 <p>Healing with Passion. Caring with Compassion.</p>	CHONG HUA HOSPITAL INSTITUTIONAL REVIEW BOARD	SOP/006/05
	<p>chh_irb@chonghua.com.ph</p> <p>Title:</p> <p>2.1 Expedited Review</p>	<p>Effective date: 01 January 2017</p> <p>Page 1 of 6</p>

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Table of Contents
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No.	Content	Page No.
	Table of Contents	1
1.	Purpose	2
2.	Scope	2
3.	Responsibility	2
4.	Flowchart	3
5.	Detailed Instruction	4
5.1	Receive the submitted documents	4
5.2	Determine protocols for expedited review	4
5.3	Assign protocol to a Primary Reviewer	5
5.4	Expedited Review Process	5
5.5	Include protocol title with decision reviewed by Expedited Process	5
6.	ANNEX (None)	5
7.	References	6

 <p>Healing with Passion. Caring with Compassion.</p>	<p>CHONG HUA HOSPITAL INSTITUTIONAL REVIEW BOARD</p> <p>chh_irb@chonghua.com.ph</p>	<p>SOP/006/05</p> <p>Effective date: 01 January 2017</p>
	<p>Title:</p> <p>2.1 Expedited Review</p>	<p>Page 2 of 6</p>

1. Purpose


The purpose of this SOP is to provide criteria for determination of which study protocols can be reviewed through expedited process as well as instructions on management, review and approval of the expedited review

2. Scope

This SOP applies to the review and approval of study proposals with minimum risk to participants, protocol amendments or informed consent changes of currently approved studies.

3. Responsibility

It is the responsibility of the CHH IRB chairman to define which study protocols should be reviewed and approved through expedited channel.

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	Title: 2.1 Expedited Review	Page 3 of 6

4. Flowchart

No.	ACTIVITY	RESPONSIBLE PERSONNEL
I	Receive submitted documents	CHH IRB Secretariat
II	Determine protocols for expedited review	CHH IRB Chairman
III	Assign protocol to a primary reviewer	CHH IRB Chairman
IV	Expedite review process	Assigned Primary Reviewer
V	Submit review to the Secretariat	CHH IRB Secretariat
VI	Include Protocol title with decision reviewed by Expedited Process	CHH IRB Secretariat

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	<p>Title:</p> <p>2.1 Expedited Review</p>	<p>Page 4 of 6</p>

5. Detailed Instructions

5.1 Receive the submitted documents.

- Receive the application documents submitted by investigators,
- Get contents of submitted package form,
- Stamp the receiving date on the letter and the documents.
- Sign the receiver's name on the receiving documents.

5.2 Determine protocols for expedited review.

- CHH IRB Chairman determines whether a study is qualified for expedited review according to the following criteria:

5.2.1 Modification /amendment of protocol


- **administrative revisions**, such as correction of types
- addition or deletion of **non-procedural items**, such as the addition of study personnel names, laboratories, etc.
- **non-significant risk** research activity
- the research activity includes only **minor changes** from previously approved protocol.

5.2.2 Proposals involve interviewing of a **non-confidential nature** (not of a private eg. relate to sexual preference *etc.*), **not likely to harm** the status or interests of the individual and **not likely to offend** the sensibilities of the people involved. Interview involving pediatric population does not qualify for expedited review

5.2.3 Those that involve **collection of small amounts of blood samples** (and not too frequent) e.g. by finger, heel or ear stick.

5.2.4 Those that involve collection of biological specimens for research purposes by **non-invasive means** (e.g. collection of body fluids or excreta non-invasively, collection of hair or nail clippings in a non-disfiguring or non-threatening manner).

5.2.5 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 include collection of data through application of EEG or ECG electrodes, acoustic testing, tests using the Doppler principle, non-invasive blood pressure and

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	<p>Title:</p> <p>2.1 Expedited Review</p>	<p>Page 5 of 6</p>

other routine clinical measurements, exercise tolerance etc. However procedures involving the *use of x-rays or microwaves are NOT recommended for expedited review.*

- 5.2.6 Research involving data, documents or specimens that have been already collected or will be *collected for ongoing medical treatment* or diagnosis.
- 5.2.7 Continuing review of research previously approved with no modifications to the original protocol and studies have taken place and *no additional risks* have been *identified*.
- If the protocol satisfies the criteria for **expedited** review, the Chairperson will assign it to a primary reviewer.

5.3 Assign protocol to a Primary Reviewer

- The chairman designates a member to do the expedited preview
- The member assigned to do the expedited becomes the primary reviewer of the protocol

5.4 Expedited Review Process

- the expedited review is done using the assessment forms (see SOP/009/05)
- The expedited review should not take longer than 2 weeks
- 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 review.

5.5 Include protocol title with decision reviewed by Expedited Process

- After the expedited review, the title of the protocol reviewed shall be included in the agenda for presentation during the meeting for the information of the board.

6. ANNEX: None

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	<p>Title:</p> <p>2.1 Expedited Review</p>	<p>Page 6 of 6</p>

7. References

- ❖ World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
- ❖ International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
- ❖ Code of Federal Regulation (CFR) 21.
- ❖ National Ethical Guidelines for Health Research 2011 PNHRs