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| Supersedes: | Previous SOPs |
| Prepared by: | SOP Team 2019 |
| Reviewed by: | Dr. Manuel Emerson Donaldo |
| Reviewed Date: | December 14, 2018 |
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**1. Policy Statement**

Active files shall be kept in a secured cabinet, arranged in an orderly manner that shall allow easy identification and retrieval. Access to the active files shall be governed by SOP on Managing Access to Confidential Files (SOP# 7.4).

**2. Objective of the Activity**

To provide instructions for preparation, circulation and maintenance of active study files and other related documents approved by the CIM-CVGH IRB.

**3. Scope**

This SOP provides instructions related to the management of active study files that include protocol submissions, all documents that reflect all actions taken by the REC before completion of the study. It also provides instructions for the maintenance and storage of other REC documents that include SOPs, REC membership files, agenda and meeting minutes, relevant international and national regulations and guidelines, etc.

**4. Responsibility**

It is the responsibility of REC Secretariat to manage all protocol submissions and documents that reflect all IRB. Actions and organize them in an orderly manner. The IRB Secretariat also manages the maintenance and storage of all IRB documents and records.

**5. Process Flow/Steps**

| ***ACTIVITY*** | ***RESPONSIBILITY*** |
|---|---|
| ***Step 1:****Design a standard coding system for all protocols submitted to the IRB for review* | *CIM-CVGH IRB* |
| ***Step 2:****File all submitted documents in an orderly sequence in a protocol folder* | *IRB Secretariat* |
| ***Step 3:****Update the active protocol files regularly by chronologically organizing the contents of the active study files according to time of receipt* | *IRB Secretariat* |
| ***Step 4:****Storeproperlylabelled active protocol file folder Keep the active protocol files in the Active File Cabinet in the office* | *IRB Secretariat* |

**6. Description of Procedures**

***Step 1:*** *Design a standard coding system for all protocols submitted to the IRB for review*

- Protocol files of CIM-CVGH IRB - approved protocols are considered active from the moment the protocol files are received for review until such time they are inactivated

either by completion or termination. It is necessary to use a unique identifier or code to refer to protocol file for efficient file management and retrieval.

- Color code for Active files: GREEN. Completed files: YELLOW. Terminated files: RED. Inactive files: GREY. STICKERS will be used to identify such files in their binders
- Protocol files are considered active from the moment the protocols are received for initial review until such time they are in activated either by its completion or termination or its withdrawal from the review process. Active protocol files are either those undergoing REC review process or REC-approved ongoing studies. It is necessary to use a unique identifier or code to refer to protocol file for efficient file management and retrieval
- Code active study files as follows: CIM-CVGH RERC – yyyy (year) –number (chronological number based on order of receipt). Protocol Code No. given by the IRB as described in SOP 2.1 on Management of Initial Submission
    - For example, if Protocol entitled “First Clinical Drug Trial on Pediatric Patients” is the first protocol received in 2016, the code (CIM-CVGH IRB 2016-01) is the code that should be used to identify this protocol.
- Study Protocols are identified using a unique identification number known as Protocol Code No. given by the REC as described in SOP 2.0 on Management of Initial submission.
- File protocol documents in sturdy file folders-binder, using one folder-binder per study protocol title. The protocol file folder is to be labeled (Protocol code no., title of the protocol, name of PI, sponsor on the front cover of the file binder.

***Step 2:*** *File all submitted documents in an orderly sequence in a protocol folder*

- The protocol file folder contains the following documents arranged chronologically in an organized manner according to the Protocol File Index per type of submission (eg. initial submission, protocol amendment, progress report, SAE Reports, Protocol Violation/Deviation, etc.):

    - All versions of study protocol
    - Related documents that came with the study protocol (ICF, CRF, recruitment materials, patient diary, IB, etc.)
    - Principal investigator and co-investigators' CVs and ((other similar documents))a
    - valid GCP Training Certificate, if required
    - Reviewers’ assessment forms (Form 2.3 & Form 2.4)
    - Amendment reports (Form 4.2)
    - Continuing review applications
    - Serious Adverse Event Reports or Safety Notifications (Form 3.3)
    - Non-compliance (Deviation or Violation) reports (Form 4.2)

- Participant Queries/ Complaints, if any (Form 8.0)
- Site Visit Reports, if any (Form 7.0)
- Notifications of IRB Decision (Form 2.6)
- Approval letters (Form 2.7)Decision letters (notification letters or approval letter/s initial and renewal)
- Post-Approval submissions (protocol amendment, progress report, SAE report, protocol deviation/violation report, early termination report) and corresponding reviewers' assessment and REC decision letters
- ((Notifications of IRB Decision (Form 2.6))
- Miscellaneous communication related to the protocol
- Final report (Form 4.4)

***Step 3:*** *Update the active protocol files regularly and ensure that all actions are also recorded in the database*

- Combine related documents of the approved study files appropriately. Attach an identity Label to the package.

***Step 4:*** *Keep the active protocol files in the office*

- Store the closed study files for at least 5 years after the study closure.
- For studies with multiple study sites, the Secretariat should maintain the files to allow cross-referencing without unnecessary duplications.
  Place the protocol file binders in the shelf in vertical position and sequentially arranged according to their Protocol Code No.
- Label the storage cabinet with the year when the protocols were submitted.
- Keep all active study files in a secure filing cabinet, with access limited only to IRB Chair and Secretariat. The IRB Staff keeps the keys of file storage cabinets.

## 7. History of SOP

| ***Version No.*** | ***Date*** | ***Authors*** | ***Main Change*** |
|---|---|---|---|
| *01* | *November 16, 2018* | *IRB Members* | *First draft* |

**8.** *Forms (none)*

**9. References:**

- Philippine Health Research Ethics Board (PHREB) Workbook 2015

- World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
- International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
- National Ethical Guidelines for Health Research 2011 PNHRS