



Document Code	EOMS-REO-GL-001, Rev 00
Effectivity Date	2024/12/08
Page/s	1 of 7

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00	December 8, 2024	December 8, 2024	Initial Issue

## ETHICS REVIEW CLEARANCE GUIDELINES FOR SMU RESEARCHERS

### I. SUBMISSION of research protocol

Note: A research proposal, when approved by the technical panel, is referred to as research protocol (or just protocol for a shorter term). It is a protocol because the approved procedures must be followed when conducting the study.

1. Only research proposals approved by a technical review board (panelists) may be submitted to SMUREB. This means the panel's comments during the proposal defense have been incorporated and approved.
  2. Requesting for ethics review clearance requires submission of two documents:
    - 2a. **Protocol Application**
      - Accomplished REB-FO-006: Protocol Application Form for studies involving human participants and human data
      - Endorsement from the Research Coordinator of the respective school or approval sheet if not accomplished in Section III of the form
    - 2b. **Protocol Document**

This document file includes the following:

      - Complete Proposal Manuscript with the CVs of research proponents and the Informed Consent Form (when applicable)
      - Other related documents to support the application, such as minutes of technical review, training certificates of research proponents, funding contracts, collaborative work, etc.
  3. Electronic copies of the Protocol Application and Protocol Document must be duly signed and dated before submission as soft copies (pdf) through the UREO Google Form available at <https://forms.gle/gnMFSNjLC9t2BFwL9>. QR Code of this link is also in circulation.
  4. The UREO staff will determine the completeness and correctness of the submitted documents. Incomplete and incorrect application documents must be rectified before UREO officially accepts them.
  5. The UREO staff will inform the research proponent of the initial assessment of their submitted documents and provide further instructions.
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Document Code	EOMS-REO-GL-001, Rev 00
Effectivity Date	2024/12/08
Page/s	2 of 7

**II. ACCEPTANCE** of the Research Protocol for Review

1. The UREO staff fills out the reference section of the application form to officially accept the submitted proposal. The reference section includes the SMUREB Code Number. The research proponent must take note of their assigned code to be used for any follow-up inquiries on the status of the application.
2. Upon initial assessment of the completeness of the submitted protocol application and protocol document, the UREO staff assigns the SMUREB code to the accepted protocol and issues a billing statement (REO-FO-018) to the research proponent to pay the review fee at the Accounting Office.
3. The researcher category of the submitted protocol determines the review fee that the research proponent must pay at the accounting office.

<b>Category of Researcher</b>	<b>Review Fee</b>
SMU Undergraduate	PHP 1,500
SMU Graduate (Masters)	PHP 1,875
SMU Graduate (Doctorate)	PHP 2,250
Faculty Research	PHP 2,250
Non-SMU Undergraduate	PHP 2,000
Non-SMU Graduate	PHP 3,000
Sponsored/Funded Research	PHP 5,000

4. The research proponent presents the billing statement to the Accounting Office, pays the corresponding review fee, and presents the official receipt to the UREO staff.
  5. Payment of the review fee is not required to accept the protocol documents for ethics review. However, the fees must be paid before issuing the certificate of approval.
  6. The scanned copy of the official receipt or the proof of payment (with reference number) for those who shall pay the review fees remotely shall be sent to the provided submission link.
  7. The UREO staff prepares the protocol document and protocol-related documents for distribution to assigned reviewers within two working days.
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Document Code	EOMS-REO-GL-001, Rev 00
Effectivity Date	2024/12/08
Page/s	3 of 7

### **III. REVIEW PROCESS for the accepted protocol**

1. Within two days after the official acceptance of the submitted protocol, the UREO staff would have prepared the documents for review and would have distributed the documents to assigned reviewers.
2. The assigned reviewers are given up to 6 working days to complete the assessment forms for the accepted research proposals.
3. The chair of SMUREB or the assigned primary reviewer consolidates the assessment forms of assigned reviewers into a decision letter that will be communicated to the research proponent.
4. The decision letter contains the findings of the research ethics board and its recommendations. It also includes specific instructions to the research proponent on how to move forward.
5. Overall, the research proponent shall receive the initial decision letter in 6 – 30 working days after officially accepting their research protocol.

#### **III-A. EXEMPTED REVIEW**

1. This is done at the level of the SMUREB officers (Chair, Vice-chair, or member-secretary).
  2. The criteria for exemption from review are as follows:
    - 2.1. The protocol does not involve human participants or identifiable human tissue, biological samples, or data.
    - 2.2. The protocol does not involve more than minimal risks or harms, such as
      - protocols for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer capability tests; and,
      - protocols that use survey, interview, or observation where there is no disclosure of human participants' responses that could put them at risk and where the identity of the human participant cannot readily be ascertained.
    - 2.3. Protocols that involve the use of publicly available data or information.
  3. Research proponents shall receive their exemption certificate within six working days of officially accepting their application for review.
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Document Code	EOMS-REO-GL-001, Rev 00
Effectivity Date	2024/12/08
Page/s	4 of 7

### **III-B. EXPEDITED REVIEW**

1. At least two reviewers do this. At least one of the reviewers designated as the primary reviewer must have a specialization aligned with the research topic.
2. A research proposal will undergo expedited review if
  - 2.1. it is a chart review,
  - 2.2. it is a survey of non-sensitive nature, and
  - 2.3. it involves anonymous or anonymized laboratory/pathology samples or stored tissues or data.
3. The assigned reviewers are given up to 6 working days to complete the assessment forms.
4. The reviewers submit their accomplished assessment form to the UREO staff.
5. The primary reviewer consolidates the reviewers' findings into a decision letter.
6. The chair notes the decision letter and instructs the UREO staff to communicate the decision to the research proponent.
7. Research proponents shall receive the decision letter within 6 -15 working days from officially accepting their application for review.

### **III-C. FULL REVIEW**

1. A full board review of protocol is done through a meeting of SMUREB members. A primary reviewer, with specialization aligned with the research topic, will be assigned to facilitate the protocol deliberation during the meeting presided over by any of the SMUREB officers.
  2. A research proposal will undergo full review if
    - 2.1. it entails more than minimal risk to the study participants,
    - 2.2. the study participants belong to a vulnerable group or
    - 2.3. the study procedures generate vulnerability issues.
  3. All the assigned reviewers will complete the Assessment forms and submit them to the UREO staff within six days of receipt of the protocol and protocol-related documents.
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Document Code	EOMS-REO-GL-001, Rev 00
Effectivity Date	2024/12/08
Page/s	5 of 7

4. Assigned reviewers will deliberate on assessed protocols during the regular meeting of the SMUREB, which is set for the 2<sup>nd</sup> Wednesday of the month.
5. Only protocols officially accepted within ten working days before the meeting will be included in the deliberations. Protocols accepted within ten working days before the meeting will be included in the next regular meeting.
6. The review result will be obtained by consensus and captured into a decision letter.
7. The presiding officer prepares the decision letter from the minutes within two days after the meeting.
8. The UREO staff communicates the decision to the research proponents.
9. Research proponents shall receive the decision letter within 14 -30 working days from officially accepting their application for review.

#### **IV. ISSUANCE OF ETHICS CLEARANCE**

1. After the SMUREB deliberations, the certificate of approval may be issued immediately if there are no further recommendations that the research proponent needs to comply with.
2. The certificate of approval to implement study procedures contains the effective date of its validity (usually one school year).
3. The certification also contains specific instructions to the research proponent for any further obligation to SMUREB.
4. The final ethics clearance certificate will be awarded to the research proponent after acceptance and approval of their final report form (REO-FO-017) by the SMUREB.

*For SMU students, this will be one of the certificates required as an attachment in the final copy of your thesis.*

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**V. TIMELINE OF REVIEW**

The turn-around time depends on the nature of the research. If it qualifies for expedited review, the committee decision shall be available within 6-15 working. Otherwise, it requires a full review, and the committee decision shall be available within 14-30 working days. The following outlines the timeline of reviews in the SMUREB:

<b>Processes</b>	<b>Number of Working Days</b>
Exempted Review	3 – 6
Expedited Review	6 – 15
Full Review	14 – 30
Management of Resubmission	7 – 29
Review of Amendments	9 – 24
Management of Protocol Deviation and Violation Report	8 – 30
Review of Reportable Negative Events Report	8 – 23
Review of Early Termination Report	12 – 32
Review of Final Report	8 – 23

A working day is defined as a weekday day when SMU offices are open.

**V. MONITORING**

1. There are after-approval review activities that the research proponent may still be involved with, depending on the SMUREB recommendations. These activities may include resubmission, continuing review, review of amendments, approval of protocol deviations, reporting of adverse events, submission of early termination report, and submission of final report.
  2. Approved protocols that do not comply with the timetable of ethics review (e.g., non-submission of the final report, non-submission of after-approval reviews when needed, expired validity of the certificate of approval) will be considered inactive and will not be issued final ethics clearance certification. All related files will be archived.
  3. Certificate of approval and ethical clearance certification can be revoked for non-compliance with SMUREB recommendations.
  4. The submission of the final report for completed research is mandatory.
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**SAINT MARY'S UNIVERSITY**

BAYOMBONG, NUEVA VIZCAYA, PHILIPPINES

**UNIVERSITY RESEARCH ETHICS OFFICE**

Document Code	EOMS-REO-GL-001, Rev 00
Effectivity Date	2024/12/08
Page/s	7 of 7

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