



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



**Ethos Universitas**  
 HONORARY COMPANION

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**

<b>ACTIVITY</b>	<b>RESPONSIBLE PERSONS</b>	<b>TIMELINE</b>
<b>Step 1:</b> 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
<b>Step 2:</b> Evaluation by the Chair and Notification of Reviewers	Member Secretary Chair	7 days post-receipt
<b>Step 3:</b> Review of the Resubmission <ul style="list-style-type: none"> <li>• Expedited Review (SOP 4, “Expedited Review”)</li> <li>• Full Review (SOP 5 Full Review”)</li> </ul>	Assigned Reviewers Admin Secretary Member Secretary	1 day 3 <sup>rd</sup> Saturday of the month
<b>Step 4:</b> Communication of Decision. (See SOP 21–Communicating REC Decisions).	Secretary	7 days post-meeting
<b>Step 5:</b> Filing of Documents in the Protocol File	Administrative	10 days post-

Index (Form 4.9), update of the Filing Form log (Form 4.7a), and RMSS DATABASE (Form 4.7)	Secretary	meeting
<b>TOTAL</b>		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.

##### **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), Filing 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**

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

**Section 8. References**

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