Title: Expedited Review

SOP Code: SOP 07/V1 dated 18th February 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 initial review and approval of study proposals with 'not more than minimum risk' to participants.

3. Responsibility

It is the responsibility of the Chairperson of the Institutional Review Board (IEC) to determine if a Project/ Protocol qualifies for an expedited review.

4. Flow chart

No.	Activity	Responsibility
1.	Receive the submitted documents	Secretariat
2.	Determine protocols for expedited review	IEC 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	IEC Secretariat/ Members

5. Detailed instructions

5.1 Check and receive the submitted documents.

- The Secretariat will check and receive documents as described in 5.1 and 5.2 of SOP 5.

5.2 Determine protocols for expedited review.

The proposal submitted for initial review 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.

- Research involving data, documents or specimens that have been already collected or will be collected for ongoing medical treatment or diagnosis.
- Research on 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.

5.3 Expedited Process

- After determining that the Protocol / Project qualifies for an expedited review, the Chairperson will nominate two or more IEC members to review the amended protocol. The Form *AX 01/SOP 07/V1* will be used by the Chairperson to nominate members.
- The comments of the IEC members will be recorded on *AX 02/SOP 07/V1.*

  The comments of the members will be discussed by the Member Secretary with the Chairperson and decision about approval will be taken by the Chairperson. The final decision by the Chairperson will be recorded on the Study Assessment Form for Expedited Review *AX 02/SOP 07/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. The final decision by the Chairperson is recorded on the Study Assessment Form for Expedited Review *AX 02/SOP 07/V1.*
- The expedited review process should be completed within 14 working days.

5.4 Communicate with the IEC and the investigator.

- The Secretary will inform the IEC members of the proposals approved by expedited review at its regular meetings. 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 in writing. 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 Chairman of the Institutional Review Board or a designated Institutional Review Board member (not the full Board) for research which involves no more than minimal risk.
Expedited	A review process by only two designated IEC members who then report the

review	decision to the full Board meeting. An expedited review is a *speedy* one for *research proposal* with *minimal risk in nature*.
Expedited meeting	A meeting that will exclusively concern only those projects, which are subjected to expedited review and will be attended by the Chairperson, Secretary/Associate Member Secretary and 2 Institutional Review Board members designated to perform the expedited review. This expedited meeting will be conducted as per SOP 16/V1.

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 August 2013)

[2] International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- *http://www.ich.org/LOB/media/MEDIA482.pdf* (last accessed 31st August 2013)

[3] WHO Operational Guidelines for Ethical Review Committee that Review Biomedical Research (Geneva 2000) - *www.who.int/tdr/publications/publications/* (last accessed 31st August 2013)

8. Annexure

Annexure 1	*AX 01/SOP 07/V1*	Form for nomination of IEC members for Review
Annexure 2	*AX 02/SOP 07/V1*	Study Assessment Form for Expedited Review

Annexure 1

AX 01/SOP 07/V1

Form for nomination of IEC Members for Review

Date: XXXX
To,
XXXXXXx,
Member, IEC,
Ref: The project no. **EC/PHARMA-XX/200X** entitled, "XXXXXXXX".

Sub: Review of XXXXXXX.

Dear Dr. XXXXXX,

The following document/s has/ have been submitted to the IEC 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 07/V1*) and send to the IEC office within 7 working days:

_____

Signature of Chairperson with date

Annexure 2

AX 02/SOP 07/V1

Study Assessment Form for Expedited Review

IEC Protocol Number :	Date of receipt at IEC office (D/M/Y):	
Project Title : _____		
Name of the Principal Investigator	Department	Telephone number (Office and / or mobile)
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 IEC member _____

Signature_____ **Date** _____

Final Decision:

Approved YES ☐ NO ☐

If disapproved, reasons for disapproval _____

Further revision or modification required/resubmission ☐

Any Other ☐ _____

Signature of the Chairperson:_____ Date: _____

Annexure 3

AX 03/SOP 07/V1

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 expedite 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**,** Institute of NephroUrology, Bengaluru-560002 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 14/V1 (Appendix XI of Schedule Y) and AX 02/SOP 14/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 been conducted within 10 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