

Title: Review of Study Completion Reports

SOP Code: SOP 11/V1 dated 18th February 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/IEC members to review the study report and notify it or request for further information, if necessary.

4. Flow chart

No.	Activity	Responsibility
1	Receipt of the study completion report	IEC Secretariat
2	Checking the contents of the report packages and assess adequacy of contents	IEC Secretariat
3	Verification of the study completion report, preparation of the study completion statement and sending them to the Chairperson	IEC Secretariat
4	Review of the Study completion report and decision regarding its handling: review by designated members, full-board review or review by Member Secretary/ Chairperson and informing members at full-board meeting	Member-Secretary/ Chairperson
5	Inclusion of the report/ review at full-board meeting	IEC Secretariat
6	Placing the report at IEC meeting and entertaining discussion	Chairperson/ Member Secretary
7	Arriving at an appropriate decision after due discussion	IEC
8	Noting the decision in the minutes of the Meeting	IEC Secretariat
9	Conveying decision to the Principal Investigator	IEC Secretariat
10	Archiving all the study-related documents along with the Study completion report	IEC Secretariat

5. Detailed instructions

5.1 Before each Board meeting

- The Secretariat will receive 1 copy (soft and hard) of Study Completion Report filled as per the format – AX 01/SOP 11/V1 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.
- The Secretariat will follow instructions as in SOP 05/01 (Management of Protocol Submission) for receiving and checking the report packages.
- It is the responsibility of the IEC Secretariat to review the report for completeness before submission for the Board meeting. If necessary, the IEC secretariat will retrieve the master file from the archiving with permission of the Member Secretary.
- The Secretariat shall verify the submitted Study Completion Report along with Study Completion Report Form- AX 01/SOP 11/V1 and sends it to the Chairperson.
- Prior to sending the Study Completion Report to the Chairperson, the Secretariat will prepare the Study Completion statement i.e. AX 02/SOP 11/V1 and attach this also to the packet sent to the Chairperson.
- 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 can designate two other IEC members (letter of nomination – AX 01/SOP 07/V1) to review the Study report and related documents. If deemed necessary, the Chairperson may keep the report for discussion at the forthcoming IEC meeting.
- The Secretariat will send the Study Completion Report Form AX 01/SOP 11/V1 and Study Completion statement AX 02/SOP 11/V1 to the designated IEC members if required.
- The Secretariat shall include the Study Completion Report Form in the agenda for IEC members as per SOP 16/V1 (Procedures for Agenda preparation, Meeting procedures and recording of Minutes) for discussion at the full board meeting.

5.2 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 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
- The Secretariat will accept and file the Final Report and get the Study Completion Report Form AX 01/SOP 11/V1 signed by the Chairperson and file it.
- With the permission of the member secretary, the secretariat will retrieve the file from the archiving. The final report will be placed in the master file and kept in the archival area.
- 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 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)

7. Annexure

Annexure 1 AX 01/SOP 11/V1 Study Completion Report Form

Annexure 2 AX 02/SOP 11/V1 Study Completion Statement

Annexure 1

AX 01/SOP 11/V1

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	
*Results (summary)with 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 <input type="checkbox"/> No <input type="checkbox"/>
No. of patients withdrawn and reasons for withdrawal:	<input type="checkbox"/>

Signature of Principal Investigator	Date :-
Assessment by the IEC member	
To be reviewed by	
<ul style="list-style-type: none">• Chairperson / Member Secretary only and informed to the IEC members at Full Board <input type="checkbox"/>• Full Board <input type="checkbox"/>• Any 2 IEC members and informed to the IEC members at Full Board <input type="checkbox"/>	
Names of IEC members:	
1. _____	
2. _____	
Signature with date: _____	
Chairperson	
Reviewer's Name: _____	
Comments(if any)	

Action taken:	
<input type="checkbox"/> Noted	
<input type="checkbox"/> Requires more information/ action as follows:	

Signature with date : _____	
of the Reviewer	
Final Decision by the Chairperson	

Signature with date: _____	
Chairperson / Member Secretary	

Annexure 2
AX 02/SOP 11/V1
Study Completion Statement

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