1. **Policy Statement**

An expedited review shall be conducted for study protocols that (1) do not entail more than minimal risk to the study participants, and (2) do not have study participants belonging to a vulnerable group, and (3) the study procedures do not generate vulnerability. The results of the initial review shall be released to the principal investigator within four weeks after the submission of all the required documents. The study protocol that underwent expedited review and approved shall be reported in the subsequent regular committee meeting.

1. **Objective of the Activity**

Expedited Review aims to demonstrate due diligence and high standards in the system of protection of human participants*.*

1. **Scope**

This SOP applies to initial review of protocols and post-approval submissions which do not entail more than minimal risk to study participants, whose participants do not belong to vulnerable groups, and where vulnerability issues do not arise. 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.

1. **Workflow**

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| ***ACTIVITY*** | ***RESPONSIBILITY*** |
| *1: Assignment of Reviewers or Independent Consultant/s (SOP#03 Appointment of Independent Consultants)* | *Chair* |
| *2: Notification of Reviewers or Independent Consultant/s* | *Staff* |
| *3: Provision of study documents and evaluation forms (Form 6C and 6D) to reviewers* | *Staff* |
| *4: Accomplishment and submission of evaluation forms* | *Reviewers* |
| *5: Finalization of review results* | *Chair* |
| *6: Communication of review results to the researcher (SOP21  Communicating ISU-IREB Decisions)* | *Chair and Staff* |
| *7: Filing of documents in the protocol file (SOP 23 Management of Active Files)* | *Staff* |
| *8: Inclusion of the Review in the Agenda of the next meeting (SOP20 Preparing the Meeting Agenda)* | *Chair and Staff* |

1. **Description of Procedures**

**5.1 -** Assignment of primary reviewers or independent consultants

5.1.1 The ISU-IREB Chairperson assigns two (2) reviewers based on the initial assessment of the research, and whose expertise are appropriate to the nature of the study/submission.

5.1.2. Independent consultants may be sought to review if the research requires a certain expertise or if there is non-availability of the assigned reviewer, or if there is refusal of the primary reviewer due to lack of expertise of conflict of interest

**5.2 –** Notification of and acceptance of primary reviewers or Independent Consultants

5.2.1 The ISU-IREB Secretariat notifies the reviewers or Independent Consultants using Form 4C NOTIFICATION   FOR REVIEW, and should be within 3 working days upon acceptance of complete documents.

5.2.2  The reviewer/s notifies the Secretariat if they are able to  review, otherwise, the ISU-IREB Chairperson appoints another reviewer/s.

**5.3 -** Provision of study protocol to primary reviewers or Independent Consultant

5.3.1 The ISU-IREB Secretariat forwards the study protocol with supplemental documents of the researcher to the Primary Reviewer/s with Form 2B PROTOCOL REVIEW ASSESSMENT FORM, Form 2C INFORMED CONSENT ASSESSMENT FORM (for studies with human participants), Form 2D ASSENT FORM IN ENGLISH AND LOCAL LANGUAGE (for studies involving minors and relevant populations deemed incompetent to sign an informed consent form).

5.3.2 The Primary Reviewer/s may request clarifications from the primary investigators regarding the request.

5.3.3. Independent consultants may be sought to review the research proposal if the research requires a certain expertise that regular member doesn’t have

**5.4 -** Accomplishment and Submission of Assessment Forms to the Secretariat

5.4.1 The reviewers submit their evaluation results completely signed and dated to the Secretariat with their recommendations within 10 working days AFTER RECEIPT OF COMPLETE DOCUMENTS OR MINIMUM OF 7 working days DAYS BEFORE THE SCHEDULE OF THE MONTHLY FULL BOARD REVIEW) (VIA courier or EMAIL TO THE SECRETARIAT)

**5.5 -** Consolidation and Finalization of the Review

5.5.1. The ISU-IREB Secretariat collates the review results and forwards the summary to the ISU-IREB Chairperson.

5.5.2. The primary reviewer cannot arrive at a definite decision, the proposal will be considered as not subject for expedition and will be included in the next full board meeting. The condition of the unavailability of a decision will be communicated by the staff to the researcher via phone notification and email within 5 working days.

5.5.3 For disapproved expedited research proposals, the researcher will be given a chance to clarify questions asked and must submit lacking or vague documents via email 7 working days before the next full board review but must notify the staff of his/her submissions via phone text/message.

5.5.4 The expedited review shall not take longer than 10 working days

**5.6 -** Communicating the ISU-IREB decision to the researcher/s

The secretariat communicates the decision of the ISU-IREB to the researcher/investigator. Should there be clarifications/concerns regarding the review, the primary reviewer shall answer the questions.

**5.7 - Filing of documents in the protocol file**

The Secretariat updates the protocol package files and database accordingly.

1. **Glossary**

*Decision – the result of the deliberations of the IREB in the review of a protocol or other submissions.*

*Exempt from Review - a decision made by the IREB Chair or designated member of the committee regarding a submitted study proposal based on criteria in the NEGHHR 2017 The Research Ethics Review Process Guideline 3.1. This means that the protocol will not undergo an expedited nor a full review.*

*Expedited Review – is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by only 2-3 members of the committee without involvement of the whole committee.* (It may be conducted online by at least 3 members including the chairperson or his designee either via virtual platform or google forms, decisions and processes duly documented and recorded)

*Full Review- Full Review – is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by the research ethics committee en banc, in the presence of a quorum, using established technical and ethical criteria.*

*Vulnerable Groups – participants or potential participants of a research study who may not have the full capacity to protect their interests and may be relatively or absolutely incapable of deciding for themselves whether or not to participate in the research. They may also be at a higher risk of being harmed or to be taken advantage.*

*Minimal Risk – term used when the probability and magnitude of harm or discomfort anticipated in a research are not greater, in and of themselves, than those encountered in daily life or during the performance of routine physical or psychological examinations or tests.*

*More than Minimal Risk - term used when the probability and magnitude of harm or discomfort anticipated in research are greater, in and of themselves, than those encountered in daily life or during the performance of routine physical or psychological examinations or tests.*

*Reviewer- a regular member of the Research Ethics Committee who is assigned to assess a research protocol, the Informed Consent, and other research-related submissions based on technical and ethical criteria established by the committee.*

*Primary Reviewer - A member of the ethics committee assigned by the chairman to comprehensively assess a study a proposal can be either expedited or needing full board review.*

*Independent Consultant- Resource person who is not a member of the Research Ethics Committee, whose expertise is needed in the review of a research protocol/proposal and who may be invited to attend a committee meeting but is non-voting during the deliberations.*

1. **Forms**

*Form ## Protocol Evaluation Worksheet*

*Form ## Informed Consent Evaluation Worksheet*

*Form ## Decision letter template*

Form 4C NOTIFICATION FOR REVIEW

Form 2C PROTOCOL REVIEW ASSESSMENT FORM

Form 2D INFORMED CONSENT ASSESSMENT FORM (for studies with human participants)

Form 2E ASSENT FORM IN ENGLISH AND LOCAL LANGUAGE (for studies involving minors and relevant populations deemed incompetent to sign an informed consent form)

1. **References**

What references did you use in the preparation of this SOP (e.g. guidelines, other institutional SOPs, institutional policies, institutional documents, local regulations)?

*CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016*

*WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011*

*National Ethical Guidelines for Health and Health-related  Research 2017*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

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| Recommending Approval: |  |
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| Approval Date: |  |