1. **Policy Statement**

The IREB shall require the submission of the final report not later than 8 weeks after the end of the study. Final reports shall undergo either expedited or full review.

1. **Objective of the Activity**

This activity aims to ensure that the conduct of the study was in compliance with the approved protocol and that the safety and welfare of study participants were promoted and the integrity of data protected until the end of the study.

1. **Scope**

This Standard Operating Procedure applies to the management and review of final reports submitted by proponents at the end of the study. This SOP begins with the receipt and entry of the final report into the logbook and ends with an update of the protocol database.

1. **Workflow**

|  |  |
| --- | --- |
| **ACTIVITY** | **RESPONSIBILITY** |
| 1: Receipt of final report and entry into logbook (SOP on Management of Active Files (SOP 23) | Staff |
| 2: Retrieval of pertinent protocol file | Staff |
| 3: Notification of Chair and Primary Reviewer | Staff |
| 4:  Full review (SOP 5) | Chair, Primary Reviewer, Committee Members |
| 5: Communication of committee action (SOP 21 on Communication IREB Decisions | Chair |
| 6: Filing of the Final Report and related documents and update of the protocol files.  | Staff |

1. **Description of Procedures**

**5.1 -** **Receipt and entry of final report into logbook**: The Staff receives and enters the date of receipt of the final report into the logbook.

**5.2 - Retrieval of pertinent protocol file**: The staff retrieves the corresponding protocol file as reference in the review of the Final Report.

**5.3 - Notification of Chair and Primary Reviewer**:  For example: “The staff notifies the Chair and the primary reviewers of the receipt of the Final Report and awaits further instructions.”

**5.4 - Full review**: “The Chair instructs the staff to include the report in the agenda of the next meeting and to ensure that the primary reviewer is given the necessary documents so that s/he can prepare the presentation during the next meeting (SOP 5-Full Review).

**5.5 - Communication of committee action** (SOP 21-Communicating IREB Decisions):It is suggested that the IREB consider the following decisions in the review of a final report: acceptance of the Final Report or to require resubmission with corrections.

**5.6 - Filing of the Final Report and related documents and update of the protocol database:** The IREB Staff files the Final Report and related documents in the appropriate folder and updates the protocol database.

1. **Glossary**

 **Final Report**– is a summary of the outputs and outcomes (including documented risks and benefits) of the study upon its completion, as well as the status of all participants. The IREB requires the accomplishment of the Final Report form within a reasonable period after the end of the study.

 **Primary Reviewers**- are members of the Research Ethics Committee (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 committee.

 **Risks** – summary of probable negative or unfavorable outcomes ranging from inconvenience, discomfort, or physical harm based on the protocol.

 **Benefits** – summary of probable positive or favorable outcomes ranging from benefit to the community (or society), indirect gains such as education, or direct therapeutic value

 **Status of participants** – summary of what happened to (condition of) participants recruited to the study, including those that completed the study, those that dropped out, or those withdrawn for specific reasons in accordance with the protocol

**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.

**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.

**Agenda** -   the list of topics or items to be taken up in a meeting arranged in a sequential manner.  It is an outline of the meeting procedure and starts with a “Call to Order”.

**Logbook** – a real-time, chronological record of incoming protocols that includes the Date /Time of Receipt, Title of the Document, Name of the Proponent, Name and Signature of the Submitting Entity, Name and Signature of the Receiver and Action done.

**Database** – a collection of information that is structured and organized so that this can *easily be accessed, managed, intepreted, analyzed and updated.*

1. **Forms**

Form 13A-Final Report Form

Form 12B - Decision Letter Form

1. **History**

|  |  |  |  |
| --- | --- | --- | --- |
| ***Version No.*** | ***Date*** | ***Authors*** | ***Main Change*** |
| 0 |  | IREB SOP Team |  |
|  |  |  |  |

1. **References**

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

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

      Philippine Health Research Ethics Board Standard Operating Procedures 2020

National Ethical Guidelines for Research Involving Human Participants 2022

|  |  |
| --- | --- |
| Prepared by:   |  |
| Recommending Approval:   |   |
| Approved by:   |  |
| Approval Date:   |  |