7B1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the Institutional Ethics Committee (IEC) members will perform an expedited review of new research proposal and using a prescribed procedure.

7B2. Scope

This SOP applies to the review and approval of research proposals and related documents, which qualify for expedited review by the IEC. These should carry not more than minimal risk and should fulfil the criteria for expedited review.

7B3. Responsibility

- After categorization of the projects, in consultation with the Chairperson if necessary, the Member Secretary is responsible, to forward the projects to the Secretariat.
- The IEC Secretariat is responsible for creation of a study specific file, distribution of the packages along with study assessment forms to the designated IEC members for review (if the study is categorized for expedited review) and communicate the review results to the investigators.
- Designated IEC members (including Member Secretary and/or Chairperson) will be responsible for reviewing the research protocols and related documents within the given time frames.
- It is the responsibility of all the designated IEC members to fill the Assessment form along with comments and recommendation they have after reviewing each study protocol.
- The IEC 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 is responsible to sign with date in the decision of the IEC.

7B4. Detailed instructions

7B4.1 Appointment of reviewers

After determining that the Proposal/ Project qualifies for an expedited review, the Member Secretary (in consultation with Chairperson) will nominate two or more IEC members to review the amended protocol.

7B4.2Distribute the protocol package

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

4.3Receive the distributed protocol package:

Designated IEC members will receive the protocol package with the Project Application Form, in a soft and/or hard copy.

4.4Verify the contents of the package

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

4.5 Review by the IEC members

- IEC members will review the protocol within the stipulated time line.
- The comments of the IEC members will be duly recorded.

4.6 Gather the assessment reports.

The IEC 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 IEC full board

- The 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.
- The reply from the PI will be discussed by the Member Secretary with the Chairperson or the designated IEC members and a decision will be reached.
- The final decision will be recorded on the Study Assessment Form for expedited review.
- The decision will be informed to the IEC members at the full board meeting.
- If deemed necessary by reviewer(s), Member Secretary/ Chairperson, the project shall be discussed at the forthcoming full committee 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 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.

7B5. Annexures

Annexure 1 *AX 01/SOP 7B/V1*- Form for nomination of IEC members for Review

Annexure 2 *AX 02/SOP 7B /V1* -Study Assessment Form for Expedited Review

Annexure 3 format should be same as Annexure 4: *AX 04/SOP 7A/V1*

Annexure 1 *AX 01/SOP 7B/VI*

Form for nomination of IEC Members for Review

Date:

To,

…….

Member, IEC,

Ref: The project no……..entitled…….

Sub: Review of ……..

Dear Dr. ……

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

1. _____
2. _____
3. _____

The following members were present to review/ carry out an expedited review of the abovementioned documents.

1. _____
2. _____
3. _____

For expedited review, you are requested to fill the study assessment form enclosed and send to the IEC office within 7 working days:

_____

Signature of Member Secretary / Chairperson with date

Annexure 2 *AX 02/SOP 7B/VI*

Study Assessment Form for Expedited Review

IEC Protocol Number :	Date of receipt at IEC office (……/……/……..):	
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-labelled □ 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)

Provisional Decision: □ Approved □ Resubmission

□ Disapproved □ Full Board

□ Approved with modifications

Reason for disapproval _____

_____

Name of the IEC member _____

Signature _____ **Date** _____

Final Decision:

Approved YES NO

If disapproved, reasons for disapproval _____

_____

_____

Further revision with minor or major amendments for Resubmission

_____

_____

Any Other _____

_____

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

Annexure 3 *AX 03/SOP 7B/VI*

Expedited Committee Approval letter

Date.....

To,

Dr/Mr./Mrs/Smt/. .....

Dept. of .....

Ref: The study no. EC/xxx/20xx entitled, "xxxxxxxxxx". Sub:

Letter no.

Dear Dr. XXXXx,

The meeting of the Institutional Ethics Committee (IEC) was held on..... at .....in the..... with ..... as Chairperson.

.....number of members attended the meeting held on ..... The list of members who attended the meeting is as follows.

Name of Members	Position on IEC	Designation & Affiliation	Qualification	Gender

It is hereby confirmed that neither you nor any of the study team members have participated in the voting/decision making procedures of the committee.

The IEC reviewed the above mentioned clinical study and approved the following documents submitted for this clinical study at the meeting.

1. Xxx
2. Xxx
3. xxx

The IEC hereby approves the proposal entitled, "....."

It is understood that the study will be conducted under your direction, in a total of ..... research participants, at ..... as per the submitted proposal.

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

It is the policy of IEC that, it be informed about any onsite serious adverse event or the unexpected adverse event report within 24 hours as per the formats specified in SOP 09/V1 to the IEC or by email if there is holiday. The report of SAE or death after due analysis shall be forwarded by the Investigator to chairman of the IEC and the head of the institution where the trial is being conducted within 14 calendar days of SAE or death.

In case of occurrence of death or injury during the period of research, 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 participant and also provide financial compensation for the clinical trial related injury or death.

No deviations from or changes in the proposal and Informed Consent Document should be initiated without prior written approval by IEC of an appropriate amendment. The IEC expects that the investigator should promptly report to IEC any such events 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 .....

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

Any publications during the approved period should be submitted to the IEC.

The IEC functions in compliance with applicable guidelines and regulatory requirements.

Sincerely yours,

Chairperson,

IEC

(Signed and dated by the IEC Chairperson)

Date of approval of the study: XX/XX/20XX

7B6. **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	Chairperson
4.	Expedited process	IEC Members/Chairperson
5.	Decision of IEC	Chairperson
6.	Communicate with the IEC and the Investigator	Member Secretary/ Secretariat