



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



**Ethos Universitas**  
 HONORARY COMPANION

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**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**

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

<b>Step 6:</b> Communication of decision to the Principal Investigator/researcher (Form 4.6 – Decision Letter)	Member Secretary and Chair	7 days post REC meeting
<b>Step 7:</b> 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	
<b>TOTAL</b>		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

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