1. Purpose

To describe the Chong Hua Hospital Institutional Review Board (CHH IRB) procedures for the review of protocols that qualify for expedited review.

2. Scope

This SOP applies to the initial and continuing review and approval of study protocols with minimal risks to study participants.

In general, Expedited Review is done:

- In minimal/low risk health research that requires personal information (ex. Review of medical records)
- About a topic that should not results in causing social stigma
- In retrospective studies using anonymized data
- In health studies using simple questionnaires without identifiers
- In laboratory research that uses anonymized human tissue/specimen

3. Responsibility

Expedited review is the responsibility of assigned primary reviewers appointed to assess a protocol that qualifies for the expedited procedure. The same assessment forms used for full board review should be used to evaluate the scientific and ethical merits of the protocol.

4. Flowchart

ACTIVITY	PERSON(S) RESPONSIBLE	TIMELINE
Step 1: Determine that the submission qualifies	Secretariat/Member Secretary/Chair	7 days
Step 2: Assign Primary reviewers (Medical/Scientific and non-medical/non-scientific members).	Member Secretary/Chair	
Step 3: Send the protocol package to the primary reviewers	CHH IRB Staff	
Step 4: Review the documents with the use of the assessment forms; requests PI to answer any queries thru the Notification Form	Primary Reviewers	7 days
Step 5: Return the accomplished assessment form to the Secretariat	Primary Reviewers	
Step 6: Collate and review the assessment forms to take appropriate action	Member Secretary	
Step 7: Communicate the IRB decision to the PI	CHH IRB Staff	7 days
Step 8: Prepare a list of all expedited review results and report to full board	Secretariat	
Step 9: File copies of the documents in the protocol file folder and update the protocol database	CHH IRB Staff	

5. Procedures

Step 1- Determine that the submission qualifies for expedited review: For initial review: The Chair/ Member Secretary checks if the submitted protocol qualifies for expedited review. The following are types of protocols that can be subjected to expedited review after initial submission:

- Protocols of a non-confidential nature (not of a private character, e.g. relate to sexual preference etc., or not about a sensitive issue that may cause social stigma), not likely to harm the status or interests of the study participants and not likely to offend the sensibilities or cause psychological stress to the people involved.
- Protocols **not** involving vulnerable subjects (individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation of benefits associated with participation or of a retaliatory response in case of refusal to participate, patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors and those incapable of giving consent). Interviews involving the pediatric population does not qualify for expedited review.
- Protocols that involve collection of anonymized biological specimens for research purposes by non-invasive means (e.g. collection of small amounts of blood, body fluids or excreta non-invasively, collection of hair or nail clippings in a non-disfiguring or non-threatening manner).
- Collection of data for research purposes through ***non-invasive procedures*** (not involving general anesthesia or sedation) routinely employed in clinical practice and using medical devices which have been already approved for use. Examples of such procedures included collection of data through application of EEG or ECG electrodes, acoustic testing, tests using the Doppler principle, non-invasive blood pressure and other routine clinical measurements, exercise tolerance, etc. However, procedures involving the ***use of x-rays or microwaves are NOT recommended for expedited review***.

- Research involving data, documents or specimens that have been previously collected or will be collected for ongoing medical treatment or diagnosis.
- Proposed continuing review of previously expedited protocols, minor protocol amendments and end of study reports, where no additional risks have been identified.

For resubmitted documents

- IRB decision for minor modification qualifies for expedited review by the Primary Reviewers or Chair/ Member Secretary.

Submissions after initial approval may qualify for expedited review as follow:

- Administrative revisions, such as corrections of typing errors
- Addition or deletion of non-procedural items, such as the addition/change in study personnel or change in their address or contact number, change in laboratories, and the like.
- The research activity includes only minor changes from previously approved protocol
- Minor protocol amendments that do not change the risk/benefit assessment
- Progress/Final reports that were initially reviewed by expedited review and that do not deviate from approval Given by the IRB.

Step 2: Assign primary reviewers (medical/scientific and non-medical/non-scientific members) to review the submitted documents.

- The IRB chairman or Vice-chairman or Member Secretary are responsible for assigning competent primary reviewers to assess the protocol and ICF. Independent consultants may also be tasked to be a primary reviewer.

- A Medical/ Scientific Reviewer (IRB member or Independent Consultant) will be assigned to review the scientific and ethical merits of the protocol related documents, while the non-medical/ non-scientific member will review the ICF.

Step 3: Send the protocol package to the primary reviewers

- The CHH IRB Staff contacts the designated Primary Reviewers to determine if they can review the protocol documents within the 14-day deadline. If not, other primary reviewers are identified.

- The Staff prepares the notice to the Primary Reviewers, the protocol package and the corresponding assessment forms and forwards them to the designated reviewers.

Step 4: Review the documents with the use of the study assessment forms.

- The Primary Reviewers read the protocol and related documents, and complete the study assessment forms. The IRB primary medical reviewer accomplishes both the protocol and ICF assessment forms while the primary non-medical reviewer evaluates informed consent documents by using the Informed Consent Assessment Form.
- The Primary Reviewers decide whether the protocol can be approved, modified or disapproved.
- When modification is required, the protocol documents are returned for the researchers to revise the documents and resubmit to the CHH IRB for approval. The document to inform the PI about queries is:
- Disapproved protocols are automatically forwarded to the full board for discussion and decision. Disapproval cannot be done at the expedited level.

- The Chairperson or the primary reviewer designate will inform the Board of the proposals approved by expedited review at its regular meetings.

- If any committee member raises concern about any of the proposals presented to it as expedited review, then that proposal shall undergo a regular (full board) review.

Step 5: Return the accomplished study assessment forms to the Secretariat

- The Primary Reviewers sign, date, the assessment form/s and return them to the Secretariat within 14 days from receipt of the protocol review package.
- The Secretariat checks completeness of the assessment forms and forwards them to the Member-Secretary to recommend appropriate IRB follow up action. Turn around time is 21 days from submission to IRB.

Step 6- Collate and review the assessment forms to take appropriate action.

- The Member-Secretary reviews the completed assessment forms to determine if there is agreement in the review/ decision. The comments and decisions are consolidated and communicated to the PI.
- If there are conflicting recommendations and/ or disagreement in the review decision or when the protocol is disapproved, the Member-Secretary includes the protocol in the next full board meeting for discussion and decision of full board.

Step 7- Communicate the IRB decision to the PI.

- The CHH IRB Staff communicates approval to the PI and uses the Proforma of Letter of Approval (CHH-IRB 2023-PROFORMA LETTER OF APPROVAL).
- In case revision is required, the comments and recommendations are sent to the PI. For the communication of comments and required revisions in the initial review, use the form Recommendations prior to Approval of Initial Review template. For the

communication of comments and required revisions in the continuing review and in other communications, use the form Letter of Recommendation and Clarification template. These forms require the PI to respond to the comments and to comply with the required revisions in his resubmission of the pertinent documents to the IRB **(Refer to SOP No. 4 on Communicating IRB Decision to PI).**

Step 8- Prepare a report on results of expedited review to full board: The CHH IRB Staff prepares a list of protocols approved through expedited review and the Member Secretary reports them during the full board meeting. The reported list of approved protocols is noted and included in the Minutes of the meeting.

Step 9- File a copy of the documents in the protocol file folder and update the protocol database: The CHH IRB Staff files copies of the approved documents in the protocol file folder. They update the protocol file index of the protocol file folder, and finally update the protocol database.

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 IRB SOP in accordance to PHREB SOP format
4	01 October 2014	Dr. Charity Ann Y. Cardenas	Revised IRB SOP in accordance to PHREB SOP FORMAT
5	01 January 2017	Rev. Fr. Benedicto P. Tao	Revised CHH IRB SOP from version 04 to Version 05
6	02 October 2017	Rev. Fr. Benedicto P. Tao	Revised CHH IRB SOP in accordance to 2017 DOH-REC SOP ver02 Template
7	04 January 2021	Rev. Fr. Roderich L. Teriote	No change
8	04 January 2024	Rev. Fr. Roderich L. Teriote	No change
9	21 August 2024	Rev. Fr. Roderich L. Teriote	No change

7. References

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