SOP 07B	Sri MANAKULA VINAYAGAR Medical college and Hospital	
SOP code: SOP 07B/ V4	*Expedited Review of Research Study Protocols*	Effective Date: 02.01.2024

Title: Expedited Review of Research Study Protocols

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the Institutional Ethics Committee (EC) members will perform an expedited review on a new research study protocol using the Assessment Form (AX 01/SOP 7B/V4).

2. Scope

This SOP applies to the review and approval of research studies and documents, which qualify for expedited review by the EC. Any protocol that carries not more than minimal risk and fulfills criteria for expedited review (SOP 07/V4) is covered in this SOP.

3. Responsibility

- The Member Secretary is responsible, after categorization of the projects (as per SOP 7/V4), to forward the projects to the Secretariat.
- The EC Secretariat is responsible for creation of a study specific file, distribution of the packages along with study assessment forms to the designated EC members for review (if the study is categorized for expedited review) and communicate the review results to the investigators.
- Designated EC members (including Member Secretary and/or Chairman) will be responsible for reviewing the research protocols and related documents within the given time frames.
- It is the responsibility of all the designated EC members to fill the Assessment form along with comments and recommendation they have after reviewing each study protocol.
- The EC Secretariat is responsible for recording and filing the decision, relevant points and deliberation about a specific protocol, including the reasons for that decision.
- The Chairman is responsible to sign and date the decision in the EC Decision Form *AX 02/SOP 7B/V4.*

4. Detailed instructions

4.1 Appointment of reviewers

- After determining that the Protocol / Project qualify for an expedited review, the Member Secretary (in consultation with Chairman) will nominate two or more EC 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 EC Members requesting initial review (*AX 01/SOP 7A/V4*) and in the study assessment form *AX 02/SOP 7A/V4*.
- The Secretariat will send a packet *(hard or soft copy)* to the designated EC members.
  - Nomination letter to EC Members requesting Initial Review,
  - Study assessment form *AX 01/SOP7A/V4,*
  - Project Submission Application Form *AX 01/SOP06/V4*,
  - Protocol and related documents

4.3 Receive the distributed protocol package:

Designated EC members will receive the protocol package with the Project Application Form AX 01/SOP 06/V4, in a CD or pen drive or as hard copy (if desired so).

4.4 Verify the contents of the package

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

4.5 Review by the EC members

- EC members will review the protocol as described in Section 4.5 of SOP 7A/V4 within the stipulated time line.

- The comments of the EC members will be recorded on *AX 02/SOP 7B/V4.*

4.6 Gather the assessment reports.

The EC 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 EC Full Board

- The Member Secretary will discuss the comments of the members with the Chairman 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.
- The reply from the PI will be discussed by the Member Secretary with the Chairman or the designated EC members and a decision be reached.
- The final decision will be recorded on the Study Assessment Form for Expedited Review *AX 02/SOP 7B/V4.*
- The decision will be informed to the EC members at the full board meeting.
- If deemed necessary by reviewer(s), Member Secretary/ Chairman, the project shall be discussed at the forthcoming full board meeting before final decision. The final decision by the Chairman is recorded on the Study Assessment Form for Expedited Review *AX 02/SOP 7B/V4.*
- 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 Principal Investigator 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. References to other applicable SOPs

SOP 06/V4: Management of Research Study Protocol and Study Related Documents Submitted for Ethics Review

SOP 07/V4: Categorization of Submitted Protocols for Ethics Review

SOP 07A/V4: Initial Full-Board Review of Research Study Protocols

6. Annexures

Annexure 1 *AX 01/SOP 7B/V4* - Form for nomination of EC members for Review

Annexure 2 *AX 02/SOP 7B /V4* -Study Assessment Form for Expedited Review

Annexure 3: AX 03/SOP/7B/V4 - Additional information to be provided with Application Form for Expedited Review

Annexure 4: AX 04/SOP 7B/V4 - Approval letter format in case of Expedited Review

Annexure 1: AX 01/SOP 7B/V4

Form for nomination of EC Members for Review

Date: XXXX

To,

XXXXXXx,

Member, EC,

Ref: The project no. **EC/PHARMA-XX/20XX** entitled, "XXXXXXXX".

Sub: Review of XXXXXXX.

Dear Dr. XXXXXX,

The following document/s has/ have been submitted to the EC 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 *AX 02/SOP 07A/V4*) and send to the EC office within 7 working days: _____

Signature of Member Secretary / Chairman with date

Annexure 2: *AX 02/SOP 7B/V4*

Study Assessment Form for Expedited Review

EC Protocol Number :	Date of receipt at EC 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/V4)*

Provisional Decision: ☐ Approved ☐ Resubmission

☐ Disapproved ☐ Full Board

☐ Approved with modifications

Reason for disapproval _____

_____

Name of the EC member _____

Signature _____ **Date** _____

Final Decision:

Approved YES NO

If disapproved, reasons for disapproval _____

_____

_____

Further revision or modification required/resubmission _____

_____

_____

Any Other _____

_____

Signature of the Chairman: _____ **Date:** _____

Annexure 3: AX 03/SOP/7B/V4

Additional information to be provided with Application Form for Expedited Review

SMVMCH-EC 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:

Annexure 4: AX 04/SOP 7B/V4

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.xxxxxxxxxx

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 EC approves the above mentioned study.

This approval is valid for the entire duration of the study.

It is the policy of EC 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 09 to EC 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 EC and the head of the institution where the trial is been conducted within 10 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 EC of an appropriate amendment. The EC expects that the investigator should promptly report to the EC 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 EC for review.

Sincerely yours

xxxxxxxxxx

Member Secretary/ Chairman

Date of approval of the study: xxxxxx

7 . Flow Chart

No.	Activity	Responsibility
1.	Receive the submitted documents	Secretariat
2.	Determine protocols for expedited review	Member Secretary
3.	Approve the Secretary's recommendation regarding the protocols for expedited review	Chairman
4.	Expedited process	EC Members/Chairman
5.	Decision of EC	Chairman
6.	Communicate with the EC and the Investigator	Member Secretary/ Secretariat

8. References

1. Forum for Ethics review Committees in India (FERCI). Standard Operating Procedures of Institutional Ethics Committee (cited 22nd October 2018). Available from: http:// www.ferci.org/sops/
2. Ethical guidelines for biomedical research on human participants. (2017). Indian Council of Medical Research. Available from: http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf
3. Ministry of Health and Family Welfare. New Drugs and Clinical Trials Rules, 2019. Available from: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf

	Name	Designation	Signature
Prepared	Dr. Girija. S	Member	
	Dr. Nishanthi. A	Member	
Reviewed	Dr. Vimal. M	Member Secretary	
Approved	Dr. Thiagarajan. T	Chairman	
Issued	Dr. R. N. Kagne	Dean	