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Revision No.	Approval Date	Effectivity Date	Amendment
00	December 8, 2024	December 8, 2024	Initial Issue

## ETHICS REVIEW GUIDELINES FOR NON-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 REO-FO-006: Protocol Application Form
- Approval sheet from a Technical Review Board (if available)

**NOTE:** *It is a must that all items from section II to section V are answered, including signatures and dates. The application for ethics review must be endorsed (Sections IV and V) by the researcher's institutional authorities.*

#### 2b. Protocol Document

This document file includes the following:

- Complete Proposal Manuscript
- Concise CVs of research proponents showing their expertise or specialization that is aligned with the research topic
- 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 SMUREB Google Form available at <https://forms.gle/gnMFSNjLC9t2BFwL9>. QR codes of the submission links to SMUREB are also available in circulation.

4. The SMUREB staff will determine the completeness and correctness of the submitted documents. Incomplete and incorrect application documents must be rectified before SMUREB officially accepts them.



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5. Upon initial assessment of the completeness of the submitted protocol application and protocol document, the 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.
6. The research proponent must take note of the SMUREB code number to be used as a reference when transacting further with SMUREB regarding the submitted research protocol.

## II. REVIEW FEES

1. SMUREB collects review fees to support its operations. For non-SMU researchers, the following fees apply:

CATEGORY OF RESEARCH	REVIEW FEE
Non-SMU Undergraduate Research	PHP 2,000
Non-SMU Graduate Thesis/Research	PHP 3,000
Funded Research	PHP 5,000

2. Researchers can pay the corresponding review fee at the accounting office of SMU or remotely through the following SMU Account:

<b>Bank:</b>	PNB - Bayombong, Nueva Vizcaya
<b>Account Name:</b>	Saint Mary's University
<b>Account Number:</b>	2251-7000-1787

3. The researcher must secure the proof of payment and send a copy to SMUREB through the Google form available at <https://forms.gle/8sd7BfDXFA1jp4fe8>. A QR code of the link is also available in circulation. The bank deposit slip must be scanned, showing the whole sheet. The screenshot of the online transfer must show the transaction reference number.



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**II. 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.

**IV. 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 based on the SMU calendar.

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**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.

<b>Prepared by:</b>	
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<b>UREO Head</b>	<b>Date Signed</b>

<b>Recommended by:</b>	
<b>PEARL VIA S. COBALLE</b>	
<b>Quality Management Representative/IDQAO</b>	<b>Date Signed:</b>

<b>Approved by:</b>	
<b>JOHN OCTAVIOUS S. PALINA, PH.D.</b>	
<b>University President</b>	<b>Date Signed:</b>

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