## 1. Purpose

To describe Chong Hua Hospital Institutional Review Board (CHH IRB) procedures related to maintaining the confidentiality of the study files and other IRB documents.

## 2. Scope

This SOP provides instructions to the CHH IRB Secretariat related to maintaining the confidentiality of all study files and documents.

## 3. Responsibility

It is the responsibility of the CHH IRB Secretariat to ensure that confidentiality is maintained in the management of all study files and records and to follow the confidentiality procedures when requests to access the files are granted.

## 4. Flow chart

| ACTIVITY | PERSON/S RESPONSIBLE |
|---|---|
| **Step 1:** Properly manage all active and inactive IRB files | CHH IRB Staff |
| **Step 2:** Receive request to access confidential files | Member-Secretary |
| **Step 3:** Approve and log in request for access and retrieval | Secretariat |
| **Step 4:** Supervise the use of retrieved confidential | Secretariat |
| Return document to the protocol file folder | CHH IRB Staff |

## 5. Procedures

**Step 1- Properly manage all active and inactive CHH IRB files.**

- Properly handle original documents and copies of these documents during the day-to-day operation of the IRB to protect the confidentiality of study files and related documents. Proper handling also involves proper control and care in the distribution and storage of confidential documents of the IRB.
- Study files submitted to the CHH IRB and related documents are considered confidential, such as:
    - Study protocols and related documents (case report forms, informed consent documents, diary forms, scientific documents, expert opinions or reviews)
    - IRB documents (Meeting minutes, advice, and decisions)
    - Correspondence (with experts, auditors, study participants, etc.)

**Step 2- Receive request to access CHH IRB confidential files:** Access to IRB confidential documents is subject to the following limitations:

- CHH IRB members and staff with a signed *Confidentiality Agreement and Conflict of Interest Disclosure* can access confidential documents outside of regular protocol review access, upon request.
- Non-members can access specific documents by submitting a formal request. The Secretariat will require a *Confidentiality Agreement Form for Non-Members* (see ANNEX 1) to be signed by the person making the request, and approved by the CHH IRB Chair or Vice- Chair or designated IRB Member in the absence of the CHH IRB Chair.
- Regulatory authorities can have full access to CHH IRB documents provided it is within their mandate (e.g. FDA), and within a reasonable notice to make the files available.
- The Secretariat records all transactions whenever any document of the CHH IRB is accessed as described above.

**Step 3- Approve and log in requests for access and retrieval of documents:** A separate log is kept in the protocol folder to record access as described above (see ANNEX 2). It contains the following information:

- Study file code
- Date borrowed
- Name of borrower
- Signature of borrower upon retrieval
- Signature of IRB Secretariat upon return of document to the file folder
- Document copied
- Number of copies made
- Number of copies received

All requests for access are recorded by the Secretariat Staff in the log before copies of any documents are released.

**Step 4- Supervise the use of retrieved confidential document**

- Access to CHH IRB documents is generally for room use only, but requests to make copies can be accommodated on a case to case basis.
- The Secretariat makes only the exact number of copies requested.
- The recipient signs the IRB log upon receipt of the copies.

**Step 5- Return document to the protocol file folder:** The CHH IRB Staff is responsible for returning the documents in the protocol file folder in the storage cabinet after making sure that all documents are complete as per Protocol File Index.

**6. History of SOP**

| Version No. | Date | Authors | Main Change |
|---|---|---|---|
| 1 | 10 September 2010 | Dr. Cheryl K. Bullo | First Draft |
| 2 | - | - | - |
| 3 | 01 September 2014 | Dr. Manuel Emerson S. Donaldo | Change of IRB SOP in accordance to PHREB SOP Format |
| 4 | 01 October 2014 | Dr. Manuel Emerson S. Donaldo | Revised IRB SOP in accordance to PHREB SOP Format |
| 5 | 01 January 2017 | Dr. Cheryl K. Bullo | Revised CHH IRB SOP from version 04 to Version 05 |
| 6 | 02 October 2017 | Atty. Geraldine Cajilig | Revised CHH IRB SOP in accordance to 2017 DOH-REC SOP ver02 Template |
| 7 | 04 January 2021 | Atty. Geraldine Cajilig | No change |
| 8 | 04 January 2024 | Atty. Dean G. Decal | Revised CHH IRB SOP in accordance with REC re-accreditation and Survey on 30 June 2023 |
| 9 | 21 August 2024 | Atty. Dean G. Decal | No change |

**7. References**


- 2017 Department of Health – SOP Version No. 2
- 2020 PHREB SOP Workbook