1. **Policy Statement**

Protocols for archiving include those (a) with approved/ accepted Final Reports, (b) with approved Early Termination reports, and (c) whose proponent/researcher/investigator has not submitted a response to the IREB recommendation after 3 months (or as specified by the IREB).

The archiving policy of IREB shall use a data management system for all IREB documents. After classifying whether the document is protocol-related or non-protocol-related, retrieval of archives shall be based on the year the protocol was submitted. For non-protocol related, retrieval shall be based on the year issued.

As per the prescriptions of the WHO Operational Guidelines/CIOMS Guidelines/ICH GCP and the National Ethical Guidelines need to be followed including security of file storage and access, document control, and document tracking. F*iles of studies that have been terminated or completed or declared inactive shall be kept in separate storage for three (3) years.  Studies of Researchers who have not resubmitted their proposals within 3 months after receiving the Notification Letter (Form ##) shall be considered inactive*

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

*Archiving inactive, terminated, or completed protocols ensures efficient retrieval of information from the files for reference and compliance with national and international guidelines.*

1. **Scope**

*This SOP includes procedures related to the storage and retrieval of protocols that are classified as inactive, terminated, or completed. This SOP begins with the acceptance of final or early termination reports and identification of a protocol as inactive and ends with the inclusion of the files in the archives and update of the protocol database.*

1. **Workflow**

The following are the different steps involved in the process of archiving of terminated, inactive, and completed files with the corresponding responsible persons in each of these steps.

|  |  |
| --- | --- |
| ***ACTIVITY*** | ***RESPONSIBILITY*** |
| *4.1: Acceptance of Final or Early Termination Reports (SOP## on Review of Final Reports, SOP No. XIV Review of Early Termination Reports, and Identification of a Protocol as Inactive.* | *IREB Members, Chair* |
| *4.2: Updating of corresponding protocol folder* | *IREB Staff* |
| *4.3: Transfer of the protocol folder in the archives and Update of the Protocol Database* | *IREB Staff* |

1. **Description of Procedures**

The following are the detailed steps involved in the SOP and documents and forms to be included in the review process:

**5.1 - Acceptance of Final or Early Termination Reports and Identification of an Inactive File:** *The Committee members approve or accept the final report or early termination report during a meeting (SOP XIII.  Review of Final, Report; SOP No. XV.  Review of an Early Termination Report).  In the identification of an Inactive File, the staff informs the Member Secretary of the failure of a concerned researcher/ proponent/ investigator to respond to the recommendations of the IREB in the last 3 months during which time the researcher/proponent/investigator has been appropriately reminded of the requirement.  This is included in the agenda of the next meeting where the protocol is declared inactive.*

**5.2 - Updating of the corresponding active file**: *The staff files the Final or Early termination report in the corresponding protocol folder, including the excerpts of the minutes that approved the report or declared the protocol as inactive.*

**5.3 - Transfer of the Protocol Folder in the Archives and Update of the Protocol Database:** *The* **staff** checks whether the documents listed in the protocol file index are complete and removes extraneous documents. Then, the staff transfers the folder to the archive section and updates the protocol database.

1. **Glossary**

The following terms/abbreviations were used in this SOP:

*Final Report – 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.*

*Early Termination - ending the implementation of a study before its completion*.

*Inactive Study – a study whose proponent has not communicated with the IREB with regard to issues pertaining to the approval or implementation of the study – within a period of time required by the IREB.*

*Active Study – is an ongoing study, implementation of which is within the period covered by ethics clearance.*

*Archiving- is the systematic keeping of protocol files in storage after the studies have been completed with final reports accepted, or terminated or declared inactive.*

*Confidentiality*

*of Documents – pertains to the recognition and awareness that certain documents that have been entrusted or submitted to the IREB must not be freely shared or disclosed.*

*Controlled*

*Document – pertains to the document that have been entrusted or submitted to the IREB that must not be freely shared or disclosed such that it is appropriately tagged and its distribution carefully tracked, monitored and appropriately recorded.*

1. **Forms**

The following forms/templates/tools were used in the implementation of this SOP?

*Borrower’s Logbook*

1. **History of SOP**

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

1. **References**

*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*