CHAPTER 3.3

EXPEDITED REVIEW

SOP NUMBER: SOP/009/01

INSTITUTIONAL REVIEW BOARD
(IRB)

Khesar Gyalpo University of Medical Sciences of Bhutan

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1. PURPOSE

The purpose of this SOP shall be 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 shall apply to the review and approval of study proposals with minimum risk to participants, protocol amendments or informed consent with minor changes of currently approved studies.

3. RESPONSIBILITY

The IRB Secretariat shall be responsible to define which study protocols shall be reviewed and approved through expedited channel. The Chairperson shall nominate two or more IRB members as the expedited reviewers to conduct the review.

4. FLOW CHART

No.	Activity	Responsibility
1.	Determine protocols for expedited review. ↓	IRB Member Secretary/ Chairperson
2	Nominate the expedited reviewers ↓	Chairperson
3.	Distribute the protocol packages to the reviewers ↓	IRB Member Secretary
4	Review the assigned protocols ↓	Reviewers
5. 6.	Communicate the review result to the investigator. ↓ Report the expedited review during the IRB meeting ↓	IRB Member Secretary IRB Member Secretary
7	Storage of the documents	IRB Member Secretary

5. DETAILED INSTRUCTIONS

5.1. Determine protocols for expedited review.

IRB Chairperson determines the expedited review for non–significant risk and IRB secretary determines the administrative issues for the study to be qualified for expedited review according to the following criteria:

5.1.1. Initial review

5.1.1.1. Proposals involve interviewing of a non-confidential nature (not of a private e.g. 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.

5.1.1.2. Those that involve collection of small amounts of blood samples (and not too frequent) e.g. by finger, heel or ear stick except with sensitive issues which involves social risk and/or vulnerable population.

5.1.1.3. 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) except with sensitive issues which involves social risk and/or vulnerable population

5.1.1.4. Collection of data for research purposes through non-invasive procedures (not involving general anaesthesia 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 other routine clinical measurements, exercise tolerance etc except with sensitive issues which involves social risk and/or vulnerable population. However procedures involving the use of x-rays or microwaves are NOT Recommended for expedited review.

5.1.1.5. Research involving data, documents or specimens that have been already collected or shall be collected for ongoing medical treatment or diagnosis except with sensitive issues which involves social risk and/or vulnerable population

5.1.2. Minor modification /amendment of protocol

5.1.2.1. Administrative revisions such as correction of typing errors; addition or deletion of non-procedural items such as the addition of study personnel names, laboratories, etc.; non-significant risk research activity; and when the research activity includes only minor changes from previously approved protocol. In such cases the Chairperson can review and approve it.

5.1.3. Continuing review of protocol

5.1.3.1. Continuing review of the study may not be conducted through an expedited review procedure, unless:

1. The study was eligible for, and initially reviewed by, an expedited review procedure; or
2. The study has changed such that only the activities that are eligible for expedited review are remaining; or
3. Continuing review with no modifications /amendment to the original protocol and no additional risks has been identified. In the third condition, the Chairperson can review the report and approve the continuation of the study for appropriate time except with sensitive issues which involves social risk and/or vulnerable population.

5.1.4. Review of previously reviewed protocol

5.1.4.1. Review of protocols that have previously gone through Full Board Review can be expedited unless otherwise specified in the minutes of the meeting. In such cases the IRB Secretary can directly send the revised protocol and related documents to the Primary Reviewer(s) for review.

5.1.4.2. Review of protocols approved with recommendations in previous submission can be expedited only with minor modifications of the protocol. In such cases the Chairperson can review and approve it unless otherwise specified in the minutes of the meeting.

5.1.4.3. If the protocol satisfied any of the criteria for **expedited** review, the secretariat shall send the protocol to the Chairperson.

5.2. Nominate the expedited reviewers

5.2.1. Chairperson nominates 2 or more IRB members with related expertise to review the protocol.

5.2.2. The selected members are normally those who reviewed and recommended the previous version of that protocol, if it is not submitted for the first time.

5.3. Send the protocol packages to the reviewers

5.3.1. The secretariat shall send the protocol packages (study protocol with all the attached documents) and the study assessment form (*AF/01-012/01*) to the selected members.

5.4. Review the assigned protocols

5.4.1. Carry out the expedited review on the complete protocol package.

5.4.2. The review may be made either by circulation of comments, telephone discussion or meeting.

5.4.3. THE EXPEDITED REVIEW SHALL NOT TAKE LONGER THAN TWO WEEKS

5.4.3.1. The reviewers shall submit the review forms within five working days.

5.4.4. The reviewers forward their comments to the Secretariat.

5.4.5. If consensus cannot be reached among the expedited reviewers, the chairperson can either take the final call or refer the proposal for a full board review.

5.5. Communicate the review result to the investigator

5.5.1. The Secretariat prepares an action letter according to the review report and sends it with the protocol package to the Chairperson.

5.5.2. The Chairperson approves the expedited review by signing on the letter

5.5.3. The Secretariat sends the letter to the investigator

5.6. Report the expedited review to the full board

5.6.1. List the expedited review items in the meeting agenda and report the review results to the full board during the meeting.

5.6.2. If any board member raises concern about any of the proposals presented to it as expedited review, then that proposal shall undergo a regular review. The previous review decision shall be recalled.

5.7. Storage of the document

5.7.1. The review report and the related meeting minutes are kept with the protocol file.

5.7.2. The copy of the action letter is kept in the Correspondence File.

5.7.3. If the protocol is approved, assign an approval number in sequential order.

Example: A protocol, submitted in November of the year 2021 and it is the 12th protocol approved by the IRB in that year, would be numbered as 012/11-21.

5.7.4. Fill in the number of the Application Review Form (*AF/01-008/01*). Place the original documents of the Application Review and the Assessment Forms in sequence of approval number in the Approved file.

5.7.5. Store the file on an appropriate shelf in the designated cabinet.

6. GLOSSARY

Administrative Documents	Documents include official minutes of board meetings as described in Standard Operating Procedures, both historical and Master Files as described in SOP/027/01
Expedited approval	An IRB approval granted only by the Chairperson of IRB for minor changes to current IRB approved research activities and for research which involves no more than minimal risk.
Expedited review	A review process by only two or more designated IRB members who then report the decision to the full board meeting. An expedited review is a *speedy* one for minor *changes to the approved protocol* and for *research proposal* with *minimal risk in nature*.

7. REFERENCES

7.1. WHO. Standards and operational guidance for ethics review of health-related research with human participants (2011). (http://apps.who.int/iris/bitstream/10665/44783/1/9789241502948_eng.pdf - accessed 28 October 2017)

7.2. ICH HARMONISED GUIDELINE. INTEGRATED ADDENDUM TO ICH E6(R1): GUIDELINE FOR GOOD CLINICAL PRACTICE E6(R2) Current Step 4 version dated 9 November 2016 (https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4.pdf - accessed 28 October 2017)

7.3. Code of Federal Regulation (CFR) 21.

7.4. Associated SOPs: SOP/008/01 and SOP/028/01