Expedited Review

For Institutional Ethics Committee

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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 fulfils criteria for expedited review 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 and 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 anaesthesia 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.

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- 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. References

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, (Geneva 2000)- *https://www.who.int/tdr/publications/documents/ethics.pdf* (last accessed 22nd October 2020).
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996-*http://www.ich.org/LOB/media/MEDIA482.pdf* (last accessed 22nd October 2020).
3. National Ethical Guidelines for Biomedical and Health Research involving Human Participants, ICMR 2017

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