	CHONG HUA HOSPITAL INSTITUTIONAL REVIEW BOARD CHH IRB	
Version No: 09 Date of Approval: 08/21/24 Date of Effectivity: 08/21/24	**SOP 2.2 USE OF ASSESSMENT FORMS**	

1. Purpose

To describe the Chong Hua Hospital Institutional Review Board (CHH-IRB) procedures related to the use of study assessment forms in ethics review.

2. Scope

This SOP applies to the use of the Study Assessment Forms in the review and assessment of protocols and related documents submitted to CHH-IRB for its initial review and approval.

The IRB uses the Study Assessment Forms No. HRP-IRB-013 and HRP-IRB-014 that are accomplished by individual primary reviewers. All comments, evaluation, recommendations and the initial decision of each reviewer regarding a protocol are all noted in these Forms.

The Study Assessment Forms (for example, No. HRP-IRB-013 and HRP-IRB-014) are designed to standardize the review process and to facilitate reporting of recommendation and comments given to each individual protocol and related documents. These are:

HRP-IRB-013

- Assessment Report Form for the Methodology
- Assessment Report Form for the Informed Consent
- Assessment Report form for the Waiver of consent
- Assessment Report Form for the Monitoring and Observation

HRP-IRB-014

- FORM 2023_HRP-IRB-014_CHH IRB DECISION FORM

3. Responsibility

It is the responsibility of the IRB reviewers to fill-in the assessment forms after reviewing each study protocol and submit to the Secretariat during the monthly full-board meeting.

The Secretariat is responsible for reminding the primary reviewers to submit the accomplished assessment forms and update the protocol folders.

4. Flowchart

ACTIVITY	PERSON (S) RESPONSIBLE	Timeline
Step 1: Fill up the Study Assessment Forms when reviewing the study protocol and related documents and submit accomplished forms	Primary Reviewers	within 2 weeks of receipt of full submission package
Step 2: For expedited reviews, If clarifications/modifications are needed, these may be requested by the primary reviewer of the PI using the Letter prior for approval.	Primary Reviewers	
Step 3: Submit expedited reviews to the irb secretariat and include protocol in the list of expedited reviews.	Primary reviewers	
Step 4: For protocols needing full board review, primary reviewer prepares a summary to be taken up in the next Regular IRB meeting	Primary Reviewers	Protocols submission for full board review is on or before 1st thursday of each month
Step 5: Submit accomplished Study Assessment forms (Methodology and ICF / WICF) to the secretariat during the monthly full-board meeting	Primary Reviewers	1 week before full board meeting
Step 6: Compile accomplished assessment forms for review by the Chair/Member Secretary	CHH-IRB Staff	Within 2 weeks of IRB decisions
Step 7: File copies of accomplished assessment forms and other review documents in the protocol binder	CHH-IRB Staff	Within 1 month of IRB decisions

5. Detailed Instructions

Step 1- Fill up the Study Assessment Forms when reviewing the study protocol and related documents.

- The Primary Reviewers read the protocol and related documents, and complete the assessment forms.
- Primary Reviewers should also do literature review to ensure updated knowledge about the protocol.
- The IRB primary medical reviewer accomplishes the Protocol Assessment and the Informed Consent Assessment Form (ICF) while the primary non-medical reviewer focuses on the ICF / Waiver of ICF only.
- The Protocol Assessment Form allows review of the technical and ethical issues as follows:
    - Rationale and significance of the study
    - Objectives of the study
    - Review of literature
    - Sample size
    - Methodology and data management
    - Inclusion/exclusion criteria
    - Control arms (placebo, if any)
    - Withdrawal or discontinuation criteria
    - Vulnerability determination
    - Risk/ benefit assessment
- The Informed Consent Assessment Form enables review of the following:
    - Full disclosure of information, including risks
    - Benefits that may be derived from the study
    - Use of understandable language, with appropriate translation
    - Voluntary participation
    - Confidentiality
    - Appropriate person to sign the consent form
- If an Assent Form is required, it should be reviewed to ensure that the proper form is available, the appropriate signature is required.
- Review the qualifications of the PI and the research team to include the following:

  - Education and specialty
  - GCP training (if necessary)
- Review the sites where the study will be conducted.

Step 2: For expedited reviews, if clarifications/modifications are needed, these may be requested by the primary reviewer of the PI using the Letter prior for approval.

Step 3- Submit expedited reviews to the IRB secretariat and include protocol in the list of expedited reviews.

Step 4: For protocols needing full board review, primary reviewer prepares a summary to be taken up in the next Regular IRB meeting

Step 5- Submit Accomplished Study Assessment Forms to the Secretariat during the monthly full-board meeting: The Primary Reviewers sign, date the assessment forms and submit to the Secretariat during the monthly full-board meeting.

Step 6 - Compile accomplished assessment forms for review by the Chair/Member Secretary

- The Secretariat checks whether the forms are complete, compiles the completed assessment forms and submits these to the Member-Secretary/Chair.
- The Member-Secretary/Chair reviews the compiled checklists. If the protocol is for expedited review, the Member-Secretary/Chair determines if there are no conflicting recommendations and if there is an agreement in the review/decision. If there are conflicting recommendations and/or disagreements in the review decision, the Member- Secretary/Chair forwards the protocol for Full-Board review.

Step 7- File copies of accomplished assessment forms and other review documents in the Google drive: File accomplished assessment forms in the Google drive by adding the Study Assessment Forms No. HRP-IRB-013 and HRP-IRB-014 with the date of submission.

6. History of SOP

Version No.	Date	Authors	Main Change
1	10 September 2010	Rev. Msgr. Joseph Tan, PC	First Draft
2	01 January 2014	Dr. Charity Ann Y. Cardenas	Change in the logo from CHH to CHH IRB logo Revised SOP and Form numbering
3	01 September 2014	Dr. Charity Ann Y. Cardenas	Change of IRB SOP in accordance to PHREB SOP Format Revised Assessment Report Forms
4	01 October 2014	Dr. Charity Ann Y. Cardenas	Revised IRB SOP in accordance to PHREB SOP Format
5	01 January 2017	Dr. Elaine L. Gallardo	Revised CHH IRB SOP from Version 04 to Version 05 Revised Assessment report form under methodology for medical device study
6	02 October 2017	Mr. Romel V. Cabazor	Revised CHH IRB SOP in accordance to 2017 DOH-REC SOP ver02 Template Revised CHH IRB Assessment Report Forms and other pertinent IRB Forms
7	04 January 2021	Mr. Romel V. Cabazor	No change
8	04 January 2024	Mr. Romel V. Cabazor	No change
9	21 August 2024	Mr. Romel V. Cabazor	No change

7. Reference

- 2017 Department of Health- SOP Version No. 2