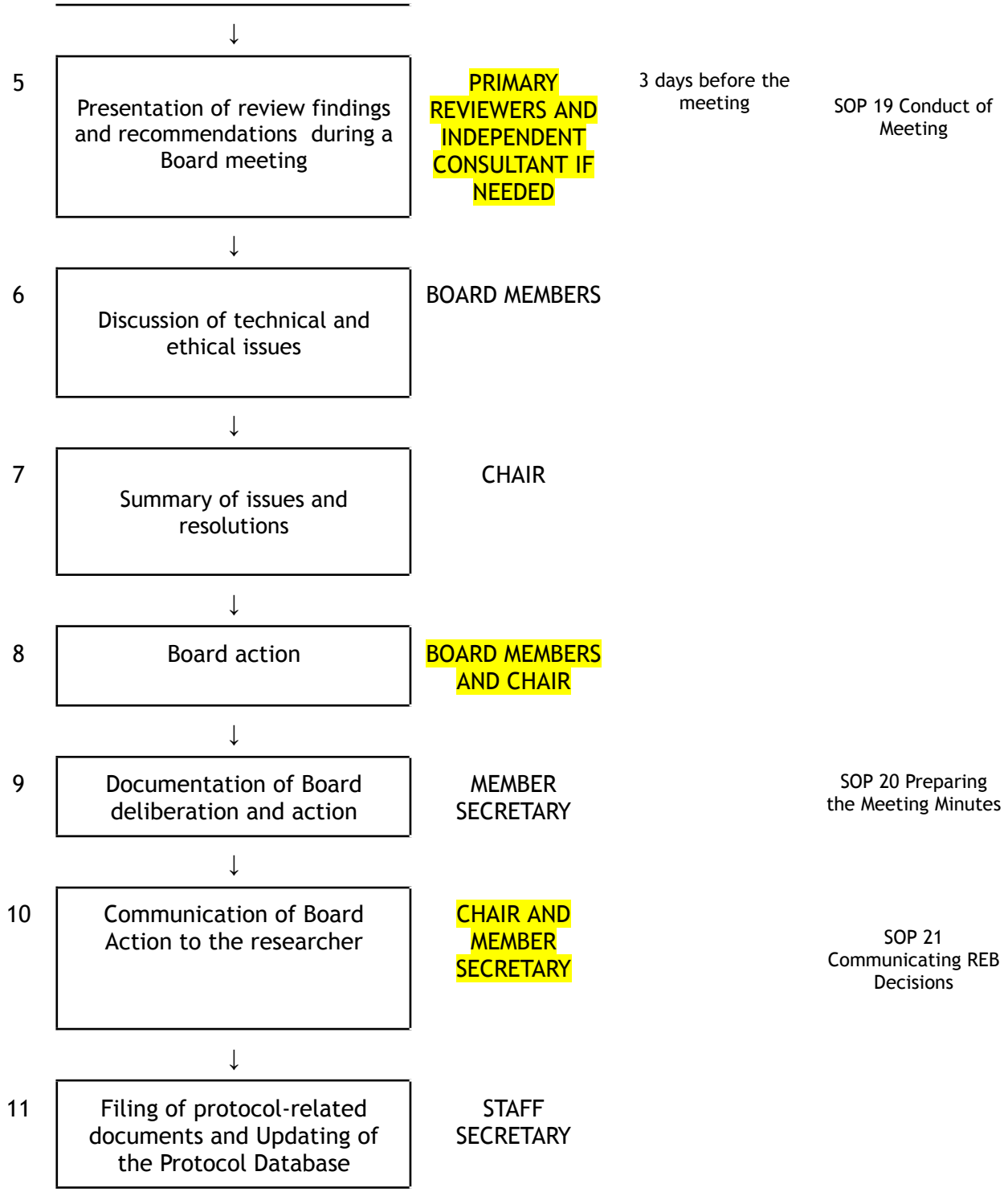
TITLE	FULL REVIEW
POLICY STATEMENT	A full review shall be conducted when a proposed study entails more than minimal risk to study participants or when study participants belong to vulnerable groups or when a study generates vulnerability to participants. Only protocols submitted for, at least, 2 weeks before a scheduled meeting shall be included in the agenda for full review. Full review shall be conducted through a primary reviewer system. If necessary, independent consultants and or the proponents shall be invited during the meeting to clarify certain issues. The decision shall be communicated to the proponent within six weeks after submission of required documents.
OBJECTIVE OF THE ACTIVITY	A full review aims to ensure compliance with technical and ethical standards in the conduct of research involving human participants and identifiable human data and materials.
SCOPE	This SOP applies to initial, resubmissions and post-approval submissions which are classified as entailing more than minimal risk to study participants or whose participants belong to vulnerable groups. This SOP begins with the assignment of primary reviewers or independent consultant/s and ends with the filing of protocol-related documents.

Workflow

STEP	ACTIVITIES	RESPONSIBILITY	TIMELINE	INTERFACE
1	Assignment of primary reviewers or Independent Consultant/s	CHAIR		SOP 03 on Appointment of Independent Consultants
	↓			
2	Notification of primary reviewers or Independent Consultants	MEMBER SECRETARY		
	↓			
3	Provision of protocol and protocol-related documents and assessment forms to reviewers	STAFF SECRETARY		
	↓			
4	Provision of protocol and protocol-related documents to the rest of the board members	MEMBER SECRETARY	three (3) days before the board meeting	



Description of Procedures

Step 1 - Assignment of primary reviewers or Independent Consultants.

The Chair assigns members who have the necessary expertise as primary reviewers, designates an independent consultant in case such expertise is not present among the members, and including a non-scientist member to review the Informed Consent Process and Form.

Step 2 - Notification of primary reviewers and/or Independent Consultants:

The REB Member Secretary notifies the assigned primary reviewers and/or independent consultants about their assignment by email with a request that they confirm their acceptance and availability within 3 days.

Step 3 - Provision of protocol and protocol-related documents and assessment forms to primary reviewers/independent consultants:

Upon receipt of confirmation/acceptance, the Staff Secretary prepares copies of the protocol and/or protocol-related documents and assessment forms for delivery to the primary reviewers and/or independent consultants.

Step 4 - Provision of protocol and protocol-related documents to the rest of the board members:

The Member Secretary provides the rest of the members of the REB with an executive summary of the study proposal (included among the submitted documents in the Application package, Form Application Form) three (3) days before the board meeting, at the latest.

Step 5 - Presentation of review findings and recommendations during a board meeting:

The primary reviewers submit their findings and recommendations (Form E01-01 Protocol Reviewer Worksheet and Form E02-01 Informed Consent Checklist) to the **chair 3 days before** the meeting and present these during the actual meeting. 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.

Step 6 - Discussion of technical and ethical issues:

The Chair leads the discussion of the technical and ethical issues using the protocol assessment check list (Form E01-01), the Informed Consent Assessment checklist (Form E02-01), and the assessment of the primary reviewers as guides for an orderly exchange of ideas. If necessary, the proponent and/or independent consultant may be invited for clarificatory interviews during or after the meeting.

Step 7 - Summary of issues and resolutions:

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

Step 8 – Board action: Based on the deliberation, the REB may take any of the following actions:

- **Approval**
- **Approval with minor modifications**
- **Request for major modifications and resubmission**
- **Disapproval**

The decision is by **voting**, where a **majority decision** is adopted. All decisions and their rationale are documented in the official meeting minutes.

Step 9 - Documentation of board deliberation and action: See SOP on Preparing the Meeting Minutes (SOP 20)

Step 10 - Communication of Board Action to the researcher: See SOP on Communicating REB Decisions (SOP 21)

Step 11 - Filing of protocol-related documents and Updating of the Protocol Database: See SOP on Managing Active Files (SOP 23)

Glossary

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 board 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 a 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.

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

Primary Reviewers – are members of the Research Ethics Board (usually a scientist and a non-scientist) assigned to do an in-depth evaluation of the research-related documents using technical and ethical criteria established by the board. The non-scientist member shall focus on the review of the Informed Consent process and form and reflect on community values, culture and tradition in order to recommend acceptance, non-acceptance or improvement of the informed consent process and form. The primary reviewers shall present their findings and recommendations during the meeting for discussion.

Major Modification – is a recommended revision of significant aspects/s of the study (e.g., study objectives, recruitment of participants, exclusion/inclusion criteria, collection of data statistical analysis, mitigation of risks, protection of vulnerability, etc.) that impact on potential risks/harms to participants and on the integrity of the research.

Minor Modification – is a recommended revision of particular aspect/s of sthe study or related documents that do not impact on potential risks/harms to participants and on the

integrity of the research, e.g. incomplete documentation, incomplete IC elements, unsatisfactory IC format)

Resubmissions - revised study proposals that are submitted after the initial review. Protocol-related Documents - consists of all other documents aside from the proposal/protocol itself that required to be submitted for review, e.g., Informed Consent Form, Survey Questionnaire, CV of proponent, advertisements, In-depth Interview Guide Questions,

Decision - the result of the deliberations of the REB in the review of a protocol or other submissions.

Voting - the act of expressing opinions or making choices usually by casting ballots, spoken word or hand raising. The rule is majority wins.

Consensus - a collective agreement.

Forms

Form E01-01 Protocol Reviewer Worksheet

Form E02-01 Informed Consent Checklist

Form C01-01 Decision Letter Template

History of SOP

Version No.	Date	Authors	Main Change
1	2025 April 23	Daguipa, Duque, Edullan, Umpad	First draft

References

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 Research Involving Human Participants 2022

Philippine Health Research Ethics Board Standard Operating Procedures 2020