Supersedes:	02
Version:	03
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	(Adapted from UPMREB SOP and 2020 PHREB SOP Workbook)
Endorsed by:	**Mary Anne R. Tumanan, Ph.D.** Chair, UPCHE REC
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7.1. Policy Statement

A full review is a type of review where the study protocol is discussed during a UPCHE REC full board meeting where there is a quorum of members including scientist members, at least one (1) non-scientist member and one (1) non-affiliated member (WHO, 2011; NEGRIHP, 2022).

A full review shall be conducted when:

a. the proposed study entails more than minimal risk to study participants,
b. the study participants belong to vulnerable groups
c. the study generates vulnerability to participants
d. there are physical, therapeutic or social interventions in the study
e. there is collection of stigmatizing information or study may cause stigmatization of the participants
f. protocols involving questionnaires and social interventions that are confidential in nature.

A primary reviewer system shall be used to conduct a full review and if necessary, independent consultant/s and or the proponents shall be invited during the meeting to clarify certain issues.

The decision shall be communicated to the proponent within six (6) weeks after submission of required documents. For disapproved protocols, the proponent/s may appeal to the REC by submitting a letter containing the justification for the appeal addressed to the Chair (see SOP 28 Management of Appeals).

7.2. Objective

A full review aims to ensure compliance with scientific and ethical standards in conducting of researches involving human participants and identifiable human data and materials.

7.3. Scope

This SOP applies to initial, revisions and post-approval submissions which are classified as entailing more than minimal risk to study participants or whose participants belong to vulnerable groups or when study generates vulnerability to participants. This SOP begins with the assignment of primary reviewers or independent consultant/s and ends with the filing of study protocol-related documents.

7.4. Full Review Workflow (14 to 21 working days)

	ACTIVITY	PERSON RESPONSIBLE	TIMELINE*
1	Assignment of primary reviewers	Chair, Member Secretary/ REC Discipline Expert	1
2	Notification of the reviewers	Administrative Secretary	1

3	Provision of documents and evaluation forms to reviewers	Administrative Secretary	1
4	Accomplishment and submission of assessment forms	Primary Reviewers	7 to 14
5	Provision of protocol and protocol related documents to the rest of the REC members	Administrative Secretary	1
6	Presentation of review findings during the REC meeting	Primary Reviewers	1
7	Discussion of scientific/technical, ethical and ICF issues	REC members	
8	Summary of discussion and recommendations	Chair	
9	Committee Action	REC and Chair	
10	Communication to the proponent	Chair, Administrative Secretary	1
11	Filing of the protocol and related documents and updating of protocol database	Administrative Secretary	1

**Working days*

7.5. Description of Procedure

7.5.1. **Assignment of Primary Reviewers**:

The Chair assigns 2 primary reviewers – scientist member with the needed expertise to review the scientific/technical and ethical issues and a non-scientist/lay member to review the informed consent process and the informed consent form. If there is no REC member with the necessary expertise, an independent consultant may be assigned.

7.5.2. **Notification of the Primary Reviewers or Independent Consultant**:

The Administrative Secretary notifies the assigned reviewers by email or call within 2 working days upon the decision of the Chair and gives them 2 days to respond. If they are not available within the timeline, the Chair assigns other reviewers and an independent consultant.

7.5.3. **Provision of study protocol documents and assessment forms to Primary Reviewers and Independent Consultants**:

The Administrative Secretary sends the copy of research protocol package and assessment forms (UPCHE REC FORM 08: Study Protocol Assessment Form and

FORM 09: Informed Consent Assessment Form) to the assigned reviewers or independent consultant/s (when applicable).

7.5.4. **Accomplishment and Submission of evaluation forms**:

The scientist reviewer fills up the different items in the assessment forms with appropriate and relevant remarks about the scientific or technical soundness, ethical issues such as inclusion/exclusion criteria, vulnerability, risk/benefit assessment, data privacy, etc.

The non-scientist member assesses the ICF information about the research procedures, risk and benefit, comprehensiveness of the language, provision of English or Filipino or dialect, others. Reviewers are encouraged to use the electronic assessment forms.

The reviewers return or email the accomplished forms to the Secretariat within 10 working days upon receipt of the documents or at least 5 days before the scheduled meeting.

7.5.5. **Provision of study protocol documents to other REC members:**

The rest of the members will be provided with an executive summary of the study proposal (included in the documents submitted by principal investigators) at least five (5) working days prior to the meeting or they may request a copy of the protocol and assessment forms for their own review before the meeting.

7.5.6. **Presentation of review findings and recommendations:**

a. During the REC meeting, the primary reviewers present a short summary of the study protocol and use as guide the assessment points and elements detailed in UPCHE REC FORM 08: Study Protocol Assessment Form and FORM 09: Informed Consent Assessment Form. The primary reviewers and members should ensure study protocol compliance with the NEGRIHP 2022 on:
   - Use of biological materials
   - Appropriate contracts or memoranda of understanding especially in collaborative studies
   - Community involvement and impact/benefit of the study to community and/or the institution are examined and if relevant, noting the following if applicable: community consultation, involvement of local researchers and institutions in the study protocol design, analysis and publication of the results, contribution to development of local capacity for research and treatment, benefit to local communities, availability of study results, and benefit sharing.

b. If a primary reviewer cannot attend the meeting, the Chair exercises his/her prerogative to take over the role of the primary reviewer so that the meeting can proceed.

7.5.7. **Discussion of scientific/ technical, ethical and ICF issues**:

a. The Chair leads the discussion of the technical and ethical issues using the protocol assessment and the informed consent assessment checklists and the assessment of the primary reviewers as guides for an orderly exchange of ideas.

b. The proponent or the independent consultant (if applicable) may be invited to attend the meeting for clarificatory interviews (Form 30: Letter for Clarificatory Interview).

7.5.8. **Summary of issues and resolutions and decide on final action**:

The Chair summarizes the scientific, ethical and ICF issues that were identified and issues that were resolved/not resolved including the recommendations for the issues that were not resolved.

For the documentation of the committee deliberation during the meeting, please see SOP 20 Preparation of Minutes of Meeting.

7.5.9. **Committee action**:

The committee may decide to approve, require minor or major modifications or disapprove the discussed study protocol.

- If approved: An approval letter [Form 16] is sent to the PI/RP
- If minor modification: A notification with recommendations using Form 17 [Modification of Protocol] is sent to the PI/RP and the resubmission undergoes expedited review or be decided at level of Chair.
- If major modification: A notification with recommendations using Form 17 [Modification of Protocol] is sent to the PI/RP and resubmission undergoes full review.
- If disapproved: A notification of decision is sent to the PI/RP with justification using Form 52 [Disapproval of protocol].

The criteria for Major and Minor Modifications are as follows:

a. Major Modification - recommended revision applying to protocols found to have significant aspect/s of the study (e.g., study objectives, recruitment of participants, exclusion/inclusion criteria, collection of data, statistical analysis, mitigation of risk, protection of vulnerability, etc.) that impact on potential risks/harms to participants and on the integrity of the research. Examples: major

revisions in protocol design or method or ICF, inclusion/exclusion criteria, safety issues, data privacy issues

b. Minor modification – a recommended revision applying to protocols found to have particular aspect/s on its study or related document that do not impact on potential risks/harms to participants and on the integrity of the research (e.g., incomplete documentation, informed consent elements, unsatisfactory informed consent format), administrative corrections like typo or grammar errors, minor changes on items not related to the procedure to be done.

7.5.10. Communication to the proponent:

The Administrative Secretary informs the PI/RP of the committee decision within 7 working days after deliberation and meeting (see SOP 21 Communicating REC Decisions).

7.5.11. **Filing of the protocol and related documents and updating of protocol database:**

A copy of the protocol and related documents are filed in the protocol files under Active Files (see SOP 21 Communicating REC Decisions; SOP 23: Management of Active Files).

The Administrative Secretary updates the protocol database with the result of the REC action on the reviewed protocol.

7.6. Forms

The following forms are used in the implementation of this SOP:

- Form 08: Study Protocol Assessment Form
- Form 09: Informed Consent Assessment Form
- Form 15: Transmittal Letter
- Form 16: Action Letter - Approval of Protocol
- Form 17: Action Letter - Modification of Protocol
- Form 30: Letter for Clarificatory Interview
- Form 52: Disapproval of Protocol

7.7. Document History

Version No.	Date	Authors	Main Change(s)
01		Maria Patricia V. Azanza, Ph.D Joanne R. Bantang, Ph.D. Cecile Leah T. Bayaga Kristyn T. Caragay Charla Rochella S. Saamong Mary Anne Ramos-Tumanan, Ph.D. Casiana Blanca J. Villarino, Ph.D.	First draft

		Fredelyn S. Gascon	
02	20 Nov 2020	Maria Patricia V. Azanza, Ph.D Joanne R. Bantang, Ph.D. Cecile Leah T. Bayaga Kristyn T. Caragay Charla Rochella S. Saamong Mary Anne Ramos-Tumanan, Ph.D. Casiana Blanca J. Villarino, Ph.D. Fredelyn S. Gascon	Policy: Added mechanism for appeals: The proponent/s may appeal any decision of the REC by submitting a letter containing the justification for the appeal addressed to the Chair. All appeals will be discussed in a regular committee meeting. Responsibilities: The responsibility of deciding the type of review is now shared by the Chair, REC discipline expert, and non-affiliate member. This was included in SOP 4 under 'Responsibilities' section. Workflow: 1. Number of steps in the workflow was reduced from 8 to 7 steps. Process now starts with sending study protocol documents to the Primary Reviewers and other REC members. The first step was removed since it was already part of SOP 4: Management of Initial Submissions. The number of days for each step was changed to ensure that REC members have ample time to review the protocols. For example, the original time frame specified as '2 working days' was changed to 'earliest within 2 working days'. References: Removed the list of references from this SOP and collated all references used for the entire SOP into one section.
02	21 September 2022	Maria Patricia V. Azanza, Ph.D. Joanne R. Bantang, Ph.D. Cecile Leah T. Bayaga, Ph.D. Kristyn T. Caragay Edgar G. Belda Jr. Mary Anne R. Tumanan, Ph.D. Rowena Grace R. Sanchez Fredelyn G. Tolete	Revised the SOP right header box to include a simplified SOP code and added date of approval Policy: Revised statement regarding appeals to "For disapproved protocols, the proponent/s may appeal to the REC by submitting a letter containing the justification for the appeal addressed to the Chair (see SOP X Management of Appeals)."
02	06 July 2023	Maria Patricia V. Azanza, Ph.D. Joanne R. Bantang, Ph.D. Cecile Leah T. Bayaga, Ph.D. Kristyn T. Caragay	Added timeline (in working days) for each step in the Workflow

		Ma. Leonora dL Francisco, Ph.D. Adelaida V. Mayo, Ph.D. Marian Michelle D. Navales Mary Anne Ramos-Tumanan, Ph.D. Casiana Blanca J. Villarino, Ph.D. Fredelyn G. Tolete	Reformatted numbering of the sections to follow the SOP number (e.g., 3.1. Policy Statement)
03	08 July 2024	See updated list of authors	Updated the list of authors to include all regular members following the change in membership of the UPCHE REC.