



Healing with Passion.  
Caring with Compassion.

# CHONG HUA HOSPITAL INSTITUTIONAL REVIEW BOARD

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## Title: 1.1 Ethical Framework and Constitution of the IRB

SOP/001/05

Effective date:  
01 January 2017

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## 1. Purpose

The CHONG HUA HOSPITAL IRB, was established on January 2009 in order to provide independent guidance, advice, and decision (in the form of approval/recommendation/clarification/disapproval) on health researches or other specific research protocols involving human participants and human biologic materials.

The CHH IRB is composed of both medical and non-medical persons. It is independent in its reflection, advice, and decision.

This Standard Operating Procedure (SOP) describes the Terms of Reference (TOR) which provide the framework for constitution, responsibilities and activities of the Institutional Review Board (IRB). The TOR is further supported by the Standard Operating Procedures of *CHONG HUA HOSPITAL*.

## 2. Scope

This SOP applies to all activities under the CHH IRB. It describes the general ethical basis or values on which the CHH IRB is based, the composition and appointment, duties and responsibilities of IRB personnel, including attendance, training, expected deliverables, and disclosure of conflict of interest.

## 3. Responsibility

The CHH Medical Directorate is responsible for the constitution and establishment of the CHH IRB, appointment of the CHH IRB and Secretariat and allocation of an annual budget for operational expenses, compensation and training, and other educational activities available locally and abroad.

The CHH IRB shall enjoin IRB personnel to attend trainings, seminars, workshop as needed and shall ensure that adequate resources are provided for continuing professional development.

The CHH IRB Chair, Board members, Secretariat must read, understand and respect the rules set by the CHH IRB

Newly appointed CHH IRB members must read, understand, and sign required appointment forms at the start of their appointment or reappointment. If a member refuses to sign such an agreement, this may be a ground for his or her disqualification to serve in the CHH IRB or participate in the deliberation of

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certain protocols. Newly appointed members must also undergo training during the course of their appointment.

Existing CHH IRB members must continuously update themselves and train on relevant knowledge and skills.

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#### 4. Flowchart

No.	ACTIVITY	RESPONSIBLE PERSONNEL
I	Selection of CHH IRB Members	CHH IRB Members and Secretariat
II	Submission and Collation of Requirements for members	CHH IRB Members and Secretariat
III	Appointment of members	COO/ IRB Chair with COO conforme
IV	Resignation, Disqualification, Replacement of Members	Medical Director, IRB Chair, CHH IRB Members and Secretariat

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## 5. Detailed Instructions

### 5.1 Selection of CHH IRB Members

The IRB is composed of members who collectively have the qualifications and experience to review and evaluate the science, medical aspects and ethics of the proposed trial.

- The CHH IRB is composed of *at least 5 voting members*
- The members shall include at least one (1) member whose primary concerns are in medical science, at least one (1) member whose primary concerns are in non-medical/non-scientific areas, and at least a member from outside the Chong Hua Hospital.
- The IRB composition shall be multidisciplinary and multi-sectoral and shall have adequate representation of members with regard to age and sex.
- Professional qualifications may include physician, pharmacist, nurse, social scientist, lawyer, statistician, paramedic and/or layperson.
- A list of IRB members and their qualifications is maintained at the IRB office and the office of the Medical Director.
- The IRB performs its functions according to written operating procedures, should maintain written records of its activities and minutes of its meeting.
- The Chong Hua Hospital IRB is in compliance with the GCP requirements as well as with the applicable regulatory requirements.
- Membership to the IRB is for the duration of 3 years from initial appointments. Reappointments depend on the discretion of the Chong Hua Hospital Board of Trustees.
- Reviewing members are given an honorarium for the whole review process.

#### A. 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 (Technical Expert)

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## 6. Legal expert

### iii. Ad hoc member (as applicable)

1. Scientific/Medical expert for the particular research (Independent consultant)
2. Representative for women's health
3. Representative for children's health

## 5.2 Appointment of Members

- The head of the institution (President/CEO/COO/Medical Director) is responsible for making the appointment of committee Chair. Likewise the Medical Director through the HRD officer appoints a secretariat staff for the IRB.
- It is the responsibility of the Chairperson to recommend for membership the other members of the CHH IRB to the Medical Director for approval.
- Members are selected in their personal capacities, based on their interest, ethical and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the IRB's work.
- Members must disclose in writing any interest or involvement – financial, professional or otherwise – in a project or proposal under consideration.
- The CHH IRB will decide the extent to which members that might have a conflict of interest may participate in bringing out an advice/decision (Refer to SOP/004/05 - Confidentiality/Conflict of Interest Agreement).
- Members will be required to sign a confidentiality agreement at the start of their term.
- The confidentiality agreement protects the privacy and confidentiality of all parties whose information may be disclosed to the CHH IRB in the course of its work.
- Members are appointed for a period of 3 years
- Their appointments may be renewed by the Medical Director or COO of *CHONG HUA HOSPITAL* for up to two consecutive terms.

The IRB will include some rotation after a period of three-year for up to two consecutive terms, but it will also strive to ensure continuity within the IRB.

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### 5.3 Roles & Responsibilities of IRB Officers

- The following officers through their respective responsibilities contribute to the good functioning of the IRB:

Chairperson	<ul style="list-style-type: none"> <li>▪ responsible to chair the meetings and liaise directly with the Director or President of <i>CHONG HUA HOSPITAL</i></li> <li>▪ invite independent consultants to provide special expertise to the EC on proposed research protocol</li> <li>▪ prepares the budget and proposes membership</li> <li>▪ recommends policy amendments and changes and updates in policies and procedures</li> <li>▪ represents the CHH IRB in the research organizational structure of CHH</li> <li>▪ represents CHH in national and international ethics fora</li> <li>▪ oversees the operations of CHH IRB</li> <li>▪ supervises the management of the CHH IRB Office</li> <li>▪ acts on suggestions, complaints and queries from stakeholders</li> <li>▪ ensures CHH IRB compliance with international, national and institutional policies governing human subject research and protection</li> <li>▪ supervises the issuance of all IRB communication with respect to IRB decisions and actions</li> <li>▪ ensures the basic training, orientation and continuing education of CHH IRB members and staff</li> <li>▪ liaises with stakeholders outside of CHH</li> <li>▪ provides updates on relevant and contemporary issues related to topics in health research (CHH IRB SOP 2017)</li> </ul>
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Co-Chairperson	<ul style="list-style-type: none"> <li>▪ responsible to chair the meetings in the absence of the Chairperson and act as vice-chair during meetings with the Chairperson</li> <li>▪ recommends the development, implementation and monitoring of CHH IRB policies and procedures to the IRB Chair</li> <li>▪ signs in behalf of the Chair in protocol-related decisions and communications</li> <li>▪ assists the CHH IRB Chair in budget planning and the preparation of annual reports to be submitted to the Medical Director</li> <li>▪ performs other IRB-related tasks assigned by the Chair (CHH IRB SOP 2017)</li> </ul>
Member Secretary	<ul style="list-style-type: none"> <li>▪ Has direct oversight of the staff secretary</li> <li>▪ responsible for the administrative aspect of the IRB</li> <li>▪ oversees all IRB protocols reviewed by members and protocols submitted to the CHH IRB</li> <li>▪ oversees accuracy of the agenda and minutes of the meeting</li> <li>▪ supervises the preparation of communication of protocol-review-related actions to the principal investigator</li> <li>▪ performs other CHH IRB-related tasks that may be assigned by the Chair</li> <li>▪ ascertains the need for new SOPs, guidelines and amendments (CHH IRB SOP 2017)</li> </ul>

- The officers are elected by the CHH IRB members for three-year terms. They may be re-elected but not for more than two consecutive terms. Should they resign or be disqualified, the CHH IRB members elect a replacement until the completion of the normal term.



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<p><b>Secretariat/ Staff Secretary</b></p>	<ul style="list-style-type: none"> <li>• The IRB staff Secretary shall carry out the following functions: <ul style="list-style-type: none"> <li>– Organizing an effective and efficient tracking procedure for each proposal received</li> <li>– Preparation, maintenance and distribution of study files</li> <li>– Organizing CHH IRB meetings regularly</li> <li>– Preparation and maintenance of meeting agenda and minutes</li> <li>– Maintaining the CHH IRB's documentation and Archive</li> <li>– Communicating with the CHH IRB members and applicants</li> <li>– Arrangement of training for personnel and CHH IRB members</li> <li>– Organizing the preparation, review, revision and distribution of SOPs and guidelines</li> <li>– Providing the necessary administrative support for IRB related activities to the Chairperson of the Committee (e.g. communicating a decision to the applicant )</li> <li>– Providing updates on relevant and contemporary issues related to ethics in health research, as well as relevant contemporary literature to the Committee members.</li> </ul> </li> </ul>
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#### **5.4 Roles and Responsibilities of CHH IRB Members**

- Participate actively in the IRB meeting
- Review, discuss and consider research proposals submitted for evaluation
- Monitor serious adverse event reports and recommend appropriate action(s) (SOP/013/05)
- Review the progress reports and monitor ongoing studies as appropriate
- Evaluate final reports and outcomes
- Maintain confidentiality of the documents and deliberations of CHH IRB meetings (SOP/004/05)
- Declare any conflict of interest
- Participate in continuing education activities in biomedical ethics and biomedical research

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- Familiarize themselves with SOPs of CHH IRB, their TOR and the national and international guidelines on research ethics
- Participate actively in CHH IRB meetings; must not have more than 25% unexcused absences or three unexplained absences during the period of appointment
- Participate in site visits and similar activities as needed
- Participate in required training with proof of attendance submitted to the Secretariat
- Refer to IRB Chair any suggestion, complaint, or grievance of research participants, principal investigators and sponsors before acting on them
- Do other CHH IRB-related duties that may be requested by the Chair
- No-medical members (lay) have the specific assignment to review the Informed Consent Forms their content and their translation.

### **5.5 Resignation, Disqualification, Replacement of Members**

- With sufficient reasons, members may resign their positions by submitting a letter of resignation to the Chairperson with 30 days prior notice (CHH IRB SOP 2017).
- Members may also be disqualified from continuance should the Chairperson provide the grounds for disqualification to the (other) members and there is unanimous agreement.
- Members who have resigned or have been disqualified may be replaced by appointing authorities.
- Members may be replaced in the event of death or long-term non-availability defined as more than 25% annual unexcused absence or for any action not commensurate with the responsibilities laid down in the guidelines and deemed unfit for a member.

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## 6. ANNEX (none)

## 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