



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



Ethos Universitas
 HONORARY COMPANION

Version No:	Draft
Date of Approval:	
Effectivity Date:	

SOP No. 7- MANAGEMENT OF INITIAL SUBMISSION

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 <ul style="list-style-type: none"> • 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:

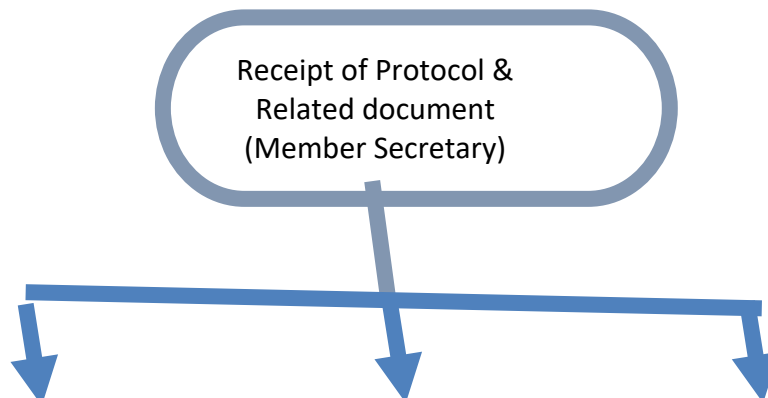
Format Example: REC Code 2026-502-001: Delacruz–HIV

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.

4) Step 4: Determination of the Type of Review: Exemption from Review (SOP 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;
populations;
Institutional evaluations;
Publicly available data.
risk.



Minimal risk protocols;
Patient chart reviews;
Non-sensitive surveys.



Vulnerable
Vulnerability created;
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

<i>Version No.</i>	<i>Date</i>	<i>Authors</i>	<i>Main Change</i>
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

Section 8. References

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

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

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.