1. Purpose

To describe the procedures in the review and approval of medical device studies submitted to the CHH IRB.

2. Scope

This SOP applies to the submission and the review processes of protocols involving the study of new medical devices in human subjects.

3. Responsibility

During the review of medical device studies, the CHH IRB may make some different decisions than those made during the review of drug studies. The CHH IRB must determine if the proposed investigation has *Significant Risk (SR)* or *Non-Significant Risk (NSR)*, and then the CHH IRB should decide if the investigation is approved or not. In determining *SR* or *NSR*, the CHH IRB must review all information submitted by the sponsor.

The CHH IRB should consider the nature of the harm that may result from the use of the device. If a device being investigated might cause significant harm to any one of the participants, the study will be considered *SR*. In deciding if a device presents significant or non-significant risks, the CHH IRB should consider the device's total risks, not those compared with the risks of alternative devices or procedures. If the device is used in conjunction with a procedure involving risk, the CHH IRB should consider the risks of the procedure in conjunction with the risks of the device. The CHH IRB may also consult with the regulatory agency to form its opinion.

The CHH IRB may agree or disagree with the sponsor's initial *NSR* assessment. If the CHH IRB agrees with the sponsor's initial *NSR* assessment and approves the study, the study may begin without submission of an IDE (Investigational Device Exemption) application to the regulatory agency. If the CHH IRB disagrees, the sponsor must notify the

regulatory agency that an *SR* determination has been made. The study can be conducted as an *SR* investigation following regulatory approval of an IDE application.

4. Flowchart

ACTIVITY	RESPONSIBLE PERSONNEL
Step 1: Receipt of submitted documents	CHH IRB Secretariat
Step 2: Assignment of Primary Reviewer	Member-secretary/CHH IRB Chair
Step 3: Reporting of protocol assessment	Primary reviewers
Step 4: Notification to the Investigators	CHH IRB Secretariat
Step 5: Storage of the documents	CHH IRB Secretariat

5. Procedures

Step 1- Receipt of submitted documents

- The CHH IRB Secretariat received the new medical device study.
- The CHH IRB Secretariat checked the submitted package for completeness.
- The CHH IRB Secretariat document the checking procedure by completing a checklist form (FORM 2023-HRP-IRB-008, Contents of a submitted package)
- The CHH IRB must receive the following documents prior to review/approval of a medical device study:

Research protocol

- Title of the protocol
- Principal investigator
- Sponsor
- Abstract
- Type of protocol (Screening, survey, clinical trial and phase)
- Objectives
- Anticipated outcome

- Inclusion/Exclusion criteria
- Withdrawal or discontinuation criteria
- Modes of treatment studies
- Methodology (Synopsis of study design)
- Analysis (Methods)
- Activity plan/Timeline
- IND Number (If applicable)
- Schedule and duration of treatment
- Efficacy or evaluation criteria (response/outcome)
- Safety parameters criteria (Toxicity)
- Investigator's brochure
- Informed consent form
- Additional information sheet
    - Description of the device
    - Description of participant selection criteria
    - Monitoring procedures
    - Reports of prior investigations conducted with the device
- Risk assessment data / information
- Statistics used in making the risk determination.
- Case Record Form (CRF)
- Study budget and budget justification
- Agreement of the study
- Application Form and Questionnaire (HRP-IRB-010)
- Document Received Form (HRP -IRB-011)

    - **Investigator's Curriculum Vitae**
    - **Investigator's professional license (s)**
    - **GCP training certificate the past 2 years**

Step 2- Assignment of Primary Reviewer

- It is the responsibility of the Member-Secretary/ CHH IRB Chair to assign the primary reviewers to review the study, according to the use of study assessment forms. (refer to SOP2.2 Use of Assessment forms).
- Prepare the documents for distribution to each CHH IRB member/ primary reviewer.
- Place the new medical device study on the meeting agenda.

- Primary reviewer clarifies the device according to the level of Risk involved.

Step 3-Reporting of Protocol assessment

- Primary Reviewers present a brief oral or written summary of the study design related to the level of risk (protocol, informed consent, investigators and site qualifications, advertisements).
- Consider whether or not the study should be approved.
- The Chairperson calls for a separate vote on each element in review. The CHH IRB votes to either:
  - Approve the study to start as presented with no modifications
  - Require further clarifications and/or request further information to be resubmitted and subjected to review in the next full Board meeting.
  - Disapprove the study and state the reason.
- Record the vote of risk assessment in the study assessment form for Medical Device Study (refer to: Form 2023-HRP-IRB-013-Methodology) and the meeting minutes (Form 2023-HRP-IRB-028-Minutes of meeting template).
- Note the recommendations for changes to the protocol and/or informed consent recommended by CHH IRB members in the minutes and will be communicated to the investigator.
- Determine the frequency of Continuing Review for the approved study.

Step 4- Notification to the Investigators

- The Secretariat sends an action letter along with the approved documents to the investigator. **(Refer to SOP No. 4.6 Communicating IRB Decision)**
- If the Board votes not to approve the study, the Chairperson or Secretariat immediately notifies the investigator in writing of the decision and the reason for disapproving the study. If the investigator wishes to appeal this decision, he or she may do so by contacting the CHH IRB Chairperson. This process is stated in the action letter provided to the investigator.
- If the Board members votes to require modifications to any of the documents, the Secretariat either generates the revisions to the documents, or sends a written request of the specific changes to the investigator asking him or her to make the necessary changes and resubmit the documents to the CHH IRB.

Step 5-Storage of the documents: Write the IRB Reference Number of the protocol on the side of the file binder. On the side cover of the protocol binder, write the following:

- IRB Reference Number
- Full title of the research
- Name of the Principal Investigator
- Sponsor Protocol Code Number
- Name of the Sponsor
- Date reviewed

- Attach a protocol file index that should serve as a Table of Contents of each protocol file.
- File the properly-labelled protocol file folders in the appropriate shelf of the storage cabinet for active study files taking note of the sequence of protocol code numbers on the file binders.

6. History of SOP

Version No.	Date	Authors	Main Change
1	10 September 2010	Rev. Msgr. Joseph Tan, PC	First Draft
2	-	-	-
3	-	-	-
4	-	-	-
5	01 January 2017	Dr. Manuel Emerson S. Donaldo	Revised CHH IRB SOP from Version 04 to Version 05 Inclusion of medical device in the SOP
6	02 October 2017	Dr. Manuel Emerson S. Donaldo	Revised CHH IRB SOP in accordance to 2017 DOH REC SOP ver02 Template
7	04 January 2021	Dr. Manuel Emerson S. Donaldo	No change
8	04 January 2024	Atty. Dean G. Decal	Revised CHH IRB SOP in accordance with REC re-accreditation and survey on 30 June 2023
9	21 August 2024	Atty. Dean G. Decal	No Change

7. References

- Code of Federal Regulation (CFR) 21, Volume 8, Part 812, April 2003, Food and Drug Administration, U.S. Government printing office via GPO Access Associated SOP: SOP#FE 007-010 AND 028
- 2020 PHREB SOP Workbook