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

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.