Title: Review of Study Completion Reports

SOP Code: SOP 08/V5 dated 26th July 2017

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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide instructions on the review of Study Completion Report for every study previously approved by the Institutional Ethics Committee (IEC).

2. Scope

This SOP applies to the review of the Study Completion Report which is an obligatory review of each investigator's activities presented to the IEC as a written report of study completed.

3. Responsibility

It is the responsibility of the IEC Chairperson/ Member secretary to review the study report and notify it or request for further information, if necessary.

4. Flow chart

No.	Activity	Responsibility
1.	Manage completion report package upon receipt and distribute to member secretary/chairperson	IEC Secretariat
2.	Assign reviewers and review the annexure/ related documents of completion report	Member-Secretary
3.	Written communication of the IEC to investigator	Member-Secretary

5. Detailed instructions

5.1 Manage completion report package upon receipt and distribute to member secretary/chairperson

- The Secretariat will receive 1 copy (soft and hard) of Study Completion Report filled as per the format – *AX 01/SOP 08/V5* from the Principal Investigator. The study completion report is expected from the investigator within 1 month of completion of the study at the site. A brief study report containing data analysis from all centres can be submitted by the investigator once available from the sponsor.
- It is the responsibility of the IEC Secretariat to review the report for completeness. If necessary, the IEC secretariat will retrieve the master file from the archiving with permission of the Member Secretary.
- The Secretariat shall forward the Study Completion Report along with Study Completion Report Form- *AX 01/SOP 08/V5* and sends it to the Member secretary.

5.2 Assign reviewers and review the annexure/ related documents of completion report

- The completion report 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 Chairperson and the Member Secretary will review the report, Study Completion Report Form and Study Completion statement and notify it to the other IEC members at the forthcoming full board meeting or the Chairperson / member secretary can designate two other IEC members to review the Study report and related documents. If deemed necessary, the Chairperson/member secretary may keep the report for discussion at the forthcoming IEC meeting.
- The Secretariat will send the Study Completion Report Form *AX 01/SOP 08/V5* and Study Completion statement *AX 02/SOP 08/V5 for regulatory studies* to the designated IEC members if required.
    - In case there is a significant finding during the review process by the designated IEC members this will be communicated to Principal Investigator. It is the responsibility of Principal Investigator to provide the required information to the IEC.

5.3 Written communication of the IEC to investigator

5.3.1 During the Board meeting

- The Secretariat shall request the IEC member(s) designated the task to review a copy of the Final Report to present his/her comments.
- The Member Secretary entertains any discussion of the study.
- If appropriate to the discussions, the Chairperson may call for voting for final decision or whether to request further information or to take other action with the investigator.

5.3.2 After the Board meeting

- The Secretariat will note the decision in the meeting minutes and the study shall be considered as closed if decision by IEC is "Noted".
- The IEC decision is notified to the investigator as
    a) noted in the IEC records
    b) request for additional information / clarification
- Once the report is accepted by IEC the decision will be communicated to the PI within 14 days of the date of the receipt from the investigator / full board meeting. The Administrative Officer will archive the entire study protocol for a period of 5 years from the date of completion of the project if the decision is noted and closed.
- For thesis / dissertations no dues certification will be stamped only after confirming the submission of study completion report.

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 08/V5* Study Completion Report Form

Annexure 2 *AX 02/SOP 08/V5* Study Completion Statement

Annexure 1

AX 01/SOP 08/ V5

Study Completion Report Form

(Filled by Principal Investigator)

IEC Protocol No	
Protocol Title: _____ _____	
Principal Investigator	
Department	
Total no. of study participants recruited	
Total no. of study participants approved by the IEC for recruitment	
Duration of the study	
*Introduction, Aims & Objectives, Material & methods, Results, Conclusion: (use extra blank paper, if more space is required). _____ _____ _____ *Note: If the final report is not available from sponsor, it may be submitted later to the IEC once it is ready.	
Number of SAEs at our center:	
Whether all SAEs intimated to the IEC	Yes ☐ No ☐
No. of patients withdrawn and reasons for withdrawal: ☐ _____ _____ _____	
Signature of Principal Investigator	Date :-

Annexure 2

*AX 02/SOP 08/V*5

Study Completion Statement for regulatory studies

Project no. and title:
Principal Investigator:
Department:
Date of project approval:

Status report/s received so far						
Dates of meeting						

Documents approved after the first approval:

1.
2.

SAE at our sites (details)

Sr. No.	Date	SAE

_____

Signature with date
Member Secretary