**Policy Statement**

The IREB needs to classify its protocol files into active or inactive.Active files shall be kept in a secured metal cabinet, arranged in an orderly manner that allows easy identification and retrieval. Access to the active files shall be governed by SOP on Managing Access to Confidential Files (SOP No. XXV)”

**2. Objective/s of the Activity**

*The management of active files ensures accessibility, easy retrieval of current files, and protection of those that require confidentiality.*

**3. Scope**

*This SOP shall cover procedures related to protocols accepted for review, undergoing review, or have been approved by the IREB. This SOP begins with the classification and coding of active files and ends with the periodic updating of the file.*

**4. Workflow**

The following are the steps involved in the process of managing active files and the corresponding responsible persons.

| ***ACTIVITY*** | ***RESPONSIBILITY*** |
| --- | --- |
| *1: Classification and coding of Active Files* | *Member Secretary and Staff* |
| *2: Preparation of the Protocol Folder* | *Staff* |
| *3:  Periodic updating of the Protocol File* | *Member Secretary and Staff* |

**5. Description of Procedure**

**5.1**. **Classification and coding of active files**: *The staff under the supervision of the member secretary classifies active files as follows:*

* *Initial Submission*
* *Resubmission*
* *Progress Report*
* *Amendment*
* *Protocol Deviation*
* *Protocol Violation*
* *SAE Serious Adverse Event (SAE*
* *SUSAR – Suspected Unexpected Serious Adverse Reaction*
* *Early Termination*
* *Continuing Review*
* *Final Report/ Close Out Report*

*The staff assigns a code to the Initial Submission and indicates the same for the rest of the submissions related to the initial submission. The code consists of the year and the serial member that indicate the sequence order of receipt. For example, a protocol received in 2019 as the 10th submission in that year will be coded as 2019-010.*

**5.2. Preparation of the Protocol Folder**: *The staff files all documents pertaining to a study in a vertical folder that is labeled on the front cover and along the spine with Protocol Code- Study Title - Proponent’s Family Name - Sponsor or Funding Agency. The staff attaches a protocol index on the inside front cover that indicates the contents of the folder.*

**5.3.** **Periodic Updating of the Protocol File**: *The staff ensures that the documents are filed in chronological order such that the most recent documents are topmost. These documents include the following:*

* *Protocol (Original and Revised) versions*
* *Informed consent (Original and Revised) versions*
* *Reports: Progress, Protocol Deviation/Violation, SAE/SUSAR, Final, Amendment, Early Termination, Site Visit Reports*
* *Assessment Forms for each of the submitted and reviewed reports should be signed and dated*
* *Excerpts of Minutes of Meetings when the protocol and reports were included in the agenda*
* *Decision and Approval Letters*
* *Communications*

*The staff updates the FORM protocol index each time a new document is added to the file. The protocol folder is periodically checked for orderliness and completeness.*

**6. Glossary**

The following terms/abbreviations were used in this SOP:

**Initial Submission** - a set of documents consisting of the full proposal and other study-related documents that is received by the IREB so that ethical review can be done.

**Resubmission-** the revised study protocol that is forwarded to the IREB in response to the recommendations given during the initial review.

**Progress Reports-** A systematized description of how the implementation of the study is moving forward. This is done by accomplishing the Review of Progress Report Form No. VIII. The frequency of submission (e.g., quarterly, semi-annually or annually) is determined by the IREB based on the level of risk.

 **Amendments-** a change in or revision of the protocol made after it has been approved.

**Protocol Deviation-** non-compliance with the approved protocol that does not

increase risk nor decrease benefit to participants and does not significantly affect their rights, safety or welfare, or the integrity of data. Example: missed visit, non-submission of a food diary on time.

**Protocol Violation-** non-compliance with the approved protocol that may result in an

increased risk or decreased benefit to participants or significantly affect their rights, safety or welfare or the integrity of data. Example: incorrect treatment, non-compliance with inclusion/exclusion criteria.

**Serious Adverse Event (SAE)** – is an event observed during the implementation of a study where the outcome is any of the following:

* Death
* Life threatening
* Hospitalization (initial or prolonged)
* Disability or permanent damage
* Congenital anomaly/ birth defect
* Required intervention to prevent permanent impairment or damage (devices)
* Other serious (important medical) events whether or not it is related to the study intervention.

**Suspected Unexpected Serious Adverse Reaction (SUSAR)** - is a noxious response to

a drug that is not described in the Investigator’s Brochure nor in the drug insert.

**Early Termination**- is ending the implementation of a study before its completion. This is a decision made by the sponsor or regulatory authority and/or recommended by the Data Safety Monitoring Board, researcher/investigator in consideration of participant safety, funding issues, protocol violations, and data integrity issues.

**Continuing Review** - is the decision of the IREB to extend ethical clearance of a study beyond the initial period of effectivity based on an appreciation that the research is proceeding according to the approved protocol and there is a reasonable expectation of its completion.

**Final Reports/Close Out Reports** – is a summary of the outputs and outcomes of the study upon its completion. The IREB requires the accomplishment of the Final Report form within a reasonable period after the end of the study.

**Protocol Index** - is a chronological record of the documents in the protocol file.  The protocol index is in table form indicating the date of filing, the nature of the document filed, the name and signature of the person who filed and an extra column to record any movement of the document. The index is pasted inside the cover page of the protocol file/folder for easy reference and checking.

**Assessment Form** – evaluation tool accomplished by the reviewers when appraising the protocol or the informed consent form.

**7. Forms:**

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

Form 7 Protocol Folder Index

**8. History of SOP**

|  |  |  |  |
| --- | --- | --- | --- |
| ***Version No.*** | ***Date*** | ***Authors*** | ***Main Change*** |
| *0* |  | *Generaldo D. Maylem, MD* | *First draft* |

**9. References**

The following references were used in the preparation of this SOP:

1. WHO Standards and Operational Guide for Ethics Review of Health-Related Research with Human Participants 2011

2.  CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

3. Philippine Health Research Ethics Board Standard Operating Procedures 2020

4. Philippine National Ethical Guidelines for Research Involving Human Participants 2022

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