



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



Ethos Universitas
 HONORARY COMPANION

Version No:	Draft
Date of Approval:	
Effectivity Date:	

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 Conformance 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 4.17a)**.

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

To prevent administrative bottlenecks, strict communication windows are enforced:

- **Formal Written Conformance:** The invited primary reviewer or independent consultant must sign and return the official Conformance 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 Conformance, 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.

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

<i>Version No.</i>	<i>Date</i>	<i>Authors</i>	<i>Main Change</i>
1	12.07.2023	Niño Ismael Pastor	<i>First draft</i>
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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