Title: Continuing Review of Study Protocols

SOP Code: SOP 07/V5 dated 26th July 2017

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1. Purpose

The purpose of this Standard Operating Procedure is to describe how continuing reviews of previously approved protocols are managed by the Institutional Ethics Committee (IEC).
The purpose of the continuing review is to monitor the progress of the entire study, not just the changes in it, to ensure continuous protection of the rights and welfare of research participants.

2. Scope

This SOP applies to conducting any continuing review of study protocols involving research participants at intervals appropriate to the degree of risk. All the projects approved by the Institutional Ethics Committee will be reviewed at least once a year. Depending upon the degree of risk to the participants, the nature of the studies, the vulnerability of the study participants and duration of the study, the IEC may choose to review or monitor the protocols more frequently.

3. Responsibility

It is the responsibility of the IEC Secretariat to remind the IEC and the principal investigators regarding study protocols that should be continuously reviewed. All the approved protocols will be reviewed annually (at least once a year). The Chairperson is responsible for determining the date of continuing review if the project will be reviewed more frequently in the year. This decision is taken during the IEC meeting wherein the project is finally approved or can be taken subsequently based on the SAE reports, monitoring reports, adequacy documentation procedures followed by the investigators or new safety data received.

The IEC is responsible for reviewing the progress made in the protocol, the occurrence of unexpected events or problems, and the rate of accrual of participants.

4. Flow chart

No.	Activity	Responsibility
1	Determine the date of continuing review and Notify the Principal Investigator or study team	IEC Secretariat
2.	Manage continuing review package upon receipt and distribute to member secretary/chairperson	IEC Secretariat
3.	Assign reviewers and review the annexure/ related documents of continuing review	Chairperson /Member Secretary/ IEC Members
4.	Written communication of the IEC decision to investigator	IEC Secretariat

5. Detailed Instructions

5.1. Determine the date of continuing review and Notify the Principal Investigator or study team

a. Determining the date of continuing review

- The Administrative Officer will look through the document archives/master chart of projects approved by the IEC for the due date of continuing reviews.

- The Secretariat will plan for continuing review of annual progress reports to be reviewed as close as possible to the due date or the anniversary of the effective date (date of original approval) of the protocol.

***b. Notifying the Principal Investigator or the study* team**

- If the Principal Investigator fails to submit the Continuing review report within one month of the due date (i.e. 11th months from the date of approval, unless specified otherwise), the IEC secretariat will send a reminder as per the format mentioned in *AX 01/SOP 07/V5* within 7 working days of this due date. If there is no response within 15 days after the date of reminder, the IEC secretariat will put up the matter for discussion at the forthcoming full board meeting for appropriate action which may consist of but not limited to

  a) A letter of reprimanding the Investigator.

Not reviewing future projects from the PI for a specified period of time / till the submission of status report of the previous study.

  b) A letter asking the Investigator to put recruitment of new participants on hold.

5.2 Managing the continuing review package upon receipt.

- The Secretariat will receive a package (soft and hard copy) submitted by the Study Team of continuing review for each approved protocol. The Secretariat will make sure that the contents of the package include the following documents:
  - Continuing Review Application Form (*AX 02/SOP 7/V5)* duly filled with an explanation for any "yes" (ticked on the Continuing Review Application Form (*AX 02/SOP 07/V5)* answers on the application form and a discussion of scientific development, either through the conduct of this study or similar research that may alter risks to research participants. The changes in the selection criteria of participants, protocol/Informed consent Document amendments, changes in the study team, any unexpected complications etc. have to be discussed in the attached narrative.
  - The Secretariat will check for complete information and for the presence of the required signatures of the Principal Investigator in the Continuing Review Application Form. The secretariat will ensure the payment of Rs 10,000 for Pharma sponsored studies and Rs 1000/- for Government sponsored studies. The Secretariat will forward the continuing review report to the Member Secretary/ Chairperson.

5.3 Assign reviewers and review the annexure/ related documents of continuing review

The Chairperson /Member Secretary will review the Continuing Review Application Form (*AX 02/SOP 07/V5)*. The Chairperson / member secretary can designate one/two IEC members to review the Study report and related documents and inform the decision to the other IEC members at the next full board meeting.

Review of Continuing Review Application

- The Continuing review submission may undergo expedited review (as per the procedure described in SOP 05-B/V5) or full board review (as per the procedure described in SOP 05-A/V5) as deemed appropriate by the IEC Chairperson/ Member Secretary

- The IEC Chairperson/ Member Secretary/ Member/s could reach one of the following decisions after review:
  1. Noted : The IEC approves the continuation of the above mentioned project without any modifications (as per the format *AX 03/SOP 07/V5*)
  2. Modifications recommended: Protocols that have been suggested modifications by the IEC may not proceed until the conditions set by the IEC in the decision have been met. Protocols should be amended and submitted to the IEC within one month for re-review.
  3. The project cannot be continued: The reasons for discontinuation of the project will be mentioned in the letter notifying the decision to the Principal Investigator.
  4. The decision will also include any significant findings that have arisen during review process and this will be communicated to Principal Investigator. It is the responsibility of Principal Investigator to provide this information to the participants and once done submit the report to IEC.

5.4 Written communication of the IEC decision to investigator

- ✓ The decision will be communicated to the PI within 14 days and for the continuing review reports which will be discussed in the full board meeting the decision will be communicated within 14 days of the meeting.
- ✓ The Secretariat will record the decision reached on the proposed continuing review report in the minutes of the meeting.

6. References

[1] World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, (Geneva 2000) - *www.who.int/tdr/publications/publications/* (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)

7. Annexure

Annexure 1	*AX 01/SOP 07/V5*	Reminder letter by the IEC to investigator
Annexure 2	*AX 02/SOP 07/V5*	Continuing Review Application Form
Annexure 3	*AX 03/SOP 07/V5*	Continuing Review report Approval Letter

Annexure 1

AX 01/SOP 07/V5

Reminder letter by the IEC to Investigator

Date:-

Name of Principal Investigator:-

Department:-

Ref: - Project Title: XXXXXX

The above referenced project was approved by the IEC-I on **xxxx** and will due for the continuing Annual Review by the IEC-I. You are requested to submit an Annual Status Report in one of the prescribed format as given below at the earliest on or before **xxx**

a) If ongoing, status report in the format as per form no. **(*AX 02/SOP 07/V5*)**

b) If completed – status report in the format as per form no. **(*AX 01/SOP 08/ V5*)**

c) If terminated / not initiated – status report in the format as per form no. **(*AX 01/ SOP 09/V5*)**

Signature with date _____

Member Secretary _____

Annexure 2

AX 02/SOP 07/V5

Continuing Review Application Form

Date: _____

Protocol No.:	**Date of IEC approval:**
Protocol Title:	
Principal Investigator : **Department :**	
Summary of protocol participants: _____ No. of participants approved by IEC _____ No. of recruited participants _____ No. of ongoing participants _____ No. of Completed participants ____ No. of participants who refused to consent **Have any participants been withdrawn from this study?** ❑ No ❑ Yes (state the number and reasons for drop-outs of each participant, attach separate sheet if	**Has any information appeared in the literature, or evolved from this or similar research that might affect the IEC/IEC's evaluation of the risk/benefit analysis of participants involved in this protocol?** ❑ No ❑ Yes (attach separate sheet if needed) _____ **Have any unexpected complications or SAEs been noted since last review at our site?** ❑ No ❑ Yes (attach separate sheet if needed) ❑ No. of patients who had SAEs- _____ ❑ Whether reports of SAEs at have been

needed)

_____

Impaired participants

- ❑ None
- ❑ Physically
- ❑ Cognitively
- ❑ Both

Have there been any amendments in protocol/ Informed Consent Document since the last review?

- ❑ NO
- ❑ YES

Were these protocol/ Informed Consent Document (ICD) amendments approved by IEC?

- ❑ No
- ❑ Yes

If no, mention the amendments not approved

_____

Which protocol amendment is the site following at this date

_____

Which ICD amendment is the site following at this date

_____

submitted to the IEC- _____

- ❑ Whether reports of SAEs at other sites have been submitted to the IEC-_____
- ❑ Types of adverse events with nos. of participants- _____

_____

- ❑ Number of unexpected AE

Have any participating investigators been added or withdrawn since last review?

- ❑ No
- ❑ Yes (Identify all changes in the attached narrative)

Is report of interim data analysis available?

- ❑ No
- ❑ Yes (submit as an attachment)

Is report of the data safety and monitoring board available?

- ❑ No
- ❑ Yes (submit as an attachment)

Have any investigators developed equity or consultative relationship with a source related to this protocol which might be considered a conflict of interest?

- ❑ No
- ❑ Yes (Append a statement of disclosure)

Signature of the Principal Investigator with Date:

_____

Annexure 3

AX 03/SOP 07/V5

Continuing Review report Approval Letter

Name of the Principal Investigator:-

Department :-
Ref: - Project Title: _____
Sub: - Letter dated: _____

This is with reference to the above stated letter regarding the continuing review report of the above mentioned project. The Continuing Review Report was reviewed in the IEC meeting held on XXXXXXXX and was noted.

The IEC allows continuation of the above mentioned project without any modifications.
You are requested to submit the next continuing review report within 1 month of the due date i.e. on or before XXXXX.

_____
Signature with date
Member Secretary

Date of approval: