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1. Purpose

To describe IRB procedures related to the protection of confidentiality of the study files as well as other documents of the IRB

2. Scope

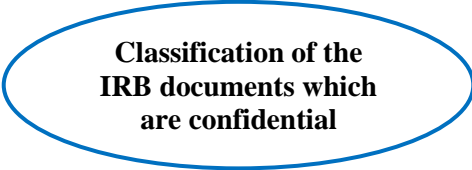



This SOP provides instructions to the Secretariat related to the protection of confidentiality of all study files as well as documents of the IRB

3. Responsibility

It is the responsibility of the IRB Secretariat under the supervision of the Member Secretary to ensure that confidentiality is maintained in the management of all study files and records.

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4. Flow chart

No.	ACTIVITY	RESPONSIBLE PERSONNEL
I		Member/ Secretariat
II		Secretariat
III		Secretariat
IV		Secretariat

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5. Detailed instructions

- 5.1 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.
- 5.2 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)
 - CHH IRB documents (Minutes of the meeting or decisions)
 - Correspondence (experts, auditors, study participants, etc.)
- 5.3 Access to CHH IRB confidential documents is subject to the following limitations:
- 5.3.1 CHH IRB members and staff with a signed *Confidentiality Agreement and Conflict of Interest Disclosure* (see ANNEX 1) can access confidential documents outside of regular protocol review access upon request.
- 5.3.2 Non-members can access specific documents by submitting a formal request. The Secretariat will provide a copy of the *Confidentiality Agreement Form for Non-members Requesting for Copies of CHH IRB Documents* (see ANNEX 2) to be accomplished by the person making the request to be signed by the Chair.
- 5.3.3 Regulatory authorities have full access to CHH IRB documents provided it is within their mandate (e.g. FDA), and upon reasonable notice to make the files available signed by the recognized official of the regulatory authority (e.g. FDA Director).
- 5.4 The Secretariat records the retrieval of CHH IRB documents.
- 5.5 The Secretariat makes a record every time a document of the CHH IRB is accessed as described above.

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5.6 A log filed in the protocol folder is dedicated for purposes of recording access as described above, which contains the following fields of information: (see ANNEX 3)

- Study File Code (Sponsor Protocol No. and IRB Reference No.)
- Date borrowed
- Number of borrower
- Name and Signature of borrower upon retrieval
- Signature of IRB Secretariat upon return
- Document copied
- Number of copies made
- Number of copies received

5.7 Access to CHH IRB documents is generally room use only but any request to make copies can be accommodated only on a case to case basis.

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

5.9 The Secretariat makes only the exact number of copies requested.

5.10 Upon receipt of the copies, the person who requested the copies will sign the Log of Request Form



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6. ANNEX 1: Confidentiality/ Conflict of Interest Agreement Form for Members

ANNEX 1



崇華醫院
Chong Hua Hospital
Fuente Osmeña, Cebu City
Tel# +63(32) 255-8000; Fax# +63(32) 253-5639

**CONFIDENTIALITY/
CONFLICT OF INTEREST
AGREEMENT FORM**
Form HRP-IRB-004

In recognition of the fact that I, _____ herein referred to as the "Undersigned", has been appointed as a member of the CHONG HUA HOSPITAL IRB has been asked to assess research studies involving human subjects in order to ensure that they are conducted in a humane and ethical manner, with the highest standards of care according to the applied national, local regulations, institutional policies and guidelines;

Whereas, the appointment of the undersigned as a member of CHONG HUA HOSPITAL IRB is based on individual merits and not as an advocate or representative of a home province/ territory/ community nor as the delegate of any organization or private interest;

Whereas, the fundamental duty of an IEC/IRB member is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions under review;

Whereas, the CHONG HUA HOSPITAL IRB must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of human subjects;

The undersigned, as a member of the CHONG HUA HOSPITAL IRB, is expected to meet the same high standards of ethical behavior to carry out its mandate.

This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a member of the CHONG HUA HOSPITAL IRB. Any written information provided to the Undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly.

As such, the Undersigned agrees to hold all Confidential or Proprietary trade secrets ("information") in trust or confidence and agrees that it shall be used only for contemplated purposes, shall not be used for any other purpose or disclosed to any third party. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the IRB.

The Undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the Undersigned confirms that his/her performance of this agreement is consistent with the institute's policies and any contractual obligations they may have to third parties.

CONFIDENTIALITY/CONFLICT OF INTEREST AGREEMENT FORM
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ANNEX 1



崇華醫院 Chong Hua Hospital Fuente Osmeña, Cebu City Tel# +63(32) 255-8000; Fax# +63(32) 253-5639

CONFIDENTIALITY/ CONFLICT OF INTEREST AGREEMENT FORM

Form HRP-IRB-004

Conflict of Interest

It is recognized that the potential for conflict of interest will always exist but has faith in the IEC/IRB and its Chairperson to manage the conflict issues so that the ultimate outcome is the protection of human subjects.

It is the policy of the CHONG HUA HOSPITAL IRB that no member may participate in the review, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the CHONG HUA HOSPITAL IRB.

The Undersigned will immediately disclose to the Chairperson of the CHONG HUA HOSPITAL IRB any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the Committee, and to abstain from any participation in discussions or recommendations in respect of such proposals.

If an applicant submitting a protocol believes that an IRB member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol.

The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the EC member(s) in question. The Committee may elect to investigate the applicant's claim of the potential conflict.

When a member has a conflict of interest, the member should notify the Chairperson and may not participate in the IEC/IRB review or approval except to provide information requested by the Committee.

Examples of conflict of interest cases may be any of the following:

- A member is involved in a potentially competing research program.
Access to funding or intellectual information may provide an unfair competitive advantage.
A member's personal biases may interfere with his or her impartial judgment.



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CONFIDENTIALITY/ CONFLICT OF INTEREST AGREEMENT FORM

Form HRP-IRB-004

Agreement on Confidentiality and Conflict of Interest

Please sign and date this Agreement, if the Undersigned agrees with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the CHONG HUA HOSPITAL IRB. A copy will be given to you for your records.

In the course of my activities as a member of the CHH IRB, I may be provided with confidential information and documentation (which we will refer to as the "Confidential Information"). I agree to take reasonable measures to protect the Confidential Information; subject to applicable legislation, including the Access to Information Act, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including any minutes or notes I have made as part of my Committee duties) to the Chairperson upon termination of my functions as a Committee member.

Whenever I have a conflict of interest, I shall immediately inform the Chairperson not to count me toward a quorum for voting.

I, _____ have read and accept the aforementioned terms and conditions as explained in this Agreement.

Undersigned Signature


Date

CHONG HUA HOSPITAL MEDICAL DIRECTOR

Date

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ANNEX 2: Confidentiality/ Conflict of Interest Agreement Form for Non-Members Requesting Copies of CHH IRB Documents



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Chong Hua Hospital
 Fuente Osmeña, Cebu City
 Tel# +63(32) 255-8000; Fax# +63(32) 253-5639

ANNEX 2

**CONFIDENTIALITY
 AGREEMENT FORM**
 FOR NON-MEMBERS REQUESTING
 COPIES OF CHH IRB DOCUMENTS

Form HRP-IRB-006

I, _____ as a non-member of CHH IRB, understand that the copy (ies) given to me by the CHH IRB is (are) confidential. I shall use the information only for the indicated purpose as described to the CHH IRB and shall not duplicate, give or distribute these documents to any person(s) without permission from the CHH IRB. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as Confidential.

I have received copies of the following CHH IRB documents:

Signature of the recipient

Date

Chairperson of CHH IRB

Date

CONFIDENTIALITY AGREEMENT FORM
 FOR NON-MEMBERS REQUESTING COPIES OF CHH IRB DOCUMENTS

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ANNEX 3: Log of Request for Copies of CHH IRB's Documents

ANNEX 3



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LOG OF REQUEST FOR COPIES OF CHH IRB'S DOCUMENTS

Form HRP-IRB-030 ver05

Table with 8 columns: Study File Code, Date borrowed, No. of borrower, Name & Signature of borrower upon retrieval, Signature of IRB Secretariat upon return, Document copied, No. of copies made, No. of copies received.