Section 1. Policy Statement

All research proposals should file an application for an REC review. The application form will be similar for all researchers. Research proponents or investigators do not have the right to determine how their proposal will be reviewed. The REC will determine how the proposal will be reviewed: exempted, expedited, or by full Committee. This SOP No. 4 concerns proposals that may be exempted from an REC review.

Research proposals may be exempted if (1) they do not use humans or animals as test subjects, (2) the proposal poses no more than a minimal risk to human interviewees, and/or (3) all research procedures or methodologies fit the exemption categories stated in this section.

The Belmont Principle requires that human subjects or respondents be given the opportunity to participate or decline to participate in the research. All human subjects or respondents must sign an Informed Consent Form, even if the proposal is exempt from REC review. A copy of this ICF is included with this proposal. This ICF should contain at least the minimum information, which includes the following (NWU, 2023):

- An explanation that they will be interviewed or asked to answer survey questionnaires to participate in a research study.
- The identity and affiliation of the researcher (s).
- A clear description of the study procedures and how data will be used in the future.
- A statement that participation in the research is voluntary.

- Contact information of researchers(s) that participants can ask questions and concerns about the research.

However, researchers must follow the ICF outlined in the SOP forms.

Changes to the proposal do not need to be submitted to the REC after an exemption is granted, as long as the modifications in research procedures and methodologies pose minimal risks and still fall within the exempted categories that the REC used as the basis for the exemption. However, if the changes do not adhere to the exemption categories cited by the REC, the proponent must notify the REC secretary.

Section 2. Objective of the Activity

The objective of the activity is to describe the policies and procedures for exempting a research proposal from ethics review when the proponent exercises due diligence in drafting it.

Section 3. Scope

The REC may decide to exempt submitted protocols from an ethics review. This SOP explains how to exempt a proposal from the ethics review process. Proposals that will be exempted may fall under the following categories (PHREB, NEGRIHP 2022, 2022):

- Protocols for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests;

- Research that only includes interactions involving survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording), if the following criteria are met:

    - There will be no disclosure of the human participants' responses outside the research that could reasonably put the participants at risk of criminal or civil liability or harm their financial standing, employability, or reputation; and

    - The investigator records the information obtained in such a manner that the identity of the human participant cannot readily be ascertained, directly or through identifiers linked to the participant.

- Protocols that involve the use of publicly available data or information.

Category A. Research involving educational practices that do not impact on the human participant's time, environment, or experience. These practices may focus on teaching methods, the medical curriculum, class management, and learning styles or strategies. Examples (NWU, 2023):

Evaluations of academic tests

Evaluations of medical education programs

Research about curricula or study modules

Evaluation of health programs

The researchers or investigators will be advised of the results of the REC review for exemption after the application is submitted. The REC will also inform the CHRI about their decision regarding the proposal.

Category B. Proposals that only involve interviews or observing human participants involving educational tests (cognitive, diagnostic, aptitude, or achievement), surveys needing responses from participants, or observing human participants who will record (visually or audibly) their behavior. Examples (NWU, 2023):

- Surveying teachers, students, nurses, or doctors about a technique or an outcome
- Interviewing managers about a management style, programs or best practice
- Conducting a focus group about an experience or an opinion of a community program

Category C. Proposals that use safe and harmless behavioral interventions while collecting data from human participants through spoken or written responses and/or audiovisual recordings of the participants who previously signed an informed consent form (ICF), as long as the data collection method is brief, safe, respects data privacy principles, and does not cause harm to the participant. Example:

- Healthy adult subjects are asked to take part in assessments of memory, attention, attitude, behavior, and information processing speed. The procedures are conducted during a

single visit, and subjects are encouraged to take breaks when desired (NWU, 2023).

Category D. Proposals that review existing data and / or laboratory results that were or will be collected for non-research (i.e., diagnosis) purposes or from related research studies. The research materials typically are publicly available materials like medical records, or existing repositories of clinical specimens. There is no contact between researchers and human participants. Example:

- A proposal reviewing medical records of patients with certain diseases.

Category E. Proposals that are conducted to evaluate the public health or clinical benefit of procedures, programs, and possible improvements of services under these programs. Example:

- Studies that evaluate the impact of a health or medical education program that reviews the records of accomplishment of said program
- Proposals evaluating the clinical efficacy of a clinical procedure using patient records

Category F. This includes proposals for flavor and food nutritional quality evaluation and consumer acceptance studies. Example:

- Studies on the nutrition of foods without additives.

- Proposals that test a food ingredient at or below the level and for a use found to be safe, or an agricultural chemical or environmental contaminant at or below the level found to be safe, as determined by the Food and Drug Administration or approved by the Department of Environment and Natural Resources or the Department of Agriculture.

The above categories of proposals do not entail more than a minimal risk to human subjects, or human subjects that do not belong to vulnerable groups and where vulnerability issues are absent. Researchers, however, are asked to provide information about the study, and participants sign informed consent forms.

This SOP begins with the assignment of reviewers or independent consultant/s and ends with the inclusion of the review in the agenda of the next meeting."

Section 3. Workflow

In order to exempt the proposal from an ethics review, here are the different steps involved in exempting a proposal from the review, and the people responsible for each of these steps.

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Application (Form 4.0 – Applicatiion for Ethics Review) for a REC review and submission of a proposal (Chp 1,2, &3), ICF, CHRI Notice To Proceed, validity of QQ certificate to REC	Student	1 day
Step 2: Assignment of Reviewers OR Appointment of Independent Consultants w conforme **(Form 3.1 AND/OR Form 4.3)**	Admin Secretary Member Secretary REC Chair	1 day
Step 3: Notification of Reviewers or Independent Consultant/s w conforme (**Form 3.1 and/or Form 4.3)**	Member Secretary	1 day
Step 4: Provision of study documents and evaluation forms**, Form 4.8. Proposal Summary Sheet, and form 4.5 ICF WS, Form 4.4 - REC Review Checklist** to the primary reviewer and other reviewers)	Admin Secreatary	5 days
Step 5: Accomplishment and submission of evaluation forms	Reviewer	7 days
Step 6: : Inclusion of the Review in the Agenda of the next meeting (Form 18.1: Preparing the Meeting Agenda)	Chair and Member Secretary	2 days
Step 7: Finalization of review results	Member Secretary Chair	3 days

Step 8: **: Communication of review results to the researcher** (Form 4.6– Decision letter), Form 4.1 (Exemption) & Form 4.11 (Certificate of Exemption).	Chair and Member Secretary	1 day
Step 9: Filing of documents in the protocol file **(FORM 4.9)**	Member Secretary |Admin Secretary	1 day
	TOTAL	**22 Days**

Sectio 4. Description of Procedures

Step 1: Application (Form 4.0 – Application for Ethics Review) for a REC review and submission of a proposal (Chp 1,2, &3), ICF, CHRI Notice to Proceed, validity of QQ certificate to REC

The ethical review lifecycle begins when a student proponent (or team of student researchers) secures the formal **REC Review Application Form (Form 4.1)**. The proponents must complete the form, affix their signatures, and attach it to their comprehensive research proposal. This complete application packet is then submitted to the REC Administrative Secretary.

Upon receipt, the Administrative Secretary will log the entry and immediately alert the Member Secretary of the new submission. The Administrative Secretary serves as the clearinghouse, compiling all incoming applications over the course of the week. Every Friday, the Administrative Secretary consolidates these weekly submissions and presents them to the Member Secretary for initial regulatory and technical evaluation.

Step 2: Assignment of Reviewers OR Appointment of Independent Consultants w conforme (Form 3.1 AND/OR Form 4.3)

Following the initial evaluation of the protocol's scope, the Member Secretary will formulate a reviewer assignment plan. The Member Secretary recommends to the REC Chairperson specific accredited reviewers or external independent consultants whose scientific credentials directly align with the protocol’s subject matter.

The Chairperson exercises final approval over these assignments, cross-referencing the potential reviewer’s files curriculum vitae and active workload

against the specialized technical needs of the proposal to ensure an objective, high-quality review.

Step 3: Notification of Reviewers or Independent Consultant/s w conforme (Form 3.1 and/or Form 4.3)

Once the Chairperson approves the assignments, formal communication is initiated to secure the reviewers' services:

- **For Accredited REC Members:** The **Notice to Review (Form 4.3)** is dispatched.
- **For External Specialists:** The **Appointment of Independent Consultant Letter (Form 3.1)** is issued.

The assigned reviewer or consultant must review the request and formally communicate their availability and willingness to assume the review. A binding confirmation of their agreement to evaluate the proposal must be received by the REC office before any confidential study documents are transmitted.

Step 4: Provision of study documents and evaluation forms, Form 4.8. Proposal Summary Sheet, and form 4.5 ICF WS, Form 4.4 - REC Review Checklist to the primary reviewer and other reviewers)

Upon receiving a reviewer's formal acceptance, the Member Secretary coordinates the secure distribution of the evaluation packet. The Member Secretary provides the assigned reviewers or independent consultants with the complete primary documentation and supporting institutional evaluation forms, which include:

- The full Research Proposal / Protocol
- The Certificate of Validity for the utilized research questionnaires
- **Protocol Summary Sheet (Form 4.8)**
- **REC Review Checklist (Form 4.4)**
- **Informed Consent Form Worksheet (ICF WS - Form 4.5)**

Step 5: Accomplishment and submission of evaluation forms.

Reviewers and independent consultants—who have undergone specific institutional training regarding health research ethics and human participant protections—will independently conduct a rigorous assessment of the protocol.

Reviewers are allocated a standard period of at least one (1) month from the date of document receipt to thoroughly study the proposal and complete the mandatory evaluation forms.

Upon completing the assessment, the reviewer fills out the **REC Review Checklist (Form 4.4)** and submits it directly to the Member Secretary. The Member Secretary collates these completed checklists and forwards them to the Chairperson. After reviewing the gathered assessments, the Chairperson instructs the Member Secretary to calendar the protocols for the upcoming committee session.

Step 6: Inclusion of the Review in the Agenda of the next meeting (Form 18.1. Preparing the Meeting Agenda)**.**

To facilitate a collective deliberation on the evaluated protocols, the Member Secretary consults with the Chairperson to finalize a date and time for the next formal REC review assembly. Once the date is locked, the Member Secretary designs the session layout using **Preparing the Meeting Agenda (Form 18.1)**. This meeting agenda is formally distributed to all active REC members, advising them of the schedule and outlining the specific protocols slated for committee discussion.

Step 7: Finalization of review results.

During the convened REC meeting, the general membership deliberates on the merits, ethical considerations, and reviewers' feedback for each protocol. The Member Secretary documents the proceedings and finalizes the official **Minutes of the Review Meeting**. Based on the collective determinations recorded in the minutes, protocols qualifying for an absolute exemption from a full Committee ethics review will be explicitly identified and categorized.

Step 8: : Communication of review results to the researcher (Form 4.6– Decision letter), Form 4.1 (Exemption) & Form 4.11 (Certificate of Exemption).

Following the finalization of the meeting minutes, the review results must be officially communicated to the student researchers within a strict administrative timeline. The Member Secretary drafts the appropriate institutional correspondence based on the committee's decision:

- **Standard Decision Letter (Form 4.6):** Issued to communicate regular review outcomes (e.g., Approval, Minor Revisions, Major Revisions, or Disapproval).

- **Exemption Correspondence (Form 4.1 & Form 4.11):** For protocols determined to be exempt from further ethical oversight, the Member Secretary issues a formal **Exemption Letter (Form 4.1)** paired with an official **Certificate of Exemption (Form 4.11)**.

Step 9: Filing of documents in the protocol file (SOP 23 Mgt of Active File.

To maintain institutional compliance, transparency, and strict audit trails, all documents generated during the review lifecycle must be systematically filed. Under the direct supervision of the Member Secretary, the Administrative Secretary will archive all physical and digital records in strict compliance with **SOP 23: Management of Active Files**.

The Administrative Secretary will generate a dedicated **Protocol Folder Index (Form 4.9)** for each new proposal, log the entries into the **Research Management Summary Sheet (RMSS - Form 4.7)**, and record the administrative track within the **Filing Form Log (Form 4.7a)**.

Protocol Review Matrix

Stage	Responsible Officer	Primary Tool / Form Used	Operational Output
Intake & Consolidation	Administrative Secretary	REC Review Application (Form 4.1)	Weekly Consolidated Dossier
Intake & Consolidation	Member Secretary & Chair	Notice to Review (Form 4.3) / Appointment Letter (Form 3.1)	Confirmed Reviewer Matrix
Reviewer Assignment	Member Secretary	Summary Sheet (Form 4.8), Checklist (Form 4.4), ICF WS (Form 4.5)	Complete Evaluation Packet
Dossier Distribution	Assigned Reviewers / ICs	REC Review Checklist (Form 4.4)	Completed Ethical Assessment
Ethical Assessment	Member Secretary	Preparing the Meeting Agenda (Form 18.1)	Distributed Institutional Agenda
Agenda Formatting	Member Secretary	Decision Letter (Form 4.6) / Cert. of Exemption (Form 4.11)	Official Notification to Proponents
Outcome Delivery	Administrative Secretary	Folder Index (Form 4.9), RMSS (Form 4.7), Filing Log (Form 4.7a)	Archived Master Protocol Folder

Section 5. Forms

Form 3.1 Invitation Tech Expert W Conforme
Form 4.0 - Application For Ethics Review
Form 4.1 Exemption
Form 4.3 Notice of Review
Form 4.4 REC Review Checklist,
Form 4.5 ICF WS.
Form 4.6 Decision Letter
Forn 4.7 Research Monitoring Surveillance System
Form 4.7a the Filing Form log.
Form 4.8 Proposal Summary Sheet
Form 4.9 Protocol folder Index
Form 4.7a Filing form (for each proposal)
Form 4.11 – Certificate of Exemption
Form 21.2 Active File Mgt

Section 6. History of SOP

This is the first time SOP 4 was formulated for a proposal that is exempted from an ethical review.

Version No.	Date	Authors	Main Change
1	2023 Dec 6	Nino Ismael Pastor	First draft
2	9.16.24	Nino Ismael Pastor	2nd Draft
3	06.04.20256	Nino Ismael Pastor	3rd Draft

Section 7. References

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