1. Purpose

To describe the procedures for the appointment of CHH IRB independent consultants.

2. Scope

This SOP describes the procedures for engaging the services of a professional/expert as a consultant to the CHH IRB. If the Chair of the CHH IRB determines that a study involves procedure(s) that are not within the area of competence or expertise of any of the IRB members, the Chair may invite individuals with expertise in special areas to assist in the review of protocols that require such expertise in addition to those available within the IRB.

Independent Consultants may be asked to provide expert review if expertise required is not present in the current membership. However, the Independent Consultants do not participate in the voting for the approval or disapproval of a study protocol.

3. Responsibility

Upon the advice or recommendation of the Secretariat or any IRB member, the CHH IRB Chair may appoint the name of the independent consultants.

4. Flowchart

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 1: Assess the need for Independent consultant and seek approval for contracting their services	Chair, Member-secretary, Members	To be done every quarter
Step 2: Recruit and appoint an Independent Consultant	Chair, Secretariat	To be completed within 30 days
Step 3: Organize and complete the documents in the independent Consultants Files	Secretariat	To be completed within 30 days

5. Detailed instructions

Step 1- Assess the need for independent consultants and seek approval for contracting their services: Considering the nature of the protocol for review, the Chair with the Members identifies the expertise needed that the CHH IRB membership may not have. The Chair submits the names of independent consultants to the Medical Director of Chong Hua Hospital to request for corresponding honorarium.

Step 2- Recruit and appoint an independent consultant: Once the Chair decides to invite an Independent Consultant, the CHH IRB Secretariat prepares the letter of invitation that includes the following:

- Terms of Reference (TOR) – duration of consultancy, general overview of deliverables
- Honorarium
- Request for a copy of the consultant's curriculum vitae (CV)

- The CHH IRB Staff sends the letter to the independent consultant after it is signed by the Chair together with the duplicate copies of the Confidentiality and Conflict of Interest Agreement form for the consultant's signature.
- The CHH IRB Staff asks the independent consultant to sign and date his acceptance of the TOR of the appointment.

- The CHH IRB Staff collects the signed and dated Confidentiality and Conflict of Interest Agreement, and the signed and dated updated CV using the prescribed format.

Step 3- **Organize and complete the documents in the Independent Consultant Files:** The Independent Consultant Files shall contain the following:

- IRB Letter of invitation signed and dated by the CHH IRB Chair
- Updated curriculum vitae that is signed and dated by the Independent
- The CV is updated every time the appointment is renewed.
- Training Record and photocopy of Training Certificates of relevant trainings
- Confidentiality and Disclosure of Conflict of Interest Agreement signed and dated by the Independent Consultant
- CHH IRB Staff creates one file for each independent consultant.

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	04 January 2021	Atty. Dean G. Decal	No change
8	04 January 2024	Atty. Dean G. Decal	Revised CHH IRB SOP due to re-accreditation and Survey
9	21 August 2024	Dr. Maria Teresa Canete	Revised statement regarding independent consultants: they can be tasked to do review but not vote for its approval.

7. References

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