Title: **Expedited Review**

SOP Code: **SOP 05- B /V5 dated 26th July 2017**

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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide criteria to determine if a study protocol qualifies for expedited review and provide instructions on management, review and approval of a project through the expedited review.

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 05-B/V5)** is covered in this SOP.

3. Responsibility

It is the responsibility of the Member Secretary / Chairperson of the Institutional Ethics Committee (IEC) to determine if a Project/ Protocol qualifies for an expedited review and designate one / two primary reviewers. 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 give comments and recommendation after reviewing each study protocol.
The Member Secretary / Chairperson are responsible to take the decision.

4. Flow chart

No.	Activity	Responsibility
1.	Receive the submitted documents	Secretariat
2.	Determine protocols for expedited review & designate the primary reviewers	Member Secretary/Chairperson
3	Review protocol & give comments and recommendations	Primary reviewers
4.	Decision of IEC	Member Secretary/Chairperson
5.	Communicate with the IEC and the Investigator	IEC Secretariat/ Members

5. Detailed instructions

5.1 Check and receive the submitted documents.

- The Secretariat will check and receive documents and forward it to member secretary.

5.2 Determine protocols for expedited review & designate the primary reviewers

The proposal submitted for initial review or where investigator have requested for the expedited review stating the reasons in the covering letter to the IEC will be evaluated for the expedited review. The protocols satisfying any of the following criteria (as per ICMR 2006 guidelines) may be considered for expedited review. The IEC Chairperson will take the final decision regarding whether a study with 'not more than minimal risk' qualifies for an expedited review. Minimal risk would be

defined as one which may be anticipated as harm or discomfort not greater than that encountered in routine daily life activities of the general population or during the performance of routine physical or psychological examinations or tests. However, in some cases like surgery, chemotherapy or radiation therapy, great risk would be inherent in the treatment itself, but this may be within the range of minimal risk for the research participant undergoing these interventions since it would be undertaken as part of current everyday life (ICMR 2006).
IEC may do expedited review only if the protocols involve -

- Research involving data, documents or specimens that have been already collected or will be collected for ongoing medical treatment or diagnosis.
- Collection of data for research purposes through non-invasive procedures (not involving general anesthesia 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. However procedures involving the use of x-rays or microwaves are NOT recommended for expedited review.
- Clinical studies of drugs and medical devices only when
    i. research is on already approved drugs except when studying drug interaction or conducting trial on vulnerable population or
    ii. Adverse Event (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature is reported.
- Research on interventions in emergency situations like serious out brakes.
- Research on Disaster management.
- After determining that the Protocol / Project qualifies for an expedited review, the Member Secretary / Chairperson will nominate two or more IEC members to review the protocol and related documents.

5.3 Review protocol & give comments and recommendations

- Primary reviewers will review the protocol and give their comments and recommendations to the member secretary within seven days from date of receipt of the protocol.

5.4 Decision of IEC

- The comments of the Primary reviewers will be discussed by the Member Secretary with the Chairperson and decision about approval will be taken by the member secretary in consultation with Chairperson.
- The decision will be informed to the IEC members at the full board meeting.
- If deemed necessary by Primary reviewers, Member Secretary/ Chairperson, the project shall be discussed at the forthcoming full board meeting.
- The expedited review process should be completed within 14 working days.

5.5 Communicate with the IEC and the investigator.

- The Secretariat will send the Project approval letter to the Principal Investigator, if the Project/ Protocol amendment are approved.

- If project is disapproved or requires resubmission after certain modifications, this will be informed to the Principal Investigator. The reasons for disapproval of a project will be specified in the letter sent to Principal Investigator.

6. Glossary

Expedited approval	An IEC approval granted only by the Chairperson of the Institutional Ethics Committee or a designated Institutional Ethics Committee member (not the full Board) for research which involves no more than minimal risk.
Expedited review	A review process by one / two designated IEC 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*.

7. References

[1] ICMR's Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006) - *http://www.icmr.nic.in/ethical_guidelines.pdf* (last accessed 31st July 2017)

[2] International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- *http://www.ich.org/LOB/media/MEDIA482.pdf* (last accessed 31st July 2017)

[3] WHO Operational Guidelines for Ethical Review Committee that Review Biomedical Research (Geneva 2000) - *www.who.int/tdr/publications/publications/* (last accessed 31st July 2017)

8. Annexure

Annexure 1 *AX 01/SOP 05-B/V5* Approval letter format in case of Expedited Review for prospective observational study

Annexure 2 *AX 02/SOP 05-B/V5* Approval letter format in case of Expedited Review for retrospective observational study

Annexure 1

AX 01/SOP 05-B/V5

Approval letter format in case of Expedited Review for prospective observational study

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 expedite review process.

1xxx
2.xxxxxxx
3.xxxxxxxxxx

It is understood that the study will be conducted under your direction, in a total of **xxx** research participants, at Dept. of xxxxxxxxx**,** Seth G. S. Medical College and K. E. M. Hospital as per the submitted protocol.

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 the unexpected adverse event report within 24 hours as per the format specified in AX 01/SOP 11-B/V5 (Appendix XI of Schedule Y) and AX 02/SOP 11-B/V5 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 been conducted within 14 calendar days of SAE or death.

The sponsor has to forward the report of SAE or death after due analysis to the chairman of the IEC and the head of the institution where the trial is been conducted within ten calendar days of occurrence of the SAE or death. The report of the SAE other than death after due analysis shall be forwarded to chairman of the IEC and the head of the institution.

In case of injury or death occurring trial subject the sponsor (whether a pharmaceutical company or an institution) or his representative, whosever 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 in the manner as prescribed in SOP 5 Annexure 6.

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 the IEC for review.

Sincerely yours

xxxxxxxxxxx
Chairperson

Date of approval of the study: xxxxxx

Annexure 2

AX 02/SOP 05-B/V5

Approval letter format in case of Expedited Review for retrospective observational study

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 expedite review process.

1xxx
2.xxxxxxx
3.xxxxxxxxxx

It is understood that the study will be conducted under your direction, in a total of **xxx** research participants, at Dept. of xxxxxxxxx**,** Seth G. S. Medical College and K. E. M. Hospital as per the submitted protocol.

The IEC approves the above mentioned study.
This approval is valid for the entire duration of the study.

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 the IEC for review.
Sincerely yours
xxxxxxxxxxx
Chairperson

Date of approval of the study: xxxxxx

Expedited Review

proposal by Investigator [as per checklist – AX 02/SOP 05/V5]

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Documents checked by the Administrative officer

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Complete → **Received by IEC** → **PROCEDURE WITHIN 14 WORKING DAYS**

Incomplete → **Returned**

The proposal submitted for initial review satisfying any of the following criteria as per SOP 05-B/V5

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- **Involving data, documents or specimens that have been already collected or will be collected for ongoing medical treatment or diagnosis.**
- **Research on Research interventions in emergency situations.**
- **Collection of data for research purposes through non-invasive procedures (not involving general anesthesia 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. However procedures involving the use of x-rays or microwaves are NOT recommended for expedited review.**
- **Clinical studies of drugs and medical devices only when**
  - **i. research is on already approved drugs except when studying drug interaction or conducting trial on vulnerable population or**
  - ii. Adverse Event (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature is reported.
- **Research on Disaster management.**

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After determining that the Protocol / Project qualifies for an expedited review, the Chairperson / Member Secretary will nominate two or more IEC members to review the protocol / project.

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Review by the nominated IEC members
Decision communicated

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To the investigator within 14 working days] decision at its (Approval/Disapproval with reasons / Modifications in the proposal)

The Secretary will inform the upcoming full board meetings.