Title: Review of Study Completion Reports

SOP Code: SOP 11/V3.2 dated 15th February 2013

Authors:

Dr. Shruti Bhide (Member Secretary, IRB - I)	
Dr. Sharmila Jalgaonkar (Member Secretary, IRB-II)	

Reviewed by:

Dr. Sunil Kuyare (Member, IRB - I)	
Dr. Yashashri Shetty (Member, IRB-II)	

Approved by:

Dr. Jigeeshu V. Divatia, Chairperson, IRB - I (Signature with Date)	Dr. Kamal Hazari, Chairperson, IRB - II (Signature with Date)

Table of Contents:

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 Review Board (IRB).

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 IRB as a written report of study completed.

3. Responsibility

It is the responsibility of the IRB Chairperson/IRB 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	IRB Secretariat
2	Checking the contents of the report packages and assess adequacy of contents	IRB Secretariat
3	Verification of the study completion report, preparation of the study completion statement and sending them to the Chairperson	IRB 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	IRB Secretariat
6	Placing the report at IRB meeting and entertaining discussion	Chairperson/ Member Secretary
7	Arriving at an appropriate decision after due discussion	IRB
8	Noting the decision in the minutes of the Meeting	IRB Secretariat
9	Conveying decision to the Principal Investigator	IRB Secretariat
10	Archiving all the study-related documents along with the Study completion report	IRB Secretariat

5. Detailed instructions

5.1 Before each Board meeting

- The Secretariat will receive 1 copy of Study Completion Report filled as per the format – *AX 01/SOP 11/V3.2* 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 IRB Secretariat to review the report for completeness before submission for the Board meeting. If necessary, the IRB 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/V3.2* 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/V3.2* 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 IRB members at the forthcoming full board meeting or the Chairperson can designate two other IRB members (letter of nomination – *AX 01/SOP 07/V3.2*) to review the Study report and related documents. If deemed necessary, the Chairperson may keep the report for discussion at the forthcoming IRB meeting.
- The Secretariat will send the Study Completion Report Form *AX 01/SOP 11/V3.2* and Study Completion statement *AX 02/SOP 11/V3.2* to the designated IRB members if required.
- The Secretariat shall include the Study Completion Report Form in the agenda for IRB members as per SOP 16/V3.2 (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 IRB 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 IRB is “Noted”.

- The IRB decision is notified to the investigator as
  a) noted in the IRB 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/V3.2* 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.

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 24 September 2008)
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- *http://www.ich.org/LOB/media/MEDIA482.pdf* (last accessed 24 September 2008)

7. Annexure

Annexure 1 *AX 01/SOP 11/V3.2* Study Completion Report Form

Annexure 2 *AX 02/SOP 11/V3.2* Study Completion Statement

Annexure 1

AX 01/SOP 11/V3.2

Study Completion Report Form

(Filled by Principal Investigator)

IRB Protocol No	
Protocol Title: _____ _____	
Principal Investigator	
Department	
Total no. of study participants recruited	
Total no. of study participants approved by the IRB 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 IRB once it is ready.

Number of SAEs at our center:	
Whether all SAEs intimated to the IRB	Yes ☐ No ☐

No. of patients withdrawn and reasons for withdrawal: ☐

_____

_____

_____

Signature of Principal Investigator	Date :-

Assessment by the IRB member

To be reviewed by

- Chairperson / Member Secretary only and informed to the IRB members at Full Board ☐
- Full Board ☐
- Any 2 IRB members and informed to the IRB members at Full Board ☐

Names of IRB members:

1. _____
2. _____

Signature with date: _____

Chairperson

Reviewer's Name: _____

Comments(if any)

_____

Action taken:

☐ Noted

☐ Requires more information/ action as follows:

_____

_____

Signature with date : _____

of the Reviewer

Final Decision by the Chairperson

_____

Signature with date: _____

Chairperson

Annexure 2

AX 02/SOP 11/V3.2

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