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|  | <p><u>FERCI MODEL SOPs</u></p> <p><u>Expedited Review of Research Study Protocols</u></p> | <p><u>SOP 07B/V1</u></p> <p><u>Effective Date: aa/bb/cccc</u></p> |
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Title: Expedited Review of Research Study Protocols

SOP Code: SOP 07B/V1

Effective Date: aa/bb/cccc

[The IEC members (author/s, reviewer/s) and Chairperson will sign and date the SOP on this first page]

Prepared by:

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| Dr. Padmaja Marathe, FERCi Member | (Signature with Date) |
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Reviewed by:


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| Dr. U. M. Thatte, FERCi Secretary | (Signature with Date) |
| Dr. S. K. Kamat, FERCi Treasurer | (Signature with Date) |

Approved by:

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|--|-----------------------|
| Dr. Vasantha Muthuswamy, FERCi President | (Signature with Date) |
| Dr. Nandini Kumar, FERCi Vice President | (Signature with Date) |

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1. Purpose


The purpose of this Standard Operating Procedure (SOP) is to describe how the Institutional Ethics Committee (IEC) members will perform an expedited review on a new research study protocol using the Assessment Form (AX 01/SOP 7B/V1).

2. Scope

This SOP applies to the review and approval of research studies and documents, which qualify for expedited review by the IEC. Any protocol that carries not more than minimal risk and fulfills criteria for expedited review (SOP 07/V1) is covered in this SOP.

3. Responsibility

- The Member Secretary is responsible, after categorization of the projects (as per SOP 7/V1), 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 and date the decision in the IEC Decision Form AX 02/SOP 7B/V1.

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4. Detailed instructions

4.1 Appointment of reviewers

- After determining that the Protocol / 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.

4.2 Distribute the protocol package


- The Secretariat will fill in the required details in the nomination form to the IEC Members requesting initial review (*AX 01/SOP 7A/V1*) and in the study assessment form *AX 02/SOP 7A/V1*.
- 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 *AX 01/SOP7A/V1*,
 - Project Submission Application Form *AX 01/SOP 06/V1*,
 - Protocol and related documents

4.3 Receive the distributed protocol package:

Designated IEC members will receive the protocol package with the Project Application Form *AX 01/SOP 06/V1*, in a CD or pen drive or as hard copy (if desired so).

4.4 Verify 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

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4.5 Review by the IEC members


- IEC members will review the protocol as described in Section 4.5 of SOP 7A/V1 within the stipulated time line.
- The comments of the IEC members will be recorded on *AX 02/SOP 7B/V1*.

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 be reached.
- The final decision will be recorded on the Study Assessment Form for Expedited Review *AX 02/SOP 7B/V1*.
- 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 board meeting before final decision. The final decision by the Chairperson is recorded on the Study Assessment Form for Expedited Review *AX 02/SOP 7B/V1*.
- The Secretariat will send the Study approval letter to the PI.

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- 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/V1: Management of Research Study Protocol and Study Related Documents Submitted for Ethics Review

SOP 07/V1: Categorization of Submitted Protocols for Ethics Review

SOP 07A/V1: Initial Full-Board Review of Research Study Protocols

6. 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 1: AX 01/SOP 7B/V1

Form for nomination of IEC Members for Review

Date: XXXX

To,

XXXXXXX,

Member, IEC,


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

Sub: Review of XXXXXXXX.

Dear Dr. XXXXXXX,

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

1. _____

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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/V1) and send to the IEC office within 7 working days:

Signature of Member Secretary / Chairperson with date


Annexure 2: AX 02/SOP 7B/V1

Study Assessment Form for Expedited Review

| | | |
|--|------------|---|
| IEC Protocol Number : | | Date of receipt at IEC 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: | | |

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| | |
|---|--|
| Duration of the Study: _____ | |
| Reviewer's name : | _____ |
| Type of the Study : | <input type="checkbox"/> Intervention <input type="checkbox"/> Epidemiology <input type="checkbox"/> Observation <input type="checkbox"/> Document based <input type="checkbox"/> Genetic <input type="checkbox"/> Social Survey <input type="checkbox"/> Others, specify..... |
| Description of the Study in brief: Mark whatever applied to the study. | |
| <input type="checkbox"/> Randomized <input type="checkbox"/> Open-labeled <input type="checkbox"/> Double blinded <input type="checkbox"/> Placebo controlled <input type="checkbox"/> Treatment controlled <input type="checkbox"/> Cross-over <input type="checkbox"/> Parallel <input type="checkbox"/> Interim Analysis <input type="checkbox"/> Use of Tissue samples <input type="checkbox"/> Use of Blood samples <input type="checkbox"/> Use of genetic materials | |
| Comments: | |
| _____ | |
| _____ | |
| (Review the protocol and related documents as per the guidelines stated in AX 05/SOP 06/V1) | |
| Provisional Decision: <input type="checkbox"/> Approved <input type="checkbox"/> Resubmission <input type="checkbox"/> Disapproved <input type="checkbox"/> Full Board <input type="checkbox"/> Approved with modifications | |
| Reason for disapproval _____ | |
| _____ | |
| Name of the IEC member _____ | |
| Signature _____ | Date _____ |

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|---|-----|--|
| Final Decision: | | |
| Approved | YES | <input type="checkbox"/> NO <input type="checkbox"/> |
| If disapproved, reasons for disapproval _____ | | |
| _____ | | |
| Further revision or modification required/resubmission <input type="checkbox"/> | | |
| _____ | | |
| Any Other <input type="checkbox"/> _____ | | |
| _____ | | |
| Signature of the Chairperson: _____ | | Date: _____ |

Annexure 3: AX 03/SOP 4B/V1

Approval letter format in case of Expedited Review

Date: xxxxxxxxx

To,

Dr. xxxxxxxxxxxxxxxx,

Dept. of xxxxxxxxx.


Ref: Your project no. xxxxxxxx entitled, “xxxxxxxxxxxxxxxxxx”.

Dear Dr. xxxxxxxxx,

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

1. xxx
2. xxxxxxxx
3. xxxxxxxxxxxx

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.

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The IEC approves the above mentioned study.

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 any unexpected adverse event report within 24 hours as per the formats specified in SOP 09 to IEC 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 IEC 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 IEC of an appropriate amendment. The IEC expects that the investigator should promptly report to the IEC 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 IEC for review.

Sincerely yours

xxxxxxxxxxxx

Member Secretary/ Chairperson

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