Title: Expedited Review of Research Study Protocols

SOP Code: SOP 7B/V2
Effective Date: 21-10-2019

SOP Constitution and Approval:

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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the Institutional Human Ethics Committee (IHEC) members will perform an expedited review on a new research study protocol using the Assessment Form.

2. Scope

This SOP applies to the review and approval of research studies and documents, which qualify for expedited review by the IHEC. Any protocol that carries not more than minimal risk and fulfills criteria for expedited review is covered in this SOP. Examples of proposals that qualify for expedited review include;

• research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples;

• research involving clinical data, documents, records / materials that are non-identifiable

• modification or amendment to an approved protocol including administrative changes or correction of typographical errors and change in researcher(s);

•revised proposals previously approved through expedited review, full review or continuing review of approved proposals;

• minor deviations from originally approved research causing no risk or minimal risk;

• progress / annual reports where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee; and

• for multicentre research where a designated main EC among the participating sites has reviewed and approved the study, a local EC may conduct only an expedited review for site specific requirements in addition to the full committee common review.

• research during emergencies and disasters.

2.1 Research proposals that have undergone ERC review should be ratified by the full committee, which has the right to reverse/or modify any decision taken by the ERC or Subcommittee.

2.2 The investigator may request for expedited review of a submitted proposal, however the decision on eligibility of such proposal for expedited review rests with IHEC.

3. Responsibility

- After categorization of the projects, the Member Secretary/Additional Member Secretary is responsible, to forward the projects to the Secretariat.
- The IHEC Secretariat is responsible for creation of a study specific file, distribution of the packages along with study assessment forms to the designated IHEC members for review (if the study is categorized for expedited review) and communicate the review results to the investigators.
- Designated Expedited Review Committee Members (ERC) (including Member Secretary / Additional Member Secretary and/or Chairperson) or an authorized Sub-committee will be responsible for reviewing the research protocols and related documents within the given time frames.
- It is the responsibility of all the designated ERC members to fill the Assessment form along with comments and recommendation they have after reviewing each study protocol.
- The IHEC Secretariat is responsible for recording and filing the decision, relevant points and deliberation about a specific protocol, including the reasons for that decision.
- The Chairperson of the ERC is responsible to sign and date the decision in the ERC Decision Form.

4. Detailed instructions

4.1 Appointment of reviewers

- After determining that the Protocol / Project qualifies for an expedited review, the Member Secretary/Additional Member Secretary (in consultation with Chairperson) will nominate two ECR members to review the amended protocol.

4.2 Distribute the protocol package

- The Secretariat will fill in the required details in the nomination form to the ERC Members requesting initial review and in the study assessment form.
- The Secretariat will send a packet *(hard or soft copy)* to the designated ERC Members.
- Nomination letter to ERC Members requesting Initial Review,
- Study assessment form
- Project Submission Application Form
- Protocol and related documents

4.3 Receive the distributed protocol package:

Designated IHEC members will receive the protocol package with the Project Application Form as hard copy or through email (if desired so).

4.4 Verify the contents of the package

- The ERC member will verify all the contents.
- The ERC member will notify the IHEC Secretariat if any documents are missing

4.5 Review by the IHEC members

- ERC members will review the protocol within the 7working days.
- The comments of the ERC members will be recorded.

4.6 Gather the assessment reports

The IHEC Secretariat will collect the Assessment Forms with the comments from each designated reviewer and file in the original study file

4.7 Decision and Communication of decision to PI and IHEC Full Board

- The Member Secretary/Additional Member Secretary will discuss the comments of the members with the Chairperson and a decision about the protocol will be taken.
- If there are queries these will be sent to the PI within one working day after receipt by the Secretariat in consultation with Member Secretary/Additional Member Secretary.
- The reply from the PI will be discussed by the Member Secretary/Additional Member Secretary with the Chairperson or the designated IHEC members and a decision be reached.
- The final decision will be recorded on the Study Assessment Form for Expedited Review.
- The decision will be informed to the IHEC members at the full board meeting.
- If deemed necessary by reviewer(s), Member Secretary/Additional Member Secretary / Chairperson, the project shall be discussed at the forthcoming full board meeting before final decision. The final decision by the Chairperson is recorded on the Study

Assessment Form for Expedited Review.

- The Secretariat will send the Study approval letter to the PI.
- If project is disapproved or requires resubmission after certain modifications, this will be informed to the PI in writing.
- The reasons for disapproval of a project will be specified in the letter sent to PI.
- The expedited review process should be completed within 14 working days.

5. Glossary

Expedited review	A review process by one / two designated IHEC members (Primary reviewers) who then report the decision to the full Board meeting. An expedited review is a *speedy* one for *research proposal* with *minimal risk in nature.*

6. Annexures

Annexure 1: *AX 01/SOP07B/V2* - Form for nomination of IHEC members for Review Annexure

Annexure 2: *AX 02/SOP07B /V2* -Study Assessment Form for Expedited Review

Annexure 3: AX 03/ SOP07B /V2 -Approval letter format in case of Expedited Review

Annexure 4: AX 03/SOP 07B/V2 – Additional information for Expedited Review

Annexure 1: AX 01/SOP 07B/V2
Form for nomination of IHEC members for Review

Date: XXXX

To,

XXXXXXx,

Member, IHEC,

Ref: The project no. **MGMCRI/RES/0X/YEAR/XX/IHEC/YY** entitled, "XXXXXXXX".

Sub: Review of XXXXXXX.

Dear Dr. XXXXXX,

The following document/s has/ have been submitted to the IHEC for review.

1. _____
2. _____
3. _____

The following members are nominated to review/ carry out an expedited review of the above-mentioned documents.

1. _____
2. _____
3. _____

For expedited review, you are requested to fill the study assessment form enclosed (Annexure *AX02/SOP 07A/V2*) and send to the IHEC office within 7 working days:

_____

Signature of Member Secretary/Additional Member Secretary / Chairperson with date

Annexure 2: AX 02/ SOP07B /V2

Study Assessment Form for Expedited Review

IHEC Protocol Number :	Date of receipt at IHEC office (DD/MM/YY):
Project Title :_____	

Name of the Principal Investigator	Department	Contact number

Total no. of Participants at the site:
No. of Study sites:
Sponsor:

Duration of the Study:

Reviewer's name :			
Type of the Study :	Intervention	Epidemiology	Observation
	Document based	Genetic	
	Social Survey	Others, specify…….	

Description of the Study in brief: Mark whatever applied to the study.

Randomized	Open-labeled	
Double blinded	Placebo controlled	Treatment controlled
Cross-over	Parallel	Interim Analysis
Use of Tissue samples	Use of Blood samples	Use of genetic materials

Comments:

_____

(Review the protocol and related documents as per the guidelines stated in *AX 05/SOP 06/V2)*

Provisional Decision: Approved Resubmission

Disapproved Full Board

Approved with modifications

Reason for disapproval _____

_____

Name of the IHEC member _____

Signature _____ **Date** _____

Final decision:

Approved YES NO

If disapproved, reasons for disapproval _____

_____

_____

Further revision or modification required/resubmission ☐

_____

_____

Any other ___

_____

Signature of the Chairperson: _____ **Date:** _____

Annexure 3: AX 03/SOP07B /V2

Approval letter format in case of Expedited Review

Date: xxxxxxxxx

To,

Dr. xxxxxxxxxxxxxx,

Dept. of xxxxxxxxx.

Ref: Your project no. **xxxxxxxx** entitled, "xxxxxxxxxxxxxxx".

Dear Dr. xxxxxxxxx,

The following documents of the above-mentioned project were reviewed and approved through an expedited review process.

1. xxx
2.xxxxxxx
3.xxxxxxxxx

It is understood that the study will be conducted under your direction, in a total of **xxx** research participants, at as per the submitted protocol.
The IHEC approves the above mentioned study.
This approval is valid for the entire duration of the study.

It is the policy of IHEC that, it be informed about any onsite serious adverse event or any unexpected adverse event report within 24 hours as per the formats specified in SOP 12 to IHEC or by email if there is holiday. The report of SAE or death after due analysis shall be forwarded by the Investigator to the chairman of IHEC and the head of the institution where the trial is been conducted within 14 calendar days of SAE or death.

In case of injury or death of participant(s) occurring during the trial, the sponsor (whether a pharmaceutical company or an institution) or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial shall make payments for medical management of the subject and also provide financial compensation for the clinical trial related injury or death.

No deviations from, or changes of the protocol and Informed Consent Document should be initiated without prior written approval by the IHEC of an appropriate amendment. The IHEC expects that the investigator should promptly report to the IHEC any deviations from or changes of the protocol to eliminate immediate hazards to the research participants and about any new information that may affect adversely the safety of the research participants or the conduct of the trial.

For studies which will continue for more than a year, a continuing review report needs to be submitted (within 1 month of the due date i.e. 11 months from the date of approval) on or before xxxxxx.

A copy of the final report should be submitted to IHEC for review.

Sincerely yours

xxxxxxxxxxx

Member Secretary/Additional Member Secretary/ Chairperson

Date of approval of the study: xxxxxx

Annexure 4: AX 03/SOP 07B/V2

Expedited Review - Additional information to be provided with Application Form/Cover letter

MGMCRI-IHEC Ref. No. (for office use):

Title of study:

Principal Investigator (Name, Designation and Affiliation):

1. Choose reasons why expedited review from EC is requested?
   (Refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 51 Table 4.2)

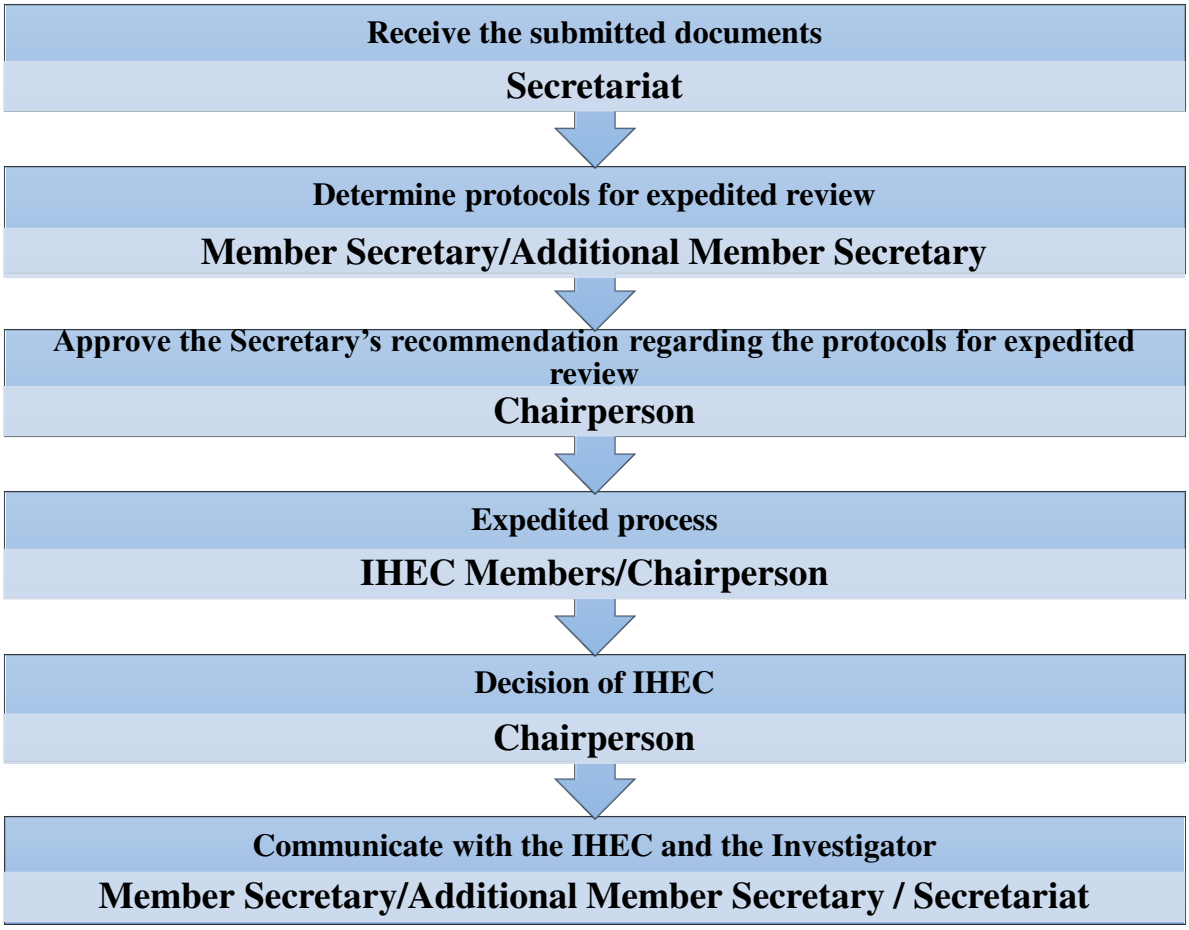
i. Involves non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples. ☐
ii. Involves clinical documentation materials that are non-identifiable (data, documents, records). ☐
iii. Modification or amendment to approved protocol (administrative changes/correction of typographical errors and change in researcher(s)). ☐
iv. Revised proposal previously approved through expedited review, full review or continuing review of approved proposal ☐
v. Minor deviation from originally approved research causing no risk or minimal risk. ☐
vi. Progress/annual report where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee. ☐
vii. For multicentre research where a designated EC among the participating sites has reviewed and approved the study, a local EC may conduct only an expedited review for site specific requirements in addition to the full committee common review. ☐
viii. Research during emergencies and disasters (See Section 12 of ICMR Ethical Guidelines, 2017). ☐
ix. Any other (please specify) ☐

Signature of PI with date:

Comments of EC Secretariat:

Signature of Member Secretary with date:

7. Flow Chart



8. References

- *Forum for Ethics review Committees in India (FERCI). Standard Operating Procedures of Institutional Ethics Committee (cited 5th October 2019). Available from: http://www.ferci.org/sops/*
- *Indian Council of Medical Research (ICMR). National Ethical guidelines for biomedical and health research involving human participants, October 2017 (cited 6th October 2019) available from: http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf*