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1. Purpose

The purpose of this SOP section is to provide procedures for engaging the expertise of a professional as a consultant to the CHH IRB in the event that a review will need a content expert to shed light.

2. Scope

If the Chairperson or the CHH IRB determines that a study will involve procedures or information that is not within the area of expertise of the CHH IRB members, the Chairperson or the CHH IRB may invite individuals with competence in special areas as Ad Hoc members to assist in the review of issues that require expertise beyond or in addition to those available in the CHH IRB.

Membership

Membership of the Chong Hua Hospital IRB is as follows:

i. Chairman
ii. At least 7 regular members with the following:
    1. One medical member
    2. One non-medical member
    3. One non-institutional member
    4. Member to represent the religious sector
    5. Methodology expert
    6. Legal expert

iii. Ad hoc member
    1. Scientific/medical expert with related expertise for the particular research (Independent consultant)
    2. Representative for women's health
    3. Representative for children's health

3. Responsibility

Upon the advice or recommendation of the secretariat or any CHH IRB member, it is the responsibility of the CHH IRB to nominate and approve the name of the special consultants to be endorsed by the Chairperson, appointed by the medical director. The consultant may be invited from the list of hospital staff or if need be from outside the hospital staff.

4. Flowchart

No.	ACTIVITY	RESPONSIBLE PERSONNEL
I	Selection of Independent Consultants	CHH IRB Members / Secretariat
II	Provision of services as appropriate per expertise	Consultant
III	Termination of the Services	Consultant / CHH IRB

5. Detailed Instructions

5.1 Selection of Independent Consultants

- Identify the experts by the CHH IRB member and Secretariat.
- Nominate the consultants.
- Conduct a qualification review of the prospective consultant. Usually the consultant is taken from previous investigators with character and integrity.
- Make decision based on expertise, availability and independence criteria.
- Get approval from the CHH IRB.
- Contact the consultant.
- The consultant provides:
  ☑ A curriculum vitae
  ☑ A signed ***Confidentiality/Conflict of Interest Agreement*** (HRP-IRB-033, see ANNEX 1 of this SOP)
- Keep the documents in a consultant's file.
- Create a roster of consultants and the areas of their expertise.

5.2 Provision of Expert Services

- CHH IRB provides the needed study protocol documents to the appropriate consultant
- He does not necessarily review the protocol but is expected to provide a expert comment on the paper. As applicable the consultant may only be invited to shed light on a part of the protocol that the IRB finds difficult to resolve.
- The consultant may be invited to attend the CHH IRB meeting, present the report and participate in the discussion but ***CANNOT VOTE*.**
- The consultant is expected to provide a written report and this becomes a permanent part of the study file.

5.3 Termination of the Services

- A consultation service is terminated by either the consultants themselves or by the CHH IRB upon conclusion of the review process.
- Upon termination of the consultant's services, a member of the Secretariat ensures that all the qualifying documentation and the reason for discontinuation of the services are filed with the administrative documents.

6. ANNEX

HRP-IRB-033 Confidentiality/Conflict of Interest Agreement Form (Independent Consultant)

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Chong Hua Hospital
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Tel# +63(32) 255-8000; Fax# +63(32) 253-5639

CONFIDENTIALITY/ CONFLICT OF INTEREST AGREEMENT FORM
Form HRP-IRB-033

In recognition of the fact that I, _____ herein referred to as the "Undersigned", has been appointed as an independent consultant 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 an independent consultant 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 an independent consultant 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 an independent consultant 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 Page 1 of 3

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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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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 an independent consultant 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 Date
MEDICAL DIRECTOR

7. References

- 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