1. Purpose

To describe Chong Hua Hospital Institutional Review Board (CHH – IRB) procedures to ensure initial and continuing training of IRB members and staff.

2. Scope

The CHH IRB recognizes the importance of training and continuing professional development. This SOP describes the training requirements of IRB members and staff from initial training to continuing education to maintain and update IRB competence in the review of different types of protocols.

3. Responsibility

It is the responsibility of the CHH IRB officers, members and staff to have themselves educated and trained regularly.

It is the responsibility of the CHH IRB Chair along with the Secretariat to assess the training needs and prepare a training plan for all members, Independent Consultants, and staff.

The Secretariat keeps track of the training records of all members, Independent Consultants, and staff in accordance with the training plan.

4. Flow Chart

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 1: Require basic research ethics training for all members and staff	CHH IRB Chair	Needs assessment to be done at the beginning of the year
Step 2: Provide opportunities for continuing education for members and staff through participation in meetings, conferences and training courses	CHH IRB Chair, Secretariat	
Step 3: Track member and staff participation in initial and continuing ethics training and file the documents in the membership file	Members, Secretariat	
Step 4: Ensuring continuity of work through proper endorsement from outgoing staff	CHH IRB Chair, Secretariat	

5. Detailed instructions

CHH IRB members should maintain competence training annually. They must ensure that they have updated knowledge of the following:

- Good Clinical Practice (GCP)
- Declaration of Helsinki
- CIOMS
- Ethical Guidelines
- Relevant laws and regulations
- Relevant developments in science, health and safety, etc.
- International meetings and conferences

Step 1-Require Basic Research Ethics Training for all members and staff: All CHH IRB members are required to have basic research ethics training that shall consist of research ethics principles, GCP, SOPs, etc. Upon appointment, a new member or staff undergoes orientation, individually or as a group, to cover the following:

- Member's/Staff's responsibilities;
- Confidentiality and Conflict of Interest Agreement;
- IRB review process and use of Protocol and ICF Assessment forms; and
- CHH IRB SOPs.

All CHH IRB members are also required to have additional training on the following:

- SJREB review and review of multicenter IND trials
- Use of Assessment Forms
- Risk/Benefit Assessment
- Vulnerability Assessment
- Review of recruitment procedures and obtaining ICF
- Use of the SOP (updated versions)

The CHH IRB Chair and Member-Secretary shall ensure that initial research ethics is provided to all new members. Inception training of all new members should be completed within the first 6 months from the time of appointment.

Step 2- Provide opportunities for continuing education for members and staff through participation in meetings, conferences and trainings courses

- The CHH IRB Chair provides training opportunities to members/staff through participation in local and national research ethics seminars, conferences and workshops, and allocating funds for this purpose.
- The CHH IRB Chair and Secretariat plan the training activities for individual IRB members based on their training needs.
- The CHH IRB Chair and Secretariat track and facilitate attendance of IRB members and staff of specific training activities needed to ensure that each one gets training at least once a year.
- The CHH IRB Members who participate in research ethics training course or seminar-workshops either through personal or through IRB efforts/funding are encourage to:
  - Share information with other members during IRB meetings; and
  - Distribute photocopies/e-copies of relevant materials to the other members.

Step 3-Track member and staff participation in initial and continuing ethics training and file the documents in the membership file

- For in-house training, the CHH IRB Staff prepares attendance sheets with relevant information about the topic, duration, date and venue. They ask member-attendees to sign the attendance sheet and keep a photocopy of the attendance in the membership files, if the Training Certificate is not given.

- All CHH IRB Members and Staff should regularly update their Training Record. They should submit proof of attendance in relevant training or continuing professional education sessions conducted outside of the institution – e.g. certificates of training to the CHH IRB Staff for filing.

5.1. Ensuring continuity of work through proper endorsement from outgoing staff

- Outgoing staff will be required at least two months' notice before tendering his/her resignation.

- Proper endorsement of all procedures and filing system will be given to prospective new staff during these two months, which will serve as a period of basic training before formal start of work in IRB.

6. History of SOP

Version No.	Date	Authors	Main change
1	10 September 2010	Dr. Manuel Emerson S. Donaldo	First Draft
2	01 January 2014	Dr. Manuel Emerson S. Donaldo	Change in the logo from CHH to CHH IRB logo Revised SOP and Form numbering
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	Mr. Romel V. Cabazor	Revised CHH IRB SOP from version 04 to version 05
6	02 October 2017	Atty. Dean G. Decal	Revised CHH IRB SOP in accordance to 2017 DOH-REC SOP ver02 Template
7	31 August 2023	Atty. Dean G. Decal	Revised CHH IRB SOP due to PHREB-FERCAP re-accreditation and survey
8	04 January 2024	Atty. Dean G. Decal	No Change
9	21 August 2024	Dr. Maria Teresa Canete	Revised CHH IRB SOP; training updates are done annually.

7. References

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

8. Training Plan for IRB members and support staff (updated 4 Nov 2023)

Chong Hua Hospital-Institutional Review Board Training Plan for IRB Members and Support Staff			
Topic	**Tentative Month/Date**	**Trainor/Lecture/Facilitator**	**Participants**
CHH IRB Refresher course on the use of Protocol Assessment and Informed Consent Assessment Forms	January	Atty. Dean G. Decal Dr. Manuel Emerson Donaldo Fr. Roderich Teriote Mr. Romel Cabazor	CHH-IRB Members
CHH-IRB Training on SOP	January	Atty. Dean G. Decal Dr. Manuel Emerson Donaldo Fr. Roderich Teriote Mr. Romel Cabazor	CHH-IRB Members/Staff
Inception training for new staff: comprehensive introduction into the IRB, SOP	January to March	Dr. Maria Teresa Canete Mr. Romel Cabazor Dr. Elaine Gallardo	
REC and SJREB Assessment of Protocol	February	Philippine Health Research Ethics Network(PHREN)	CHH-IRB Members
Basic Research Seminar & GCP Training Workshop	February	Philippine Health Research Ethics Network(PHREN)	CHH-IRB Members
CHH-GCP Training & Workshop	March	Philippine Health Research Ethics Network(PHREN)	CHH-IRB Members

Update Training on: -CIOMS 2016 -GCP E6 (R2) -National Ethical Guidelines 2017 -ICH Guidelines -Relevant Laws and Regulation	April to August	Atty. Dean G. Decal Dr. Manuel Emerson Donaldo Fr. Roderich Teriote Mr. Romel Cabazor	CHH-IRB Members
CHH IRB Training on Evaluation of Medical Device Study	September	Philippine Health Research Ethics Network(PHREN)	CHH-IRB Members