure a legally binding quorum is achieved, the panel notification process follows a rigorous timeline overseen by both secretaries:

On the third (3rd) Tuesday of each calendar month, the Member Secretary prepares the official Notice of Meeting (Form 17.1) and distributes it to all active REC panel members. Committee members are required to formally confirm or decline their attendance at least three (3) days prior to the scheduled meeting date, allowing the leadership to adjust schedules if a quorum is at risk. The Administrative Secretary provides operational backups by sending automated text alerts and reminders to all members at least four (4) days before the event, followed by a final, direct reminder in the morning on the day of the scheduled meeting.

Panel members opting to attend via virtual links are required to log into the secure digital platform at least ten (10) minutes prior to the official call-to-order to resolve any potential technical anomalies. The official institutional attendance sheet must be physically or digitally signed by all participating

Section 6. Forms

Form 17.1 - Notice of Meeting
Form 17.1 - Agenda
Form 18.1 – Meeting Agenda Template
Form 19.1 - Attendance Sheet

Section 7. History of SOP

Version No.	***Date***	***Authors***	***Main Change***
1	6.19.24	NINO ISMAEL S. PASTOR	1st DRAFT
2	10.18.24	Aljoriz Dublin & Nino Ismael Pastor	Form labels Content
3	05.06.26	Nino Ismael Pastor	Form labels Few Content

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SOP NO. 18 - PREPARING THE MEETING AGENDA

Section 1. Policy Statement

Documents submitted on or before the 2nd Wednesday of the month shall become part of the provisional meeting agenda every 3rd Saturday of the month. Issues and concerns about a proposal that requires immediate consideration may become part of an emergency or special meeting agenda. When the Chair approves the provisional agenda, its items become part of the Notice of Meeting (Form 17.1). It shall follow an established template for meeting agenda. The provisional agenda shall be included in the Notice of Meeting. This provisional agenda shall be approved by a majority vote of the REC members present and becomes the agenda of the meeting.

Section 2. Objective/s of the Activity

Meetings should be proactively prepared to ensure a smooth, orderly, inclusive, and efficient conduct of meetings.

Section 3. Scope

This SOP starts with the drafting of a provisional agenda of a regular, special or emergency meeting and ends with its approval by REC member present during the meeting as the final meeting agenda.

Section 4. Workflow

ACTIVITY	**RESPONSIBILITY**	**TIMELINE**
Step 1: Preparation of the draft meeting agenda	Administrative Secretary and Member Secretary	1 day Every 2nd Friday of the month or Emergency meet
Step 2: Preparation of the provisional meeting agenda	Chair	
Step 3: Distribution of the provisional meeting agenda (SOP 17 - Preparing for a Meeting)	Administrative Secretary	1 day Every 3rd Tuesday of the month
Step 4: Approval of the provisional meeting agenda	REC Members	1 day Every 3rd Saturday of the month

Step 5: Filing of the final meeting agenda (SOP 23 on Management of Active Files)	Administrative Secretary	1 day post-meeting
	TOTAL	4 days

Section 5. Detailed Procedures

Step 1: Preparation of the provisional agenda.

To ensure a structured and efficient review process, all incoming research protocols and administrative documents must adhere to a strict submission timeline.

Submission Cut-off and Classification: Only documents submitted to the Research Ethics Committee (REC) Secretariat on or before the second Saturday of each month will be officially classified and considered for inclusion. Submissions received after this deadline will automatically be deferred to the following month's cycle.

Drafting Timeline: Under the direct supervision of the Member Secretary, the Administrative Secretary is responsible for compiling these classified documents and preparing the initial draft of the Provisional Agenda using Form 18.1. This draft must be finalized on or before the second Friday of each month.

Preliminary Review: The Member Secretary will comprehensively review the compiled draft to ensure appropriate categorization of items and execute any necessary administrative or technical modifications before processing.

The Provisional Agenda must strictly follow the standardized institutional format detailed below:

1. Call to Order
2. Declaration of Quorum
3. Approval of the Provisional Agenda
4. Disclosure of Conflict of Interest (COI)
5. Review and Approval of the Minutes of the Previous Meeting
6. Business Arising from the Minutes (Updates on ongoing actions or deferred items)
7. New Business:
    a. Initial Review of Full Review Protocols
    b. New Protocols
    c. Protocols for Modification
    d. Protocols for Clarification
    e. Report on Expedited Review of Protocols
    f. New Protocols
    g. Protocols for Modification
    h. Protocols for Clarification
    i. Report on Exempted Protocols
    j. Review of NEW & OLD Resubmissions

k. Review of Post-Approval Submissions
l. Protocol Withdrawals / Terminations
m. Protocol Amendments
n. Queries, Grievances, and Complaints
o. Serious Adverse Events (SAEs) / Suspected Unexpected Serious Adverse Reactions (SUSARs) / Protocol Deviations and Violations (RNE Reports)
p. Appeals of REC Decisions
q. Final Study Reports
r. Report on Site Visits and Monitoring Actions
s. Tracking of Borrowed Institutional Files

8. Other Matters (General announcements or non-protocol discussions)
9. Adjournment

Step 2: Preparation of the provisional meeting agenda

Once the initial draft of the Provisional Agenda (Form 18.1) has been vetted by the Member Secretary, it is formally transmitted to the REC Chair.

The Chair will critically review the document to ensure that all critical items are appropriately prioritized and that the scheduled topics align with the committee's scope and current operational capacity. Upon the Chair's official sign-off and approval, the document is elevated from a draft to the official Provisional Meeting Agenda.

Step 3: Distribution of the provisional meeting agenda (see also SOP 17 Preparing for a Meeting).

To grant committee members sufficient time to review the protocols and associated documentation thoroughly, a strict distribution timeline must be maintained:

- Timeline: The Administrative Secretary must distribute the approved Provisional Meeting Agenda on or before the third Tuesday of each month.

- Documentation Packet: The agenda must be accompanied by an official Notice of Meeting (Form 17.1), the minutes of the previous meeting, and all relevant protocol dossiers assigned to specific reviewers.

- Delivery Logistics: Distribution may be executed via two primary channels depending on the member's preference and location:

- Digital Distribution: Sent via secure, confidential institutional email or uploaded to the committee's secure document-sharing portal.

- Physical Distribution: Delivered as printed hard copies via a trusted courier service.

Step 4: Approval of the provisional meeting agenda

During the opening segments of any regular, special, or emergency REC meeting, the Provisional Meeting Agenda is presented to the floor for final validation. REC members present may propose last-minute amendments, such as the deferral of an item, the addition of urgent "Other Matters," or reordering the sequence of business to accommodate guest presenters or specific expertise availability. Following any agreed-upon modifications, a formal motion to adopt the agenda must be made and seconded. Approval requires a simple majority vote (calculated as 50% of present members + 1) among the voting members present, provided a quorum has been established. The entire voting and amendment process shall strictly observe Robert's Rules of Order to ensure democratic and transparent parliamentary procedure. Once approved, the document serves as the definitive roadmap for the session.

Step 5: Filing of the final meeting agenda (SOP 23 on Management of Active Files)

Following the adjournment of the meeting, the approved agenda—reflecting any changes made during Step 4—becomes the permanent Final Meeting Agenda.

The Administrative Secretary is charged with the proper archiving of this document to maintain an airtight institutional audit trail. The Final Meeting Agenda (Form 18.1) must be filed in the dedicated corporate folder designated for committee agendas. Filings must be arranged in strict chronological order to ensure rapid retrieval during internal quality checks or external regulatory audits, in full compliance with SOP 23 - Managing Active Files.

Section 6. Forms:

Form 17.1 – Notice of Meeting
Form 18.1 – Meeting Agenda Template
Form 19.1 – Attendance Sheet
Form 20.1 – Minutes of the Meeting

Section 7. History

Version No.	***Date***	***Authors***	***Main Change***
01	6.21.24	NINO ISMAEL S. PASTOR	DRAFT
02	10.22.24	Dr. Marie Fe Abejar	Form labels Contents
03			

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SOP NO. 19 - CONDUCT OF MEETINGS

Section 1. Policy Statement

The Chair, or as the case maybe, the Vice-Chair, or Chairperson-designate shall preside over a meeting after a quorum is declared. The order of meetings shall follow the approved agenda and follow Robert's Rules of Order. All members should disclose no conflict of interest before they approve the Provisional meeting agenda. To ensure all Committee members are thoroughly prepared to facilitate an efficient review process, the distribution of meeting materials must follow a strict administrative timeline and protocol

Section 2. Objective/s of the Activity

Meetings allow the REC to reach collegial decisions regarding study protocols, REC operations, and information about GCM research proposals and REC administrative matters.

Section 3. Scope

This SOP begins with the distribution of meeting documents. It describes how meetings will be prepared, conducted, called to order, and adjourned. It ends with the collection, storage, and disposal of meeting materials.

Section 4. Workflow

ACTIVITY	***RESPONSIBILITY***	***TIMELINE***
Step 1: Distribution of meeting materials	Administrative Secretary	4 days before monthly meetings (3rd Saturday every month)
Step 2: Declaration of quorum (formal start)	Chair or designate	During meeting
Step 3: Approval of the provisional agenda	REC Members	
Step 4: Declaration of conflict of interest (COI)	REC Members	During meeting
Step 5: Approval of minutes of the previous meeting	REC Members	

Step 6: Discussion of "Business arising from the minutes"	REC Members	During meeting
Step 7: Review of protocols and protocol-related submissions (SOP 6, Full Committee review)	REC Chair and Members	During meeting
Step 8: Report of results of expedited review (SOP 4 on Expedited Review (SOP 5).	Designated Reviewers	During meeting
Step 9: Discussion of operations-related and administrative matters	REC Chair and Members	During meeting
Step 10: Adjournment	Chair	During meeting
Step 11: Collection, storage, and disposal of meeting materials	Administrative Secretary	1 day post-meeting
	TOTAL	6 Days

Section 5. Description of Procedures

Step 1: Distribution of meeting materials

The Member Secretary shall officially transmit the finalized Notice of Meeting (Form 17.1) and the Provisional Agenda (Form 18.1) to the Administrative Secretary. S/he is responsible for gathering all pertinent physical and digital documents—including protocols, investigator brochures, informed consent forms, and previous review notes—from the Chair, Member Secretary, and assigned reviewers. The Administrative Secretary shall also generate the official meeting attendance sheet. All compiled materials must be systematically distributed to assigned primary reviewers, independent consultants, and other concerned committee members.

For protocols requiring a full-board Committee review, a complete physical copy of the dossier must be explicitly prepared and delivered to the Chair.

To accommodate remote participants, the Administrative Secretary must transmit secure electronic or digital copies of all meeting materials on or before the second Wednesday of each month. For special or emergency meetings, electronic dossiers must be dispatched no later than 24 hours prior to the scheduled meeting time.

Step 2: Declaration of quorum (formal start)

The formal commencement of any Research Ethics Committee (REC) meeting is strictly contingent upon the establishment and declaration of a valid quorum by the Chair.

quorum is officially established when a simple majority—specifically at least five (5) out of the eight (8) voting members—is actively present. This presence may be fulfilled either face-to-face (in person) or via synchronized online video-conferencing platforms.

If a voting member is entirely unable to attend the session (either in person or online) but has submitted a comprehensive, written protocol review evaluation report prior to the call to order, their submission may be counted toward the establishment of the quorum for that specific protocol slot.

For protocols that target vulnerable populations or require specific cultural/societal context, the presence of a guest advocate or subject-matter representative is mandatory. The Chair must ensure this representative is present before the specific protocol review begins. Guest advocates, subject-matter experts, and independent consultants are present in an advisory capacity only; they do not constitute part of the official quorum and do not possess voting privileges.

Step 3: Approval of the provisional agenda

Once a quorum is formally declared, the Chair will officially open the floor to finalize the session's agenda.

The Chair will direct all members to examine the distributed Provisional Agenda. Members may propose modifications, such as reordering the sequence of protocols to accommodate guest speakers or adding urgent administrative items. If no further changes are requested, or once all accepted amendments are integrated, the Chair will call for a formal motion to approve the agenda. A committee member must explicitly move to approve the agenda, and another member must second the motion. The Chair will ask the floor for any objections or abstentions. Hearing none, the Chair will formally declare the provisional agenda approved as the definitive, binding agenda for the current meeting.

Step 4: Declaration of conflict of interest (COI)

To preserve the absolute integrity, objectivity, and credibility of the review process, the Chair must strictly enforce the committee’s Conflict of Interest policy.

The Chair ensures that all participating REC members maintain complete independence from the principal investigators, co-investigators, research staff, and funding sponsors associated with the protocols under review. A Conflict of Interest occurs when a member’s personal, professional, financial, familial, or social factors could compromise, or reasonably appear to compromise, their professional judgment and objectivity. Members are permitted to discuss and vote only on research submissions where they have absolutely no conflicting interests. Any member possessing a COI for a specific protocol must declare it immediately during this part of the meeting.

When the conflicted protocol is called for review, the affected member must physically or digitally exit the meeting room. They may only rejoin the session after the discussion, voting, and final decision-making for that specific protocol have concluded.

The Administrative Secretary is accountable for documentation and must explicitly record the exact timestamps when the conflicted member exits and rejoins the meeting room within the official minutes.

Step 5: Approval of minutes of the previous meeting.

The Committee must review and validate the minutes of the preceding meeting to maintain an accurate legal and institutional record.

The Member Secretary shall present or digitally project the minutes of the previous meeting for collective review. Members will evaluate the text for accuracy regarding past decisions, modifications, and attendance records. Any identified errors or omissions will be noted by the Secretariat and corrected on the master document. Following the integration of corrections, the Chair will request two separate members to formally move and second the approval of the minutes. The Chair will call for objections. In the absence of any dissent, the Chair will officially declare the minutes approved, confirming them as a true and verified historical record of the committee's business.

Step 6: Discussion of Business arising from the minutes.

The Chair will systematically lead the committee through matters left pending, deferred, or requiring follow-up from previous sessions.

The Chair will report on the status of action items identified in the newly approved minutes, such as investigator responses to conditional approvals or outstanding site monitoring requests. The Chair will moderate the floor discussions regarding these ongoing issues. If a policy interpretation or final decision is required to clear an item, the Chair will call for a formal vote to resolve the matter and guide the committee toward a definitive resolution.

Step 7: Review of protocols and protocol-related submissions (SOP 5 – Expedited Review, SOP 6 Full Review)

This step represents the core evaluative component of the meeting. To preserve the accuracy of the deliberations, the Member Secretary shall ensure the entire session is audio recorded.

The Chair will recognize the assigned Primary Reviewers, request them to present their comprehensive evaluations of their designated protocol dossiers. To maintain consistency, presentations must be systematically driven by institutional criteria, utilizing the REC Reviewer Checklist (Form 4.4) and the Informed Consent Form (ICF) Evaluation

Worksheet (Form 4.5). Each protocol evaluation must strictly prioritize patient safety and rights by addressing issues in the following hierarchical order:

- Ethical issues, risk-benefit ratios
- Scientific validity.
- Informed consent process
- Documentation flaws, and
- Language accessibility.

The primary author or principal investigator of a protocol undergoing full committee review may be invited into the session. Their presence is strictly limited to providing real-time clarifications regarding their study design or safety measures; they must exit before the committee deliberates on a decision. If a protocol requires highly specialized technical knowledge, independent consultants may be invited to present their expert opinions (per SOP 4 & 5). However, they are barred from proposing motions or participating in the final vote.

Following floor discussions, the Chair will steer the committee toward a consensus on one of the following official board actions:

- Approval: The protocol is ethically and scientifically sound; no further modifications are required.
- Minor Modification: The protocol requires simple, specific administrative corrections or text clarifications that can be vetted via an expedited secretariat review.
- Major Modification: The protocol exhibits significant ethical or design flaws and must undergo substantial revisions before being brought back for a full-board review.
- Disapproval: The protocol fails to meet crucial ethical or safety standards, posing unjustifiable risks to human participants.
- Needs More Information: The committee cannot render a fair judgment due to severe data omissions and requests a comprehensive resubmission from the investigator

If an absolute consensus cannot be reached naturally through floor discussions, the Chair will call for a formal vote. The decision will be carried by a simple majority of the voting members present.

The Member Secretary shall record the meeting.

Step 8: Report of results of expedited review (SOP 5).

Protocols that qualified for and underwent expedited review pathways since the last full-board meeting must be officially entered into the committee’s record.

The assigned Primary Reviewers for expedited research will present a streamlined summary of their evaluations and final determinations to the full board. This reporting is strictly for the information of the full committee and to maintain total organizational transparency. Because these protocols have already been vetted and approved via the expedited pathway, floor discussions are generally unnecessary unless a full-board member identifies a critical safety oversight that warrants re-classification. All expedited review outcomes must be formally recorded and appended to the current meeting's minutes.

Step 9: Discussion of operations-related and administrative matters

To prevent administrative matters from encroaching upon the time allocated for critical protocol reviews, general operations will be handled systematically.

The Chair will lead brief discussions regarding pressing institutional operations, including incoming/outgoing external communications, upcoming bioethics training programs, committee accreditation statuses, and membership appointments. To ensure a thorough treatment of institutional governance, a standalone meeting dedicated strictly to administrative, financial, and operational policy matters shall be independently convened at least once every three (3) months.

Step 10: Adjournment

A meeting can only move toward adjournment once every single item listed on the approved agenda has been fully discussed, resolved, or formally deferred to a future session.

The Chair will formally request a motion for adjournment from the floor. One committee member must move for adjournment, and another must second it. The Chair will ask the body if there are any outstanding objections or emergency items. Hearing none, the Chair will officially state the final timestamp and declare the meeting adjourned.

Step 11: Collection, storage, and disposal of meeting materials

To maintain data privacy, institutional confidentiality, and an uncompromised audit trail, post-meeting clean-up must follow strict document-retention guidelines.

Immediately following adjournment, the Administrative Secretary is tasked with collecting all distributed physical notes, provisional documents, and draft checklists used during the session. In strict compliance with SOP 23 - Managing Active Files, the Administrative Secretary will oversee the secure filing and long-term storage of official documents (such as signed attendance sheets, approved agendas, and finalized evaluation checklists). Any duplicate physical printouts, scratch papers, or redundant copies containing confidential investigator data or patient identifiers must be immediately destroyed via secure industrial shredding to prevent data breaches. Digital draft files must

be scrubbed from temporary local drives and safely archived in the committee's encrypted cloud database.

Section 6. Forms

Form 19.1 - Attendance Sheet
Form 4.4 - Protocol Reviewer Form
Form 4.5 - INFORMED Consent worksheet

Section 7. History of SOP

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1	6.21.24	NINO ISMAEL S. PASTOR	DRAFT
2	10.29./24	Aljoriz Dublin & Nino Ismael Pastor	Form labels, Content
3	06.05.26	Nino Ismael Pastor	Form labels Few Content

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SOP NO. 20 - PREPARING THE MINUTES OF THE MEETING

Section 1. Policy Statement

The minutes of the meeting shall be grounded on the approved meeting agenda. This agenda will also be the basis for drafting Decision Letters (Form 4.6) and other documents.

Section 2. Objective of the Activity

The minutes ensure proper documentation of the discussion and decisions in a REC meeting.

Section 3. Scope

This SOP begins with recording the discussion and decisions during the meeting and entering information on the minutes template (Form 20.1). It ends with filing the approved minutes in the REC Meeting files (Form 20.2).

Section 4. Workflow

ACTIVITY	***RESPONSIBILITY***	***TIMELINE***
Step 1: Entry of the discussion and decisions of the previous meeting on the minutes template (Form 20.1)	Administrative Secretary Member Secretary	1 day 4th Monday of current month
Step 2: Notation of the draft minutes of the previous meeting	Chair	
Step 3: Approval of the minutes of the previous meeting in the next REC meeting	Chair and rec Members	1 day 3rd Saturday of next month
Step 4: Preparation of draft minutes	Administrative Secretary Member Secretary	1 day 4th Monday of next month
Step 5: Filing of the approved minutes (SOP on Managing Active Files (SOP 23). Fill-up R.E.C. (Form 20.2)	Administrative Secretary	
	TOTAL	3 days

Section 5. Description of Procedures

Step 1: Entry of the discussion and decisions of the previous meeting on the minutes template (Form 20.1)

During every regular, special, or emergency meeting, the Administrative Secretary is responsible for taking comprehensive, manual shorthand notes. Concurrently, an official digital voice recorder must be used to capture all verbal deliberations, side-table clarifications, and final collegial agreements. Special attention must be dedicated to tracking specific ethical debates, safety concerns, and required adjustments to Informed Consent Forms (ICFs). Following the conclusion of the session, the Administrative Secretary shall synthesize the manual notes and audio recordings, transcribing them directly into the standardized Minutes of the Meeting Template (Form 20.1).

To maintain compliance with international ethical auditing bodies, the draft minutes must explicitly contain the following structural components:

The exact calendar date, geographic or virtual venue, official call-to-order timestamp, and adjournment timestamp.

A detailed list of all members present (including their mode of attendance: face-to-face or online), members absent, and a definitive statement validating the maintenance of a legal quorum throughout the review sessions.

- The full name and designation of the presiding officer directing the meeting.
- A meticulous record of any COI declarations made by members, explicitly including the specific protocol numbers involved, the names of the recused members, and the exact timestamps of when they exited and re-entered the session.
- A chronological summary of discussions matching the approved agenda items, documenting the core arguments, technical advice from independent consultants, and investigator justifications.
- A clear record of the final collective action taken for each protocol (e.g., Approval, Minor Modification, Major Modification, Disapproval, Deferral), along with the specific actionable recommendations or conditions imposed by the board.
- The full name, title, and wet or authenticated digital signature of the Administrative Secretary who compiled and prepared the draft document.

Regular REC board meetings occur systematically on the third Saturday of every month. To maintain operational efficiency, the Administrative Secretary must finalize and securely transmit the initial draft minutes to the Member Secretary on or before the fourth Monday following that meeting (providing an approximate 9-day window for transcription).

Step 2: Review of the Draft Minutes

The Member Secretary shall critically review the draft prepared by the Administrative Secretary. This review serves as a quality control mechanism to verify that all statutory items from the Step 1 checklist are accurately represented. The Member Secretary will cross-reference the draft decisions against the signed REC Reviewer Checklists (Form 4.4) and investigator dossiers handled during the meeting to ensure there are no clerical discrepancies or misinterpretations of the board's final rulings. Any necessary corrections must be applied during this window.

Step 3: Notation of the Draft Minutes of the previous meeting

Following the endorsement of the Member Secretary, the polished draft minutes are routed to the Chair for executive clearance. The REC Chair shall perform a final, comprehensive check of the minutes, ensuring that the tone is appropriately objective, formal, and free of ambiguity. If the document meets all institutional standards, the Chair shall officially notate the draft. This notation serves as an executive clearance, certifying that the document is clean, verified, and ready for full-board visibility.

Once notated, the Administrative Secretary is authorized to officially schedule and append these draft minutes to the distribution packet for the upcoming REC meeting's agenda.

Step 4: Approval of the minutes of the previous meeting in the next REC meeting

The draft minutes remain a provisional document until they are formally validated and adopted by the collective body during a live session.

During the next scheduled REC meeting, the Member Secretary shall project or distribute the notated draft minutes to all members present for their final collective review (per SOP 19). The Chair will invite members to point out any typographical errors or oversights regarding their contributions to the past meeting. If corrections are raised, they are noted for immediate integration. In accordance with parliamentary procedure, the Chair will call for a motion to approve the minutes. One member must formally move to adopt the minutes, and a second member must second the motion. The Chair will ask the floor for any objections. Hearing none, the Chair will officially declare the previous meeting's minutes approved, instantly converting the document from a "Draft" to the final, legally binding institutional record.

Step 5: Preparation of draft minutes

Immediately following the floor approval obtained in Step 4, the Administrative Secretary must finalize the document to prepare it for permanent archival.

The Administrative Secretary must immediately integrate any final amendments or corrections mandated by the board during the floor review. The Administrative Secretary shall scan the documents and paste it in the R.E.C. Meeting Files (Form 20.2). This form acts as an official cover sheet and checklist, confirming that the voice recordings have been reviewed, text has been finalized, all necessary administrative signatures have been collected, and the file is cleared for permanent storage.

Step 6: : Filing of the approved minutes (SOP on Managing Active Files (SOP 23). Fill-up R.E.C. (Form 20.2)

A high-resolution copy of the approved minutes must be printed, signed by the preparing and approving officers, and filed in a dedicated, heavy-duty binder folder. This binder must be locked inside a fireproof, restricted-access filing cabinet located within the secure REC Secretariat office.

The Administrative Secretary must immediately log this entry into the Filing Form Log (Form 4.7a) physically affixed to that specific cabinet or folder, documenting the date of filing and the identity of the archivist to ensure strict chain-of-custody tracking. The finalized digital file must be converted into an undatable PDF format containing the electronic signatures of the Chair and Secretariat. This file must be uploaded securely to the institutional REC Meeting Files (Form 202). The digital file must be named using a standardized institutional nomenclature (e.g., EC_MINUTES_YYYY_MM_DD_FINAL) to enable instantaneous searchability and indexing within the cloud database.

Section 6. Forms

Form 20.1 - Minutes of the Meeting
Form 20.2 – REC Meeting file

Section 7. History of SOP

Version No.	***Date***	***Authors***	***Main Change***
1	6.26.24	NINO ISMAEL S. PASTOR	DRAFT
2	10.30.24	Aljoriz Dublin & Nino Ismael Pastor	Form labels, Form, Content
3	06.06.26	Nino Ismael Pastor	Form labels, few content

Section 8. References

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

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		Date of Approval:	
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SOP NO. 21 - COMMUNICATING REC DECISIONS

Section 1. Policy Statement

The REC is required to send out its decisions and research-related communications on or before the earliest of these two timelines:

- The 1st Friday of every month
- 10 working days after the regular REC monthly meeting

Note: This timeline is strictly conditional upon the REC receiving a complete set of required documents from the researcher.

When the researcher receives the communication, it must meet the following formal standards:

- Clear Content: It must include explicit instructions or recommendations to guide the researcher on their next steps.
- Official Branding: It must be written on the official REC stationery.
- Authentication: It must be officially signed by the REC Chair.

Section 2. **Objective of the Activity.**

This warrants that all stakeholders are correctly, exactly, and promptly informed of the results of deliberations of the REC.

Section 3. Scope

This SOP begins with the finalization of REC or reviewers' recommendations and ends with filing of the documents in the protocol folder and ends updating the Protocol Folder Index (Form 6.1) and the RMSS DATABASE (Form 4.7).

Section 4. Workflow

ACTIVITY	**RESPONSIBILITY**	**TIMELINE**
Step 1: Finalization of recommendations of the committee in case of a full review (SOP 6 Full Review)) or Finalization of recommendations of reviewers (in case of expedited (SOP 5 Expedited Review)	Member Secretary then Chair	1 day 1st Friday every month @ 10 working days after the

Step 2: Transfer information from meeting minutes or reports to REC decision LETTER (Form 4.6)	Administrative Secretary supervised by Member Secretary	regular REC monthly meeting
Step 3: Approval of the REC decision document	Chair	
Step 4: Transmittal of REC decision to the researcher or concerned stakeholder. The Admin Secretary Fill-up Certificate of Exemption from Review (Form 4.1), Approval letter (For 21.1) or Decision Letter (Form 4.6)	Administrative Secretary Member Secretary REC Chair	
Step 5: Filing of the decision document in the correct protocol folder (SOP 23 - Managing Active Files), and update of the Protocol Folder Index (Form 4.9), and update the RMSS DATABASE (Form 4.7) and Filing form Log (Form 4.7a), .	Administrative Secretary	1 day 1st Saturday of every month
	TOTAL	11 days

Section 5. Description of Procedures

Step 1: Finalization of recommendations of the committee in case of a full review (SOP 6 Full Review)) or Finalization of recommendations of reviewers (in case of expedited (SOP 5 Expedited Review).

Following the official adjournment of an institutional review session, all evaluative findings must be systematically finalized and translated into actionable administrative text.

In accordance with SOP 6 (Full Review), the Administrative Secretary shall compile the collective determinations, voting outcomes, and specific ethical or methodological provisions recorded during full committee deliberations.

For Expedited Review (SOP 5 - Expedited Review), the Administrative Secretary shall compile the individual evaluation reports, queries, and specific technical corrections submitted by the designated primary reviewers. The Administrative Secretary, operating under the direct oversight of the Member Secretary, is responsible for accurately encoding these consolidated recommendations into the committee's master data management system. This ensures that no discrepancy exists between the live board discussions and the documented mandates.

Step 2: Transfer information from the meeting minutes or reports to Certificate of Exemption from Review (Form 4.1), REC decision letter (Form 4.6), or Approval letter (For 21.1) .

Once the review outcomes are verified, they must be converted into formal, legally binding correspondence tailored to the specific nature of the board's action.

Under the strict supervision of the Member Secretary, the Administrative Secretary shall extract data from the official meeting minutes or reviewer logs and populate the appropriate institutional templates.

Form 4.1 (Certificate of Exemption from Review) is generated for protocols determined to pose zero or negligible risk, officially exempting them from further oversight. Form 4.6 (REC Decision Letter) is utilized to convey detailed board actions requiring investigator action, specifically outlining mandates for Minor Modifications, Major Modifications, Disapprovals, or formal requests for Clarifications. Form 21.1 (Approval Letter) is issued exclusively when a protocol has met all scientific and ethical thresholds and is granted full clearance to commence data collection. Form 26.1 (Complaint Resolution Form) is compiled to address and document resolved grievances, whistle-blower reports, or participant complaints.

Before any document is cleared for external transmittal, the Member Secretary must conduct a thorough quality-assurance check on the drafts. Upon verification, the Member Secretary shall forward the dossier packet to the Chair for final executive endorsement, notation, and formal signing.

Step 3: Approval of the REC decision document

The Chair retains the ultimate legal and institutional accountability for all outgoing ethical communications and must validate each document before release.

The Chair shall perform a comprehensive review of each drafted decision letter, certificate, and approval document to ensure accuracy, professional tone, and compliance with institutional policies. To prevent administrative delays in ongoing research projects, the Chair must officially approve and sign all finalized decision documents within ten (10) calendar days following the conclusion of the regular REC meeting. This executive window aligns with the standard deadline arriving approximately on the first Friday of every month.

Step 4: Transmittal of REC decision to the researcher or concerned stakeholder. The Admin Secretary Fill-up Certificate of Exemption from Review (Form 4.1), Approval letter (For 21.1) or Decision Letter (Form 4.6).

To guarantee transparency and maintain an ironclad timeline for investigator notifications, a dual-channel transmittal protocol must be executed:

- Digital Dispatch Timeline: The Administrative Secretary must transmit an undatable, authenticated PDF copy of the signed REC decision document to the Principal Investigator's (PI) registered institutional email account exactly ten (10) days after the regular meeting, or on or before the first Friday of every month.

- Physical Handover Notification: In the body of the digital transmittal email, the PI or their authorized research representative shall be formally instructed that the official, wet-signed physical hard copy has been archived and is ready for pickup from the REC Secretariat Office. The recipient must sign an acknowledgment logbook upon physical retrieval.

Step 5: Filing the decision document in the correct protocol folder (SOP 23 - Managing Active Files) and updating the Protocol Folder Index (Form 4.9), Filing Form log (Form 4.7a), and the RMSS DATABASE (Form 4.7).

All outward correspondence signed decision letters, and incoming investigator replies must be bound securely within the specific study's dedicated protocol folder. Under no circumstances may documents from separate research projects be co-mingled.

The Protocol Folder Index (Form 4.9) must be permanently pasted on the interior front cover of the binder file. Each time a new correspondence is added, the Administrative Secretary must immediately log the document chronologically on this index sheet. The placement of the binder within the locked, restricted-access filing cabinets must be tracked in real-time by updating the physical Filing Form Log (Form 4.7a) attached to that designated cabinet zone. Concurrently, the Administrative Secretary must access the cloud-secured Research Management and Submission System (RMSS) Database (Form 4.7).

The tracking profile for the respective protocol must be updated to reflect the current study life-cycle status (e.g., Approved, Pending Modifications, Exempted), including the exact dates of letter generation, transmittal**, and the Chair's sign-off, in full compliance with SOP 23 - Managing Active File**

Section 6. Forms

Form 4.6 - Decision Letter
Form 4.7 - RMSS DATABASE
Form 4.7a – Filing Form log
Form 4.9 - Protocol Folder Index
Form 4.11 - Certificate of Exemption from Review
Form 21.1 - Approval Letter
Form 26.2 – Complaint Resolution Form

Section 7. History of SOP

Version No.	***Date***	***Authors***	***Main Change***
1	6.28.24	NINO ISMAEL S. PASTOR	DRAFT

2	10.30.24	Aljoriz Dublin & Nino Ismael Pastor	Forms, form labels, Content
3	6.11.26	Nino Ismael Pastor	Form labels Few content

Section 8. References

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

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

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

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SOP NO. 22 - MANAGEMENT OF INCOMING/OUTGOING COMMUNICATION

Section 1. Policy Statement

All communications shall be recorded accurately and appropriately in each Protocol Folder Index (Form 4.9), and the Research Monitoring Surveillance Database (Form 4.7) for research-related communications in the RMSS (Form 4.7), the Filing Form Log (Form 4.7a) and/or in Form 1.9 (ARTS) for administrative communications. Incoming communications shall be acted upon promptly.

Section 2. Objective/s of the Activity

This aims to establish accountability to an efficient and effective communication tracking system.

Section 3. Scope

This SOP covers REC procedures to organize incoming and outgoing communications and documents to guide an appropriate REC response. It begins with sorting incoming/outgoing communications, storing or filing incoming/outgoing communications, and updating the Protocol Folder Index (Form 4.9) for the concerned protocol, and the RMSS DATABASE (Form 4.7) for research-related communications or in Form 1.9 (ARTS) for administrative communications. All shall be entered in the Filing Form log (Form 4.7a).

Section 4. Workflow

ACTIVITY	**RESPONSIBILITY**	**TIMELINE**
Step 1: Sorting of incoming/outgoing communications	Administrative Secretary	1 day upon receipt
Step 2: Recording in the RMSS (Form 4.7), Filing form Log (Form 4.7a) of incoming/outgoing communications	Administrative Secretary	
Step 3: Acting on incoming communications	Chair or Member Secretary	5 days post-receipt
Step 4: Filing of incoming/outgoing communications and updating of the Protocol File Index for the concerned protocol (Form 4.9) and the RMSS (Form 4.7) for research-related	Administrative Secretary	1 day post-action

communications or in Form 1.9 (ARTS) for administrative communications. All shall be entered in the Filing Form Log (4.7a)		
	TOTAL	7 days

Section 5. Description of Procedures

Step 1: Sorting of incoming/outgoing communications

All incoming and outgoing correspondence must be subjected to a rigorous taxonomy and sorting protocol immediately upon receipt or generation.

Every piece of communication entering or leaving the REC must feature a clear, descriptive, and unambiguous subject line. Materials must be explicitly categorized into one of the following recognized institutional document classes:

- Official Memoranda (Internal institutional directives)
- Formal Letters (External or sponsor-driven correspondence)
- Electronic Mail (Digital transmissions requiring tracking)
- Form 4.6 (REC Decision Letters)
- Form 21.1 (Official Approval Letters)
- Form 17.1 (Notice of Meetings and Agendas)
- Formal Invitations (For independent consultants or guest advocates)
- Miscellaneous/Other Regulatory Documents

The Administrative Secretary is responsible for physically and digitally sorting these documents into their respective processing streams. Crucially, the Administrative Secretary must document not just the primary document, but also all subsequent responses, board actions, and administrative instructions linked to that specific file. The Member Secretary shall directly supervise the classification and sorting process to ensure that sensitive or urgent protocol-related communications are prioritized for board review.

Step 2: Recording in the RMSS (Form 4.7), Filing form Log (Form 4.7a) of incoming/outgoing communications

Once a document has been classified and sorted, it must be permanently logged into the committee's registry systems to establish an uncompromised administrative audit trail.

The Administrative Secretary must immediately enter the metadata of all incoming and outgoing communications into the master RMSS for the concerned protocol (Form 4.7) and Filing Form Log (Form 4.7a). Under the close supervision of the Member Secretary, the Administrative Secretary must verify that every entry is complete and includes the following tracking parameters without exception:

The exact calendar date and timestamp when the communication was officially received or sent.

A concise summary of the purpose of the communication, including any associated protocol reference numbers.

- The full name, title, and institutional affiliation of the sender, complete with their verified wet or digital signature.
- The full name and signature of the specific REC Secretariat staff member who accepted the document.
- The type of document entered

A clear description of the immediate administrative action taken or the next steps triggered by the communication (e.g., Forwarded to Chair, Filed in Protocol Folder, Deferred to Full-Board Meeting).

Step 3: Acting on incoming communications

All incoming communications must be acted upon using a strict hierarchy of administrative authority.

The Member Secretary is empowered to independently draft and execute responses to routine administrative inquiries, provided these actions fall squarely within their delegated authority and the REC Chair is kept fully appraised of the matter. If an incoming communication involves policy interpretations, legal matters, severe protocol violations, or items exceeding the Secretariat's mandate, the Member Secretary must immediately escalate and refer the matter to the REC Chair. Following explicit instructions or directives from the Chair, the Member Secretary shall draft the official institutional resolution or response. To maintain legal and institutional accountability, ALL outgoing communications must receive the final review, approval, and signature of the REC Chair before dispatch.

All external and official outgoing correspondence must be printed or digitally rendered exclusively on the official GCM institutional letterhead to certify its authenticity.

Step 4: Filing of incoming/outgoing communications and updating of the Protocol File Index and RMSS DATABASE for research-related communications or in Form 1.9 (ARTS) administrative communications. All shall be entered in the Filing Form log (Form 4.7a).

The final stage of the communication lifecycle requires immediate, synchronized archiving across both physical and digital repositories to fulfill regulatory compliance standards.

A. Research- and Protocol-Related Communications

Hard copies of communications tied to an ongoing or completed study must be filed immediately in that study's specific, dedicated protocol folder. The Protocol Folder Index (Form 4.9), which is affixed to the inside front cover of the binder, must be updated chronologically by the Administrative Secretary every single time a new document is inserted. Concurrently, the digital tracking profile for that protocol must be updated within the cloud-secured Research Monitoring Surveillance System(RMSS) Database (Form 4.7) and the Fii9ng Form Log ($.7a).

B. Administrative and Governance Communications

Communications that deal with general committee operations, institutional policies, or non-protocol governance must be routed away from study files and logged securely within Form 1.9 of the Automated Research Tracking and Submission System (ARTSS).

C. Final Chain of Custody Securement

For both research and administrative hard copies, the Administrative Secretary must record the exact storage location and filing date into the physical Filing Form Log (Form 4.7a) and the digital RMSS (Form 4.7) attached to the locked, fireproof storage cabinets.

This multi-tiered data storage and encryption process shall be executed by the Administrative Secretary under the strict quality-assurance verification of the Member Secretary, in full compliance with SOP 23 - Managing Active Files.

Section 6. Forms

Form 4.7a – Filing Form Log
Form 4.9 - Protocol Folder Index
Form 4.7 - Research Monitoring Surveillance System
Form 4.7a – Filing Form Log
Form 1.9 Administrative `Research Tracking System

Section 7. History of the SOP

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1	6.28.24	NINO ISMAEL S. PASTOR	DRAFT
2	10.30.24	Aljoriz Dublin & Nino Ismael Pastor	Forms, Form labels, Content
3	06.06.26	Nino Ismael Pastor	Form labels, Few Content

Section 8. References

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SOP NO. 23 - MANAGEMENT OF ACTIVE FILES

Section 1. Policy Statement

The Research Ethics Committee (REC) should maintain a rigorous information-management framework. The security and confidentiality of all files shall be strictly maintained in compliance with the Data Privacy Act. Hard copies of documents must be safeguarded in secured cabinets within a locked room. Digital records must be backed up twice by the Administrative Secretary before the end of each working day, with one backup copy securely held by the Member Secretary. To ensure security, efficient identification, and authorized access, all files shall remain under the custody of the Member Secretary. Access to these documents is strictly governed by the SOP on Managing Access to Confidential Files (SOP 25).

Section 2. Objectives

This SOP defines the procedures for receiving, labeling, retrieving, releasing, storing, and maintaining hard and digital copies of active files. It aims to ensure information accessibility, facilitate the efficient retrieval of current files, and guarantee the protection of confidential records.

Section 3. Scope

This SOP governs the organization and management of receiving, classifying, encoding, labeling, updating, storing, and maintaining documents—including initial submissions, resubmissions, and revisions—in accordance with existing regulations. The process begins with identifying the category of the received document and concludes with the periodic updating of the file.

Section 4. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Classification and coding of Active Files	Member Secretary	1-day post-receipt
Step 2.: Preparation of the Protocol Folder Index (Form 4.9) or Administrative Research Tracking System (Form 1.9)	Administrative Secretary	
Step 3: Storage of Active Files. Update protocol folder index (Form 4.9), RMSS	Administrative Secretary	1-day post-coding

(Form 4.7), or ARTS (Form 1.9). ALL are entered in the Filing Form Log (Form 4.7a)		
Step 4: Periodic updating of the Files: ● Protocol Folder Index (Form 4.9), ● Form 4.7a Filing Form Log ● RMSS DATABASE (Form 4.7), Approval Letter (Form 21.1)	Member Secretary Administrative Secretary	PRN

Section 5. Description of Procedure

Step 1. **Classification and coding of active files**:

A protocol file is officially designated as "Active" immediately upon its initial submission to the REC Secretariat for ethical review. It remains in this state throughout its active implementation, continuing annual reviews, and post-approval monitoring phases. A file transitions to an "Inactive" state when the research lifecycle concludes. This occurs upon the submission and board acceptance of a Final Close-Out Report (e.g., a successful medical or academic proposal oral defense), an official written request for withdrawal by the Principal Investigator (PI), or an executive board action resulting in early termination.

All incoming documents must be classified into specific administrative or research tracks, logged in the RMSS (Form 4.7), Filing Form Log (Form 4.7a), Protocol Folder Index (For 4.9) and/or the ARTS (Form 1.9) indexed across institutional systems.

Research-Related Files (Protocol Folder Index Form 4.9) or in (RMSS Database Form 4.7)

Initial submissions, resubmissions, chronological protocol versions, related study documents (Informed Consent Forms [ICFs], Case Report Forms [CRFs], recruitment advertisements, patient diaries), formal amendments, decision letters, approval letters, continuing review applications, progress reports, serious adverse event (SAE) logs, suspected unexpected serious adverse reaction (SUSAR) reports, protocol deviation/violation filings, site visit reports, patient queries/complaints, and early termination or final close-out reports.

Administrative Files (Administrative Research Tracking System (ARTSS - Form 1.9) or REC Meeting Files (Form 20.2)

Institutional emails regarding operations, administrative incident reports, REC activity invitations, institutional memoranda, notices of meetings, provisional and final agendas, previous meeting minutes, safety and strategic blueprints, work and financial plans, purchase requests, equipment maintenance records, and general secretariat records.

Every research proposal submitted shall immediately be assigned a unique, immutable alphanumeric identity code by the Secretariat. This tracking number must be utilized across all subsequent correspondence, amendments, and Committee actions. The standardized construction of the institutional code follows a strict chronological model:

[Year of Submission]−[Month/Day of Receipt]−[Sequential Four-Digit Identifier]

Example 1 (First Submission of the day): 2026 – 06/11 – 0001

Example 2 (Second Submission of the day): 2026 – 06/11 – 0002

Example n (Subsequent Submissions): 2026 – 06/11 – 000n

To enable rapid visual auditing within the secure archive room, the committee utilizes a strict, color-coded binding folder standard (1-inch-thick plastic binders with secure vertical fasteners). The PI is required to provide these folders upon submission or transition milestones. If the specified color binders are unavailable, a heavy-duty black binder may be substituted, provided a prominent, color-matching institutional sticker is permanently affixed to the center front cover.

- Blue Binders: Reserved exclusively for Active Files currently undergoing review or active field implementation.
- Green Binders: Reserved for Completed Files that have successfully submitted an approved Final Report.
- Black Binders: Reserved for Terminated Files that have been halted early due to safety or compliance issues.
- Yellow Binders: Reserved for Inactive/Withdrawn Files where research never officially commenced.

Step 2.: Preparation of the Protocol Folder Index (Form 4.9) or Administrative Research Tracking System (Form 1.9)

Upon submission of a new study, the PI must provide the primary active blue binder alongside four (4) empty, 1-inch-thick plastic binders in the remaining lifecycle colors (Green, Black, and Yellow) to accommodate future study transitions.

The Administrative Secretary is responsible for the physical assembly of the master research file. The front cover and the vertical spine of the active blue binder must be legibly labeled with the following metadata:

- REC Unique Protocol Code: (e.g., YYYY – MM/DD – NNNN- key word)
- Complete Study Title: (Including active version numbers and dates)
- Proponent Details: Full family name and initials of the Principal Investigator.
- Sponsorship Metrics: Name of the corporate sponsor, funding agency, or institutional grant provider.

To ensure internal inventory integrity, the Administrative Secretary must fill up the Protocol Folder Index (Form 4.9) and permanently paste it to the interior front cover of the binder. Under the direct supervision of the Member Secretary, every document embedded within the folder must be explicitly categorized, titled, and recorded on this index sheet in chronological order.

Step 3: Storage of Active Files. Update protocol folder index (Form 4.9), RMSS (Form 4.7), or ARTS (Form 1.9). ALL are entered in the Filing Form Log (Form 4.7a).

The storage of ethics committee files is highly regulated to preserve participant confidentiality and satisfy international audit readiness.

The pathway of a submitted protocol is shown below.

1. Active File Room
2. Study Concluded
3. Inactive Cabinet: after 5 Years
4. Executive Incineration Witnessed by Member Sec.

Active Blue binders must be stored horizontally and arranged in ascending sequential order according to their Protocol Code Number within the designated Active File Cabinet. This cabinet must remain locked at all times inside the restricted-access REC Secretariat Office. Access permissions are strictly limited to the REC Chair, Member Secretary, and authorized Administrative Secretary.

To optimize physical storage limits, the Member Secretary shall audit multi-center studies to ensure that central documents (e.g., investigator brochures, core protocols) are not redundantly duplicated across separate site folders. Storage units must feature explicit, high-visibility external face labels categorized by the Year of Protocol Submission. Inactive, completed, withdrawn, and terminated files are immediately moved to a separate Inactive Storage Cabinet. These files must be retained in their physical format for a mandatory minimum period of five (5) years. Upon completing the 5-year retention cycle, the physical files must be destroyed via secure incineration or heavy-duty industrial shredding, executed in the mandatory presence of the Member Secretary to verify absolute data destruction. Validated digital clones of the archives may be maintained indefinitely within the cloud server database, contingent upon institutional data storage capacities.

Step 4: Periodic updating of the Files: Protocol Folder Index (Form 4.9), Form 4.7a Filing Form Log , RMSS DATABASE (Form 4.7), Approval Letter (Form 21.1)

The Administrative Secretary update the protocol folders regularly. New materials must be integrated chronologically, ensuring that the most recently received document sits topmost within its respective section. Every time a modification, report, or letter is filed,

the Administrative Secretary must immediately append the item to the internal Protocol Folder Index (Form 4.9) on the inside front cover of the blue folder.

The active update cycle must capture and cross-reference the following:

- Amending text and revised protocol versions (stamped with approval dates).
- Corresponding sign-off and dated reviewer Assessment Forms for every submitted report.
- Official excerpts of the Minutes of Meetings where the specific protocol or its safety reports were tackled by the board.
- Final signed copy of the Approval Letter (Form 21.1) or associated decision communications.

Concurrently with physical filings, the Administrative Secretary must transcribe these updates into the digital RMSS Database (Form 4.7) and log the physical cabinet movement into the Filing Form Log (Form 4.7a), maintaining perfect symmetry between digital records and physical assets under the quality assurance of the Member Secretary.

Section 6. Forms:

Form 1.9 – ARTS
Form 4.7 – RMSS database
Form 4.7a – Filing Form Log
Form 4.9 - Protocol Folder Index
Form 21.1 – Approval Letter

Section 7. History of SOP

Version No.	***Date***	***Authors***	***Main Change***
1	6.20.24	NINO ISMAEL S. PASTOR	DRAFT
2	10.31.24	Aljoriz Dublin & Nino Ismael Pastor	Contents, Form labels, Form
3	06.06.26	Nino Ismael Pastor	Form Labels Few content

Section 8. References

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

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

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

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

UPMREB. (2012). *SOPs & Formks*. 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.

SOP NO. 24 - ARCHIVING

Section 1. Policy Statement

The Research Ethics Committee (REC) must formally close out study files to ensure that all research activities involving human participants are accounted for and concluded ethically. Terminated, completed, or inactive protocol files will be kept in a separate filing cabinet for five years, after which they may be incinerated or shredded. The protocol folder binders shall be as follows:

- Active files (Blue)
- Completed files (Green)
- Terminated files (Black)
- Inactive files (Yellow).

Approved proposals that have not been updated for five months may be considered inactive after informing the PI. Efficient retrieval of information from inactive files shall be kept for future reference and compliance with national and international guidelines

Section 2. Objective/s of the Activity

This SOP describes archiving inactive, terminated, or completed protocols guarantees well-organized retrieval of information from the files for future reference and observance of national and international guidelines.

Section 3. Scope

This SOP begins with the acceptance of final reports, early termination reports, identification of a protocol as inactive, inclusion of the files in the archives, and ends with updating the RMSS DATABASE (Form 4.7), Filing Form Log (Form 4.7a) and/or ARTSS (Form 1.9).

Section 4. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Acceptance and selection of Final Report (Form 13.1) or Early Termination Reports (Form 14.1) and classifying a Protocol as Inactive.	(For final & terminal files): Chair & REC members	1 day PRN

	(For inactive files): Member Secretary, Administrative Secretary	
Step 2: Updating of corresponding protocol folder	Administrative Secretary	3 days post-acceptance/selection
Step 3: Transfer the protocol to another folder, place it in the archives, and update the RMSS DATABASE (Form 4.7), Filing Form Log (Form 4.7a) & Protocol Folder Index (Form 4.9)	Administrative Secretary	1-day post-update
	TOTAL	5 days

Section 5. Description of Procedures

Step 1: Acceptance and selection of Final or Early Termination Reports (Form 14.1), Final Report (Form 13.1), and classifying a Protocol as Inactive.

The Administrative Secretary shall formally accept incoming close-out dossiers—specifically Form 13.1 (Final Close-Out Report) or Form 14.1 (Early Termination Report)—submitted by the Principal Investigator (PI). Upon verifying the completeness of the submission packet, the Administrative Secretary shall immediately alert the Member Secretary.

A research protocol folder shall be officially slated for transition out of active status under any of the following parameters:

- The study has reached its natural end, and a satisfactory Form 13.1 has been vetted.
- The study is halted prematurely by the sponsor, investigator, or board via Form 14.1 due to safety, funding, or recruitment issues.
- If a PI fails to respond to outstanding board conditions, submit mandatory modifications, or answer formal ethical queries within five (5) months from the documented receipt of an REC decision letter, the file is automatically classified as administratively non-compliant and marked for an "Inactive" transition.

The Member Secretary shall slate these pending closures and non-compliance files onto the draft agenda for the upcoming regular REC session. During the live meeting, the full committee shall deliberate on the reports (per SOP 13 and SOP 14). The Committee will vote to officially declare the protocol status as Completed, Terminated, or Administratively Inactive, recording the final decision within the meeting minutes to legalize the file's state change.

Step 2: Updating of corresponding protocol folder.

Following the formal Committee action, the physical and digital records of the protocol must be immediately consolidated to reflect its new legal status.

The Administrative Secretary shall extract the specific, finalized excerpt from the approved meeting minutes detailing the board's decision regarding the study closure. This official minute's excerpt, along with the signed reviewer assessment forms and the original Form 13.1 or Form 14.1, must be physically filed directly into the corresponding study binder. This ensures that any external auditor can instantly verify the exact meeting date and rationale behind the study's official closure.

Step 3: Transfer the protocol to another folder, place it in the archives, and update the RMSS DATABASE (Form 4.7), Filing Form Log (Form 4.7a), & Protocol Folder Index (Form 4.9).

The final stage of the study closure lifecycle requires a thorough audit of the folder's contents before it is moved to long-term storage. It will follow the following steps:

1. Verify Folder Contents
2. Purge Duplicates/Drafts
3. Re-house into Green/Black/Yellow Binder
4. Sync RMSS (For 4.7) & Filing Form Log (Form 4.7a)
5. Storage in Cabinets

The Administrative Secretary must perform a page-by-page audit of the folder against the Protocol Folder Index (Form 4.9) to confirm that all mandatory historical records—including all past versions of protocols, consent forms, amendments, and signed approval letters—are completely present. S/he shall carefully extract and securely shred all non-essential administrative clutter, such as duplicate physical printouts, intermediate working drafts, and informal sticky notes, leaving a clean and concise regulatory dossier.

The Protocol Folder Index must be updated to reflect the final inventory, signed, and dated by the archivist. To maintain the visual integrity of the archive room as mandated by SOP 23, the physical documents must be extracted from their active blue binder and re-housed into a new 1-inch-thick plastic binder reflecting the board's final classification:

- Green Binder: For successfully concluded studies (Form 13.1).
- Black Binder: For studies halted early due to safety or compliance issues (Form 14.1).
- Yellow Binder: For studies abandoned by the investigator or declared administratively non-compliant via the 5-month rule.

The Administrative Secretary shall log into the cloud-secured Research Management and Submission System (RMSS) Database (Form 4.7) and change the status of the protocol from "Active" to its corresponding inactive designation (Completed, Terminated, or Inactive), capturing the final date of board closure. The new physical binder must be placed into the dedicated Inactive Storage Cabinet. The exact location, cabinet number,

shelf row, and filing date must be logged into the master Filing Form Log (Form 4.7a). This entire archiving sequence shall be executed by the Administrative Secretary under the strict quality-assurance verification and final sign-off of the Member Secretary.

Section 6. Forms

Form 13.1 – Final Report
Form 14.1 – Early Termination Report
Form 4.7 – RMSS Database
Form 4.7a – Filing Form Log
Form 4.9 – Protocol Folder Index

Section 7. History of SOP

Version No.	***Date***	***Authors***	***Main Change***
1	6.26.24	NINO ISMAEL S. PASTOR	DRAFT
2	10.31.24	Aljoriz Dublin & Nino Ismael Pastor	Form labels, content

Section 8. References

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

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

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

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

UPMREB. (2012). *SOPs & Formks*. 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.

SOP NO. 25 - MANAGEMENT OF ACCESS TO CONFIDENTIAL FILES

Section 1. Policy Statement

The REC shall strictly respect data privacy, intellectual property rights, and the confidentiality of all files. All documents processed by the Research Ethics Committee (REC) are treated as restricted assets.

Access to these files shall be strictly managed to protect researchers, participants, and the REC. Access to confidential files is restricted to REC members and the Administrative Secretary. Other parties with a legitimate interest (e.g., educational authorities, government agencies, or sponsors) may be granted access to specific files only upon providing proper justification. Researchers and investigators shall be permitted access only to their own protocol files upon formal request. No confidential files may be released to external parties without formal committee oversight.

Section 2. Objectives

The objective of this SOP is to manage REC file access in order to protect researchers' intellectual property rights, safeguard the data privacy of human participants, and uphold the REC's institutional credibility and integrity.

Section 3. Scope

This SOP covers the processes for classifying documents, accessing confidential files, and handling or distributing records. The workflow begins with the receipt of an access request, proceeds through document classification, and concludes with the return of the documents to their respective protocol folders.

Section 4. Workflow

ACTIVITY	**RESPONSIBILITY**	**TIMELINE**
Step 1: Classifying documents	Member Secretary	1 day
Step 2: Receipt and logging of request for access to confidential files	Administrative Secretary	1 day
Step 3: Approval of requests for access and retrieval of documents	Member Secretary Chair REC Members	1 day Every 3rd Saturday of the month

Step 4: Supervision of the use of the retrieved document	Administrative Secretary	1-day post-approval
Step 5: Return of the document to the files	Administrative Secretary	
	TOTAL	5 days

Section 5. Description of Procedures

Step 1: Classifying documents.

Under the direction of the Member Secretary, all data files are systematically categorized under a strict confidentiality framework.

There are two categories of documents: Protocol related and Administration related.

The first category covers all information linked to a submitted protocol dossier. These assets are protected against unauthorized competitive exposure or data leaks and include:

- Full clinical study protocols and investigator brochures (including all revised versions).
- Informed Consent Forms (ICFs) and participant-facing recruitment materials.
- Comprehensive Curriculum Vitae (CVs), medical licenses, and training certificates of study authors.
- Laboratory certificates, reference ranges, and diagnostic data.
- All written and electronic correspondence exchanged between the PI, sponsor, and the REC.
- The digital profiles within the Research Management and Submission System (RMSS) database.

The second category covers administrative and committee governance files. This category covers internal operations, reviewer evaluations, and institutional records, which are protected to ensure uncompromised ethical oversight:

- Independent reviewer evaluation reports and peer-review notes.
- REC board member CVs, training profiles, and institutional appointment letters.
- Official Minutes of Meetings and Provisional or Final Agendas.
- Executed Form 1.5 (Conflict of Interest Disclosures) and signed institutional Confidentiality Agreements.
- Executed Data Privacy Consent Forms, institutional endorsements, and core system tracking logs within the Automated Research Tracking and Submission System (ARTSS).

Step 2: Receipt and logging of request for access to confidential files

Confidential REC files are stored in a secure environment. Access by internal or external entities is strictly regulated through a formal credentials-verification pipeline.

Active REC Board Members, Independent Consultants, and the Secretariat staff are granted operational access to dossiers for standard review purposes. To maintain this access, individuals must have a valid, signed copy of Form 25.1 (Confidentiality Agreement) and Form 1.5 (Conflict of Interest Disclosure) on file with the institution.

Individuals outside the active REC roster must submit a formal, written request detailing the specific files required and the legitimate justification for access. External applicants must fully execute the non-member variant of Form 25.1 (Confidentiality Agreement) before their request can be processed.

Accredited government regulatory authorities (e.g., the Food and Drug Administration [FDA] Director or legal officers acting under a court order) may retrieve records, provided the request falls within their statutory mandate. Regulatory requests require reasonable written notice signed by the agency's recognized commanding official.

Upon receiving any access request, the Administrative Secretary must log the application metadata into the master RMSS (Form 4.7), the Filing Form Log (Form 4.7a) and cross-reference it within the specific study's Protocol Folder Index (Form 4.9) or the Reviewer Registry inside ARTSS (Form 1.9). The file is then routed to the Member Secretary for initial administrative review.

Step 3: Approval of requests for access and retrieval of documents.

The Member Secretary shall place all evaluated external access applications onto the agenda for the next scheduled regular REC session. The full committee shall deliberate on the request, evaluating the applicant's credentials, the scope of the requested files, and potential risks to participant anonymity or investigator intellectual property. Formal approval requires a simple majority vote from the board. Once approved, the Administrative Secretary shall contact the applicant to sign the final Form 25.1 Request and Confidentiality Binding Agreement, which details the strict parameters of document usage.

Step 4: Supervision of the use of the retrieved document

Once approved and signed, file release and utilization are conducted under the direct supervision of the Secretariat to prevent data loss or unauthorized reproduction. Before retrieving any files from the secure vaults, the Administrative Secretary must verify that the approval is recorded in the Filing Form Log (Form 4.7a), the Protocol Folder Index (Form 4.9), or Form 1.9 (ARTSS). All retrieved physical files are strictly limited to room-use only within the secure confines of the REC Secretariat Office. Materials may not be left unattended or removed from the room under any circumstances. Photocopying, scanning, or digital photographing of confidential files is prohibited. Duplication requests are evaluated on a case-by-case basis and are typically limited to the Principal Investigator or authorized regulatory inspectors.

Step 5: Return of document to the files

Following the conclusion of the approved viewing session, the files must be returned to long-term storage and the tracking systems updated.

The Administrative Secretary shall conduct an immediate, page-by-page audit of the physical folder against the master Protocol Folder Index (Form 4.9) to confirm that all original pages, attachments, and signatures are intact and unaltered. The folder must be returned to its designated location within the locked, fireproof active or inactive filing cabinets. The Administrative Secretary shall update the cloud-secured RMSS Database (Form 4.7) and log the official return date, timestamp, and the archivist's initials into the Filing Form Log (Form 4.7a). This administrative step closes the tracking loop and ensures the system reflects that the file is secure.

Section 6. Forms

Form 1.9 - ARTSS
Form 4.7 – RMSS database
Form 4.7a – Filing Form Log
Form 4.9 -, Protocol Folder Index
Form 25.1 - Confidentiality Agreement

Section 7. History of SOP

Version No.	Date	Authors	Main Change
1	7.2.24	NINO ISMAEL S. PASTOR	DRAFT
2	11.01.24		Forms, form labels, content
3	06.06.26	Nino Ismael Pastor	Form labels Few content

Section 8. References

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

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

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

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

UPMREB. (2012). *SOPs & Formks*. 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.

SOP NO. 26 - MANAGEMENT OF QUERIES AND COMPLAINTS

Section 1. Policy Statement

The REC shall promptly and accurately address all queries and complaints from clients, patients, community members, research participants, or other stakeholders while exercising due diligence.

All queries and complaints shall be referred to the Chair, who will determine whether they can be resolved by the Member Secretary or the primary reviewer, or if they require a full Committee decision.

Complaints involving minimal risk shall be referred to the primary reviewers for resolution. Complaints involving more than minimal risk shall be elevated to a special meeting within 48 hours for deliberation by the committee *en banc*, with the primary reviewers leading the discussion.

Section 2. Objectives

The objective of this SOP is to define the procedures for managing all requests, queries, and complaints regarding GCM research in order to foster public trust and institutional confidence in the GCM REC.

Section 3. Scope

This SOP applies to the entire lifecycle of managing stakeholder input. The workflow begins with the receipt, logging, and acknowledgment of requests, queries, or complaints regarding GCM research. It extends through inclusion in the REC meeting agenda, documentation of the formal response, and notification of the stakeholders, and concludes with the final update to the Protocol Folder Index.

Section 4. Workflow

ACTIVITY	**RESPONSIBILITY**	**TIMELINE**
Step 1: Receive the query or complaint	Administrative Secretary	1 day
Step 2: Review the query/complaint	Member Secretary Chair	2 days-post receipt

Step 3: Discuss in a convened meeting or report the decision/action taken to the full Committee	Chair REC members	1 day: regular or special meeting
Step 4: Communicate REC response	Member Secretary Chair	2 days post-meeting
Step 5: File pertinent documents	Administrative Secretary	
	TOTAL	6 days

Section 5. Description of Procedures

Step 1: Receive the query or complaint

The request, query, or complaint related to research participation or research protocols may come from research participants, community members, or other interested parties. The Administrative Secretary receives, studies, and writes/documents the request, query, or complaint on Form 26.1 (Query/Complaint form). The Administrative Secretary records the submitted document in the Filing Form Log (Form 4.7a), RMSS (Form 4.7) of that concerned research and the Protocol Folder Index (Form 4.9) of the research in question). The Administrative Secretary responds to the request, query, or complaint if it is within his/her authority to do so or refers this to the Member-Secretary for appropriate action.

Step 2: Review the query/complaint

The Member-Secretary reviews the request, query, or complaint. The Member Secretary responds to the request, query, or complaint if it is within his/her authority to do so but informs the Chair or refers this to the Primary Reviewer for appropriate action and informs the Chair about the request, query, or complaint.

The reviewer assesses the query/complaint for the level of risk generated by the query/complaint. The primary reviewer may act if the risk is minimal. If the query/complaint generates more than minimal risk, the Primary Reviewer will refer it to the Chair who decides to call an emergency Full Committee meeting within 48 hours.

A request, query, or complaint is considered serious if it may hurt the integrity and reputation of the REC, any of its members, or the safety and well-being of participants, community members, and/or other stakeholders

The PI may be contacted to provide clarification or further information.

Step 3: Discuss in a convened meeting or report the decision/action taken to full Committee.

The REC Chair calls for an emergency Full Committee meeting for discussion of a serious requests, queries, or complaints. The REC members arrive at a decision, and the primary reviewer(s) accomplish the Form 26.2 (Complaint Resolution Form).

The primary reviewer(s) accomplish Form 26.2 - Complaints Resolution Form for minimal risk complaints.

For more than minimal risk, the committee may choose any of the following options:

- Constitute a site-visiting team to gather more information, verification, and clarification regarding the source and cause/s of the complaint for its early resolution.
- Designate the primary reviewers to meet with the complainants and the researcher (preferably separately) for clarification of issues and obtain suggestions for resolution.
- Formulate recommendation if satisfied with the adequacy of information:

    - request for explanation/justification from the researcher
    - accept the request/demand of the participant
    - suspension of further recruitment
    - amendment of protocol and re-consent of participants
    - others

Step 4: Communicate REC response.

The Member Secretary may respond to the query or complaint if it is within the Competence to do so but must inform the Chair.

For minimal risk complaints, the primary reviewer(s) accomplish Form 26.2 (Complaints Resolution Form) and asks the Member Secretary to send it to the Complainant but first ask the Chair's approval and notation before sending it to the Complainant(s).

For complaints with more than minimal risk, the REC members arrive at a decision during a Full Committee meeting, and after the discussion, the primary reviewer(s) fill-up Form 26.2 (Complaints Resolution Form). The Member Secretary then sends the duly signed Form by the Chair or any communication to the complainant(s) (See SOP 21 - on Communicating REC Decisions.

Step 5: File pertinent documents

The Administrative Secretary collects and files the accomplished Forms, communication documents/letters, the letter of request, inquiry, or complaint, the excerpts of the meeting minutes when this matter was deliberated or reported, and other related documents in the correct protocol folder.

The REC Administrative Secretary updates the protocol folder index (Form 4.9), records the entry in the Filing Form Log (Form 4.7a) and the RMSS DATABASE (Form 4.7).

Section 6. Forms:

Form 4.7 – RMSS Data Base
Form 4.7a – Filing Form Log
Form 4.9 – Protocol Folder Index
Form 26.1 – Query Complaint Form.
Form 26.2 - Complaints Resolution Form

Section 7. History of SOP:

Version No.	***Date***	***Authors***	***Main Change***
1	6.28.24	Nino Ismael S. Pastor	DRAFT
	11.05.24	Aljoriz Dublin & Nino Ismael Pastor	Forms. Form Labels, Content
3	06.06.26	Nino Ismael Pastor	Form labels Few content

Section 8. References

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

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

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

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

UPMREB. (2012). *SOPs & Formks*. 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.

Gullas College of *Medicine* **RESEARCH ETHICS COMMITTEE**	Ethos Universitas HONORARY COMPANION	Version No:	Draft
		Date of Approval:	
		Effectivity Date:	

SOP NO. 27 - WRITING AND REVISING SOPS

Section 1. Policy Statement

The REC shall annually review its set of SOPs to determine its current relevance and effectiveness to its operations.

Section 2. Objective of the Activity

To maintain the SOP manual's relevance and effectiveness it shall be regularly revise and rewritten.

Section 3. Scope

This SOP applies to all REC activities involved in the development of its SOPs and their revisions as published and distributed by the institution. This SOP begins with the proposal and approval for revision or writing of a new SOP and ends with the inclusion of the new or revised SOP in the SOP Manual and its dissemination.

Section 4. Workflow

ACTIVITY	**RESPONSIBILITY**	**TIMELINE**
Step 1: Propose a revision or writing of a new SOP	Any REC Member	1 day
Step 2: Designation of the SOP drafting Team	Chair	1-day post-receipt of proposal
Step 3: Drafting, Structuring, and Formatting of New or Revised SOPs	SOP Team	PRN
Step 4: Review and finalization of SOP	Chair REC Members	1 day 3rd Saturday of every month
Step 5: Executive Submission to Institutional Authorities	Chair GCM President	10 days post-meeting approval
Step 6: Integration, Archiving, and Stakeholder Dissemination	REC Admin Secretary	5 days post-approval by GCM authority
	TOTAL	@ 18 days

Section 5. Description of Procedures

Step 1: Propose a revision or writing of a new SOP

Any two (2) active members of the Research Ethics Committee (REC) may formally file a resolution to propose amendments, revisions, or deletions to existing Standard Operating Procedures (SOPs). This resolution must be presented openly during a regularly scheduled REC meeting for preliminary Committee consideration.

Step 2: Designation and Alignment of the SOP Drafting Team

If the Committee raises no formal objections to the initial resolution, the REC Chair shall officially constitute a dedicated, volunteer SOP Team. This team will comprise representatives from the REC Research Department and the Center for Health Research and Innovation (CHRI) who possess relevant procedural expertise.

Following the formation of this team, the Member Secretary (MS) is tasked with formally integrating the proposed initiative into the provisional agenda (**Form 18.1**) for detailed deliberation at the next scheduled committee meeting.

Step 3: Drafting, Structuring, and Formatting of New or Revised SOPs

The designated SOP Team must utilize the most recent edition of the Philippine Health Research Ethics Committee (PHREB) SOP Workbook, alongside other validated national and international ethical frameworks, to guide the drafting process.

To ensure institutional uniformity and automated document indexing, the drafting process must comply with the following technical and structural regulations:

A. Typography and System Formatting

- The document title and all major section headers must strictly utilize the **HEADING 1** formatting style in Microsoft Word. This setting is mandatory to ensure the automated generation of an accurate Table of Contents.
- The document alphanumeric coding must follow a strict sequential numbering and version tracking schema:

  SOP [Number] Version [Number] (Starting at 01, e.g., SOP 1 Version 1.0)

B. Document Template Requirements

All drafts must be composed exclusively on the most up-to-date layout of the official REC letterhead. The content must include the following eight (8) mandatory components:

- **Title:** A clear, concise, and highly descriptive designation of the specific procedural workflow.

- **Section 1. Policy Statement:** A high-level directive outlining the core principles, ethical standards, and legal compliance mandates governing the SOP.
- **Section 2. Objectives of the Activity:** A detailed statement defining the explicit administrative purpose and the expected operational outcomes of the protocol.
- **Section 3. Scope:** An exhaustive demarcation identifying the boundaries, operational extent, inclusions, and inherent limitations of the SOP.
- **Section 4. Workflow:** A clear, sequential graphic representation (such as a flowchart) illustrating the critical steps necessary to execute the SOP, explicitly identifying the personnel or entities responsible for each phase.
- **Section 5. Detailed Instructions:** A comprehensive, step-by-step prose elaboration of the individual phases mapped out in the visual workflow.
- **Section 6. Forms:** A catalog of all official documents, templates, and logs that must be completed by the respective stakeholders under this SOP.
- **Section 7. Document History:** A matrix tracking the lineage of the document from its initial draft to its final configuration. This section must tabulate the authors, specific version markers, dates of modification, and summarized justifications for all primary changes.
- **Section 8. References:** An exhaustive list of the legal instruments, institutional guidelines, external datasets, or peripheral SOPs utilized to establish the framework for the current document.

C. Manual Organization and Appendices

- **Glossary Consolidation:** All acronyms, specialized technical terminology, and operational definitions will be extracted from individual drafts and consolidated into a unified Glossary section located at the end of the master SOP Manual.
- **Appendix Integration:** All functional, blank templates and administrative forms associated with the SOP must be cleanly separated from the main body text and incorporated into the designated Appendices.

Step 4: Multi-Stage Review and Committee Approval

To facilitate a thorough ethical and operational analysis, the complete draft version of the proposed SOP must be distributed electronically or physically to all standing REC members exactly **one (1) month prior** to the next regular meeting. All recipients are required to review the text critically and document their professional notes or recommendations before the floor opens for discussion.

The review process will proceed based on Committee consensus:

1. **When Amendments Are Requested:** If comments or revisions are raised during the meeting, the Member Secretary will log these critiques in the current meeting minutes (**Form 20.1**). The SOP Team will modify the draft as instructed, and the

Member Secretary will schedule a follow-up review on the agenda of the subsequent meeting to evaluate the adjustments.

2. **When No Amendments Are Requested:** If the Committee presents no further objections or comments, two (2) REC members may immediately move to file a resolution for formal approval during the session. The Member Secretary will record this final authorization in the current meeting minutes (**Form 20.1**).

Step 5: Executive Submission to Institutional Authorities

Following Committee approval, the finalized draft is not considered legally binding until it undergoes institutional review. The final text must be formally endorsed and signed into effect by the President of Gullas College of Medicine (GCM).

Step 6: Integration, Archiving, and Stakeholder Dissemination

A. Document Distribution and Public Access

Upon receiving executive approval, the Member Secretary is responsible for updating the master SOP Manual. Distribution will be handled across physical and electronic platforms:

- **Hard Copies:** Printed versions of the newly approved SOP will be systematically distributed to every active REC Member, the Institutional Librarian, the Chairperson of the Research Department, the College Dean, and the CHRI Director.
- **Digital Copies:** Secure electronic copies (PDF format) will be uploaded to the GC of BRET Reviewers database and published directly onto the official CHRI website for public transparency.
-

B. Retention and Archival Protocols

To preserve historical records and ensure strict version control, all outmoded iterations of the document are immediately decommissioned. Superseded SOPs must be retained in their entirety, clearly stamped with a permanent **"SUPERSEDED"** watermark, and safely archived in the REC Historical File under the direct care of the Member Secretary.

C. Personnel Training and Implementation Timeline

Prior to enforcement, all active REC members and administrative staff must undergo formal training to guarantee proficient execution of the updated protocols.

- Following the completion of training, individual Curriculum Vitae (**Form 1.7**) and the corresponding Attendance and Training Records (**ARTS Form 1.9**) must be updated immediately to maintain institutional compliance.

- The definitive **Date of Effectivity** for any new or revised SOP will be set automatically as the date of the next regularly scheduled REC meeting taking place immediately after the official training session has concluded

Section 6. Forms

Form 18.1 – Provisional Agenda
Form 20.1 - Minutes of the meeting
Form 1.7 – CV template
Form 1.9 – ARTS

Section 7. History of SOP

Version No.	***Date***	***Authors***	***Main Change***
1	7.3.24	NINO ISMAEL S. PASTOR	DRAFT
2	11.05.24	Aljoriz Dublin & Nino Ismael Pastor	Content, Form labels
3		Nino Ismael Pastor	Content, Form labels

Section 8. References

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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.

GLOSSARY

Active Files – are documents about protocols that are currently being assessed, managed or monitored by the REC.

Active Study – is an ongoing study, implementation of which is within the period covered by ethics clearance.

Adjournment – an official end of a meeting made by a seconded motion for adjournment recorded in the minutes as the time the motion was approved.

Administrative Document(s) – a document(s) and information in a document created, received, or maintained by the REC that serves to record the administrative, financial, personnel, or management functions, Policy Statement, decisions, procedures, and operations of the REC. Examples include the SOPs, Membership files, Agenda and minutes files, and administrative issuances.

Administrative Issuance – official communications or announcements from institutional authorities.

After-approval reports – progress report, protocol deviation/violation report, amendments, early termination reports, final reports, application for continuing review, required by the REC for submission by the researcher/investigator after the study has been approved for implementation.

Agenda – the order of business made by a sequential list of topics or items for discussion in a meeting that starts with a "Call to Order".

Alternate Members – individuals who possess qualifications of specified regular members. They are called to attend a meeting and substitute for regular members to comply with the quorum requirement when regular members cannot attend the meeting.

Amendment – a change in or revision of the protocol made after it has been approved.

Anonymization – process of removing the link between the research participant and the personally identifiable data, in such a way that the research participant cannot be determined nor traced.

Appeal – a request of a researcher/ investigator for a reconsideration of the REC recommendation.

Appointing authority - the institutional official that has the power to designate or appoint individuals to specific offices or roles.

Appointment document – a document signed by the Vice President assigning an official position to a member of the REC

Archiving - is the systematic keeping of protocol files in storage after the studies have been completed with final reports accepted or terminated or declared inactive.

Assessment Form– evaluation tool accomplished by the reviewers when appraising the protocol or the informed consent form.

Ballot – voting (indicating a choice) by writing the choice on a form for the purpose. Ballots are subsequently counted to determine how most members voted for decision making.

Benefits – list of favorable outcomes ranging from direct indirect gains such as education, or direct therapeutic value benefit to the community (or society), and/or individual.

Business Arising from the Minutes – these are issues, concerns, or actions that came up from discussions in the previous meeting needing attention, resolution, and recording.

Chief Executive Director – the managing director of GCM

CHRI Adviser – head of the Center for Health Research & Innovation (CHRI)of GCM

CHRI Administrative Secretary – the administrative Secretary of the REC of GCM

Clarificatory Interview/meeting – is a face-to-face consultation between the REC and the researcher to obtain explanations or clarity regarding some research issues identified by the REC to make these issues less confusing or more comprehensible.

Clinical Auditor – an individual who systematically and independently examines research-related activities and documents at a particular period as a significant step in quality control.

Clinical Monitor- an individual who oversees the progress of a clinical trial.

Clinical Trial – a systematic study on pharmaceutical products, medical procedures in human or animal subjects (including research participants and other volunteers to discover or verify the effects of and/or identify adverse

reactions to investigational products with the object of ascertaining their efficacy and safety.

Coding – a unique number assigned to a particular protocol that reflects its serial position, year, and month among the submitted protocols.

Collegial Decision – a shared decision reached and accepted through a democratic and participatory approach during a meeting among equal REC members based on consensus.

Competent Authority –designated officer or member of the REC with the authority to respond to queries and complaints regarding studies approved by the REC.

Complaint – a research-related or non-research-related statement about a situation or event in relation to a study.

Confidentiality – REC restrictions on access and disclosure, including means for protecting proprietary information from documents entrusted to it.

Confidentiality of Documents – pertains to the recognition and awareness that certain documents that have been entrusted or submitted to the REC must not be freely shared or disclosed.

Conflict of Interest – occurs when a REC member's interests (family, friendships, financial, or social factors) affect his or her judgment, or decisions for a protocol.

Conforme - acceptance of or agreement to an assignment or designation

Consensus – a collective agreement of deciding without voting but by generating the overall sentiment of a group such that deliberations continue until no more strong objections are registered.

Continuing Review – a regular and official review conducted at a designated interval after a project has received initial review and approval by the IREC.

Controlled document – pertains to the document that has been entrusted or submitted to the REC that must not be freely shared or disclosed such that it is appropriately tagged and its distribution carefully tracked, monitored, and appropriately recorded.

Credentials – aspects or entries in a person's CV indicating suitability for becoming an officer or member of the GCM REC

Data privacy - protection of personal information of REC members and REC applicants and the right to access and transfer that data when desired.

Database – a collection of information that is structured and organized so that this can easily be accessed, managed, interpreted, analyzed, and updated. Data about proposals are contained in the RESEARCH MONITORING SYSTEM (RMS DATABASE). Data about personnel are contained in the ADMINISTRATIVE RESEARCH TRACKING SYSTEM (ARTS). Data about administrative matters are contained in the R.E.C. FILE DATABASE. These databases are all in the Excel spreadsheet.

Date of Effectivity – the date when the guidelines shall be enforced.

Date of Effectivity – the date of a regular meeting when after the enforcement of a SOP guideline was approved or decided upon.

Decision – a judgment, conclusion, or resolution reached as the result of the REC review of a research protocol or other submissions.

Draft Meeting Agenda – the order of business that includes the list of topics or items recommended for discussion in a meeting. This is endorsed to the REC Chair for his/her approval.

Draft Meeting Minutes – Proceedings of the meeting prepared by the Administrative Secretary under the supervision of the member secretary for approval by the Chair.

Early Termination - a study that ends sooner than scheduled due to a decision by the REC, sponsor, or PI.

Endorsement – the approval by GCM directors for a REC member to become a REC officer.

Exempt from Review - a decision made by the REC Chair or designated committee member regarding a submitted study proposal based on criteria in the NEGHHR 2017, "The Research Ethics Review Process Guideline 3.1". This means that the protocol will not undergo an expedited or full review.

Exemption Report – a list of protocols submitted for review that were deemed not to require the conduct of either expedited or full review. This report is presented during a regular committee meeting or as required by the institutional authority.

Expedited Review - is the ethical evaluation of a research proposal and other protocol related documents, a resubmission, and after-approval submissions, conducted by only 13 members of the committee without involvement of the whole committee.

Expedited Review Reports – is an enumeration of protocols (including titles, code number, proponent, submission date, names of reviewers, and decisions) that underwent expedited review and presented during a regular REC meeting for information of the REC members and record purposes.

Expert – *a* person with a comprehensive and authoritative knowledge of or skill for an area.

Expertise – It is a comprehensive and authoritative knowledge/skill that is possessed by a person in an area/ field.

Facility and Maintenance Department – a GCM department in charge of physical facilities.

Filing – an activity of putting documents in a secure place or cabinet

Final Meeting Agenda - is the order of business that includes the list of topics or items approved for discussion in a meeting by the REC Members in a regular or special meeting that had been approved by the Chair and REC members.

Final Meeting Minutes – Proceedings of the meeting that have been approved by the REC members.

Final Reports/ Close Out Reports – is a summary of the outputs and outcomes (including documented risks and benefits) of the study upon its completion, as well as the status of all participants. The REC requires the accomplishment of the Final Report form within a reasonable period after the end of the study. **Finance Department**- a GCM department in charge of procuring goods and services.

Format- general style or layout of the document based on the latest template from the GCM Research Department.

Full Review - is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission, and after-approval submissions, conducted by the research ethics committee en banc, in the presence of a quorum, using established technical and ethical criteria.

Full Review Committee – applies to research study and other protocol-related documents, a resubmission and after-approval submissions involving subjects who might be exposed to more than minimal risk, or whose procedures and materials require wider range of independent consultants with various expertise. A full Committee review requires a quorum.

Government authorities - individuals that constitute the authority of a political unit or organization.

High-Risk Studies – research where harm or danger resulting from the study is very likely to affect participants.

Honorarium- monetary payment in recognition of acts or professional services for which custom or propriety forbids a price to be set

Inactive Study – a study whose proponent has not communicated with the REC about issues with the approval or implementation of the study – within a period required by the REC.

Incoming Communications –digital, and/or written documents directed to and received at the REC office.

Independent Consultant- a non-voting but REC meeting participant resource Person whose expertise is needed in the review of a research protocol/proposal.

Information Technology (IT) – a GCM unit in charge of audio-visual and computer equipment

Initial Review – an evaluation to determine if the submitted study documents can be exempted or need an expedited or full review.

Initial Review – the ethical assessment of the first complete set of study documents submitted to the REC so that an expedited full review can be conducted.

Initial Submission – refers to the first (initial) package of study documents forwarded to the REC for review.

Intellectual property – creations from the mind of the researcher(s) /inventor(s) / entrepreneur (s) that are considered as owned by the one who thought of it. Intellectual property includes information and intellectual goods.

Logbook – a real-time, chronological record of incoming protocols that include the Date/Time of Receipt, Title of the Document, Name of the Proponent, Name and Signature of the Submitting Entity, Name and Signature of the Receiver, Action done and any document related to the research study.

Major Modification – is a revision of important features of the study (e.g., study objectives, recruitment of participants, exclusion/inclusion criteria, collection of data, statistical analysis, mitigation of risks, protection of vulnerability, etc.) that impact on potential risks/harms to participants and the integrity of the research.

Majority rule- a policy based on the principle that the decision made by the greater number should be carried/accepted.

Medical Members – are individuals with academic degrees in the medical profession and a master's degree in the nursing profession. **Meeting Agenda** - a list of topics or activities during a REC meeting.

Meeting Minutes - – the official narration and record of the proceedings of the assembly of REC Members, based on the agenda.

Minimal Risk – a term used when the probability and magnitude of harm or discomfort anticipated in the research are not greater, in and of themselves than those encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Minor Modification – is a revision of specific features of the study or related documents that do not influence the potential risks/harms to participants and on the integrity of the research, such as lack of documents, incomplete or unsatisfactory Informed Consent elements format.

More than Minimal Risk - a term used when the probability and magnitude of harm or discomfort anticipated in research are greater, in and of themselves than those encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Non-affiliated Member/s – are regular members who are not in the roster of personnel or Administrative Secretary of the Institution. They are not employees of the institution, nor do they receive regular salary or stipend from the institution.

Non-affiliated Member/s – are regular members who are not in the roster of personnel or Administrative Secretary of the Institution. They are not employees of the institution since they do not receive regular salary or stipend from the institution.

Non-disclosure agreement (NDA) - a legal contract between GCM and the REC members that establishes a confidential relationship where both parties agree that sensitive information, they may obtain will not be made available to any others. An NDA may also be referred to as a confidentiality agreement.

Non-medical members- are individuals without academic degrees in the medical profession or a master's degree in the nursing profession.

Non-scientists – are individuals whose primary interest is not in any of the natural, physical and social sciences and whose highest formal education is a bachelor's degree.

Non-Teaching Position - refers to a position whose primary duties and responsibilities contribute to the delivery of basic education services and achievement of agency outcomes, but do not involve nor directly support the actual conduct of teaching or delivery of instruction.

Operations-related Matters – are items included in the agenda that are not directly related to any protocol under review.

Outgoing Communications – are documents generated within the REC office and sent to individuals or offices related to the operations of the REC.

Physical Plant Division – a unit within the institution that oversees the maintenance and use of physical facilities. In GCM it is called the Facilities Management Division (FMD).

Post-approval Reports – are accounts of the ongoing implementation of an approved study (e.g., progress report, amendment, safety report, protocol deviation/violation, early termination, final report, or application for continuing review) that are required to be submitted by the researcher to the REC for monitoring purposes.

Primary Reviewers – are members of the Research Ethics Committee (usually a scientist and a non-scientist) assigned to do an in-depth evaluation of the research-related documents using technical and ethical criteria established by the committee. The nonscientist member shall focus on the review of the Informed Consent process and form and reflect on community values, culture, and tradition to recommend acceptance, nonacceptance, or improvement of the informed consent process and form. The primary reviewers shall present their findings and recommendations during the meeting for discussion.

Principal Investigator - the person mainly responsible for the implementation of a research project.

Progress Report – an organized report using an approved form in which information or events of an approved and ongoing research proposal are updated for the REC to know the exact status of approved research. The frequency of submission (e.g., quarterly, semiannually or annually) is determined by the REC based on the level of risk.

Protocol – documentation of the study proposal that includes a presentation of the rationale and significance of the study, background, and review of literature, study objectives, study design and methodology, data collection, dummy tables, plan for analysis of data, ethical consideration, and dissemination plan.

Protocol database - a collection of information about protocols that is structured and organized for easy access, management, interpretation, analysis,

and updating. It is usually in an electronic platform used for tracking and monitoring the implementation of a study.

Protocol Database – Significant information about protocols that are organized systematically so that these can easily be accessed, managed, interpreted, and analyzed and it is usually in an electronic platform used for tracking and monitoring the implementation of a study. In GCM this refers to the Research Monitoring System (RMS), and the Protocol Folder Index.

Protocol Deviation – non-compliance with the approved protocol that does not increase risk nor decrease benefit to participants and does not significantly affect their rights, safety or welfare or the integrity of data. Example: missed visit, non-submission of a food diary on time.

Protocol File/Folder – is a container of an organized document (physical or electronic form) related to a study that is compiled in a color-coded 1-inch binding folder.

Protocol Folder Index - is a chronological tabular record of the documents pasted on the inside front cover of a BLUE protocol file binder that indicates the date of filing, the nature of the document filed, the name and signature of the person who filed, an extra column to record any movement of the document, and any other document related to the protocol. The index is pasted inside the cover page of the protocol file/folder for easy reference and checking

Protocol Index – is a chronological record of the documents in the protocol file. The protocol index is in table form indicating the date of filing, the nature of the document filed, the name and signature of the person who filed, and an extra column to record any movement of the document. The index is pasted inside the cover page of the protocol file/folder for easy reference and checking.

Protocol Violation - non-compliance with the approved protocol that increases risk or decreases benefit to participants or significantly affects their rights, safety or welfare, or the integrity of data. Example: incorrect treatment, non-compliance with inclusion/exclusion criteria.

Protocol-related Documents- consists of all other documents aside from the proposal/protocol itself that are required to be submitted for review, e.g., Informed Consent Form, Survey Questionnaire, CV of the proponent, advertisements, In-depth Interview Guide Questions, etc.

Protocol-related submissions– other documents that are included (required) in the submission of the protocol, e.g., Informed Consent Forms, study tools (Interview guide, survey questionnaire, FGD guide), and CVs of the proponents and certificates of training.

Protocols for Full Review – Study proposals that require an en banc ethical review because they entail more than minimal risks to the participants and/or that participation generates vulnerability issues.

Provisional Meeting Agenda – is the order of business that includes the list of topics or items approved for discussion in a REC meeting presided by the REC Chair.

Provisional Meeting Agenda – the order of business made by a list of topics or items for discussion in a meeting where it can be changed It is sent to REC members for comment. The comments alter the provisional agenda which is endorsed to the REC Chair for his/her approval.

Provisional Meeting Minutes – Proceedings of the meeting that have been noted or approved by the Presiding officer for discussion during the current meeting.

Query – a question asking for information or clarification about ongoing research

Quorum– the presence of at least 5 of the 8 regular members including the non-affiliated and the non-scientist members. If a pre-identified committee member submits their review but cannot join the meeting, they should be considered as part of the quorum requirement. **Real-time Recording** – the process of documenting the minutes of the meeting as the meeting proceeds simultaneously.

REC File database – the record of REC activities, meetings, trainings, site visits. This is in Excel format.

REC Operations- the overall activities of the REC that reflect the performance of its functions and responsibilities.

Regular Meeting – a periodically scheduled assembly of the REC, which is every 3rd Saturday of the month.

Regular Meeting – an assembly of the REC every 3rd Saturday afternoon of the month

Regular Members – are members constituting the research ethics committee, who receive. official appointments from the institutional authority with specific terms and responsibilities including review of research proposals and attendance of meetings.

Regulatory Authorities – refer to government agencies or institutions that have oversight or control over the conduct of research, e.g., the Department of Health, Food and Drug
Administration, Research Institutions

Related-Teaching Position - refers to a position whose primary duties and responsibilities contribute to the delivery of basic education services and achievement of agency outcomes, through the provision of direct support to teaching and the delivery of instruction, such as standard setting, policy and program formulation, research, and sector monitoring and evaluation.

Reportable Negative Events (RNE) - are occurrences in the study site that indicate risks or actual harm to participants, research site residents, and members of the research team and to integrity of data. Examples are brewing hostilities in the research community, natural calamities, unleashed dogs, threats of harassment, etc.,

Research Monitoring System – a real-time, chronological collection of digital information that records incoming protocols that include the Date/Time of Receipt, Title of the Document, Name of the Proponent, Name and Signature of the Submitting Entity, Name and Signature of the Receiver, Action done, name of adviser, SGD #, Group leader, etc.

Researcher- is the individual primarily responsible for the conceptualization, planning, and implementation of a study.

Researcher-initiated studies – are research activities whose conceptualization, protocol development, and implementation are done by a researcher or group of individuals who may request external funding support.

Resubmission – the revised study proposal that is re-forwarded to the REC after complying with the recommendations from the initial review.

Review - a formal examination and assessment of the CVs of REC members.

Reviewer- a regular member of the Research Ethics Committee who is assigned to assess a research protocol, Informed Consent, and other research-related submissions based on technical and ethical criteria established by the committee.

Risks – unfavorable outcomes ranging from inconvenience, discomfort, or physical harm based on the protocol.

RNE – an occurrence in the study site that indicates risks or actual RMS Database to participants and members of the research team. Examples are brewing hostilities in the research community, natural calamities, unleashed dogs, threats of harassment, etc.

Room-use Restriction – use of a document within the designated REC premises.

SAE (Serious Adverse Events) – An undesirable medical occurrence in a patient or participant in a clinical investigation after exposure to an investigational product or service. The SAE may or may not be related to the study product or service.

SAE / SUSAR team or Subcommittee – a group of individuals with the necessary expertise, assigned by the REC when needed to review SAEs and SUSARs and provide the pertinent recommendation for action of the REC.

School Administration Positions - refer to positions that are directly engaged in supervisory, managerial, and/or administrative functions in all schools and learning centers.

Scientists – are individuals whose formal education is at least a master's degree in a scientific discipline, e.g. biology, physics, social science, etc.

Second Level Positions - include professional, technical, and scientific positions that involve professional, technical, and scientific work in a non-supervisory or supervisory capacity up to the Division Chief level or its equivalent.

Secret Ballot – a system of casting votes (opinions or choices) such that the voters are not identified or are anonymous.

Serious Adverse Event (SAE) – is an event observed during the implementation of a study where the outcome is any of the following:

- Death
- Life-threatening
- Hospitalization (initial or prolonged) o Disability or permanent damage o Congenital anomaly/ birth defect o Required intervention to prevent permanent impairment or damage (devices) o Other serious (important medical) events whether it is related to the study intervention.

Site Visit – a visit to a research site, or office by an appointed group of REC member(s) for specific monitoring reasons.

Site Visiting Team – members/Administrative Secretary of the REC (2-4 members) assigned by the REC Chair to formally go to the research site, meet with the research team, and evaluate compliance with the approved protocol and Informed Consent Form and Process, including other related research

procedures to ensure the promotion of the rights, dignity, and well-being of participants and protection of the integrity of data.

Special meeting – an assembly of the Committee outside of the regular schedule of meetings for a specific purpose, usually to decide on an urgent matter like the selection of an officer, approval of a revised or new SOP, or report of a critical research problem that requires immediate action.

Sponsor- an individual, company, institution, or organization responsible for initiating, managing, and financing a clinical trial or novel medical service.

Sponsored Clinical Trials – are systematic studies on pharmaceutical products in human subjects (including research participants and other volunteers), whose conceptualization, protocol development, and support for their conduct are the responsibilities of sponsors who manufactured the products, in compliance with the requirements of regulatory authorities.

Administrative Secretary – institutional personnel hired to assist in the operations of the REC.

Standard Operating Procedures - are the step-by-step description of the different procedures done to accomplish the objective of an ethics review. They consist of clear, unambiguous instructions for ethical review to ensure quality and consistency.

Status of participants – summary of what happened to (condition of) participants recruited to the study, including those who completed the study, those who dropped out, or those who withdrew for specific reasons following the protocol.

Study Documents- include all materials (protocol, forms, certificates, research tools) pertinent to a research proposal that must be submitted to the REC for review.

Study Site - physical location of where the study is being conducted, e.g., community, institutional facility.

Study-related Communications – documents that refer to an exchange of information or opinions regarding a study, usually between the REC and the researcher.

SUSAR (Suspected Unexpected Serious Adverse Reactions) -Serious unexpected adverse reactions due to an investigational medicine product or service.

System of Ranking Positions - refers to the hierarchical arrangement of positions from highest to lowest, which shall be a guide in the determination of

which position is next-in rank, taking into consideration the following: a) organizational structure; b) salary grade allocation; c) classification and functional relationship of positions; and d) geographic location.

Teaching Position - refers to a position that is directly engaged in teaching or in the delivery of instruction in the elementary and secondary levels (junior high school and senior high school), whether on a full-time or part-time basis, in schools and learning canters. **Technical expert –** A person who is very proficient and skillful in an area/field of specialty.

Term of office – the specified length of time that a person serves in a particular designation
/Role.

Term of office - the specified length of time that a REC member serves as an officer of the REC. In this case, it will be six years.

Termination package - refers to the entitlements of study participants in the event of discontinuance of the study, which can come in the form of access to the study intervention, treatment, or information, for purposes of adherence to the principle of fairness for all concerned. This is a decision made by the sponsor or regulatory authority and/or recommended by the Data Safety Monitoring Committee, researcher/investigator in consideration of participant safety, funding issues, protocol violations, and data integrity issues.

Vice-President - the institutional official that has the power to designate or appoint individuals to specific offices or roles

Voting – a formal act expressing a choice during a meeting.

Voting – the act of expressing opinions or making choices usually by casting ballots, spoken word or hand raising. The rule is fifty percent plus 1 vote is a majority that wins.

Vulnerable Groups – participants or potential participants of a research study who may not have the full capacity to protect their interests and may be relatively incapable of deciding for themselves whether to participate in the research. They may also be at a higher risk of being harmed or to be taken advantage.

Vulnerable Groups – participants or potential participants of a research study including but not limited to prisoners, persons with disabilities, Indigenous groups, pregnant women, minors, psychiatric/cognitively impaired patients, or economically disadvantaged who may not have the full capacity to protect their interests and may be relatively or absolutely incapable of deciding for

themselves whether to participate in the research. They may also be at a higher risk of being harmed or to be taken advantage.

APPENDICES

PART 1: HUMAN RESURCES

..\..\..\SOP Forms\Forms v3\SOP 1\Form 1.1 Invitation.docx

..\..\..\SOP Forms\Forms v3\SOP 1\Form 1.2 – Conforme.docx

..\..\..\SOP Forms\Forms v3\SOP 1\Form 1.3 Appointment letter for REC member.docx

..\..\..\SOP Forms\Forms v3\SOP 1\Form 1.5 - COI Declaration Forrm.docx

..\..\..\SOP Forms\Forms v3\SOP 1\Form 1.6 Data Privacy.docx

..\..\..\SOP Forms\Forms v3\SOP 1\Form 1.7 - CV temjplate.docx

..\..\..\SOP Forms\Forms v3\SOP 1\Form 1.9 ADMINISTRATIVE RESEARCH TRACKING SYSTEM (ARTS) 9.25.24.xlsx

..\..\..\SOP Forms\Forms v3\SOP 2\Form 2.1 - Endorsemnent note.docx

..\..\..\SOP Forms\Forms v3\SOP 2\Form 2.2 – Appointment of REC Officer letter.docx

..\..\..\SOP Forms\Forms v3\SOP 3\Form 3.1- Invitation tech expert w conforme.docx

..\..\..\SOP Forms\Forms v3\SOP 3\Form 3.2 – Appointment letter independent consultant.docx

PART 2: OPERATIONAL SERVICES

..\..\..\SOP Forms\Forms v3\SOP 4\Form 4.0 - Application for ethics reviuew.docx

..\..\..\SOP Forms\Forms v3\SOP 4\Form 4.1 Ëxemptionn.docx..\..\..\SOP Forms\Forms v3\SOP 4\Form 4.10 Waiver of Informed Consent.docx

..\..\..\SOP Forms\Forms v3\SOP 4\Form 4.11 Certificate of Exemption from Review (1).docx

..\..\..\SOP Forms\Forms v3\SOP 4\Form 4.2 ICF template.docx

..\..\..\SOP Forms\Forms v3\SOP 4\Form 4.2a ICF for children less 18 yrs.docx

..\..\..\SOP Forms\Forms v3\SOP 4\Form 4.2b ICF for clinical studies.docx..\..\..\SOP Forms\Forms v3\SOP 4\Form 4.2c ICF for qualitative studies.docx..\..\..\SOP Forms\Forms v3\SOP 4\Form 4.3 Notice of Review w conforme.docx

..\..\..\SOP Forms\Forms v3\SOP 4\Form 4.4 REC Review Checklist.docx

..\..\..\SOP Forms\Forms v3\SOP 4\Form 4.5 ICF EVAL WORKSHEET.docx

..\..\..\SOP Forms\Forms v3\SOP 4\Form 4.6 DECISION LETTER.docx

..\..\..\SOP Forms\Forms v3\SOP 4\Form 4.7 RESEARCH MONITORING SURVEILLANCE SYSTEM.xlsx

..\..\..\SOP Forms\Forms v3\SOP 4\FORM 4.7a FILINGM FORM.docx

..\..\..\SOP Forms\Forms v3\SOP 4\Form 4.8 Proposal Summary Sheet.docx

..\..\..\SOP Forms\Forms v3\SOP 4\Form 4.9 - Protocol Folder Index.docx

..\..\..\SOP Forms\Forms v3\fORM 10.1 AMENDMENT FORM.docx

..\..\..\SOP Forms\Forms v3\Form 7.1 RESUBMISSION fORM.docx

..\..\..\SOP Forms\Forms v3\form 8.1 Progress Report Form.docx

..\..\..\SOP Forms\Forms v3\Form 11.1 Deviation or violation form (edit).docx

..\..\..\SOP Forms\Forms v3\Form 11A.1 - Report of RNE.docx..\..\..\SOP Forms\Forms v3\Form 11B.2 - SAE SUSAR Assessent report.docx

..\..\..\SOP Forms\Forms v3\Form 11B.1 - SAE SUSAR Report Form.docx

..\..\..\SOP Forms\Forms v3\Form 11B.2 - SAE SUSAR Assessent report.docx

..\..\..\SOP Forms\Forms v3\FORM 12.1, Application for continuing Review.docx

..\..\..\SOP Forms\Forms v3\Form 13.1 - Final Report Form.docx

..\..\..\SOP Forms\Forms v3\Form 14.1 - Early Termination Report.docx

..\..\..\SOP Forms\Forms v3\Form 15.1 Appeal Eval Report.docx

..\..\..\SOP Forms\Forms v3\FORM 16.1 - SITE VISIT REPORT.docx

PART 3: ADMINISTRATIVE SERVICES

..\..\..\SOP Forms\Forms v3\Form 17.1 - Notice of Meeting.docx

..\..\..\SOP Forms\Forms v3\FORM 18.1 -Meeting AGENDA template.docx

..\..\..\SOP Forms\Forms v3\Form 19.1 - Attendance sheet for study.docx

..\..\..\SOP Forms\Forms v3\Form 20.1 - Minutes of the meeting.docx

..\..\..\SOP Forms\Forms v3\Form 20.2 REC Meeting Files.xlsx

..\..\..\SOP Forms\Forms v3\Form 21.1 - Approval letter.docx

..\..\..\SOP Forms\Forms v3\Form 25.1 - Confidentiality Agreement for Non-members.docx

..\..\..\SOP Forms\Forms v3\Form 26.1 - QUERY COMPLAINT FORM.docx

..\..\..\SOP Forms\Forms v3\Form 26.1 - QUERY COMPLAINT FORM.docx