Institutional Review Board, Tata Memorial Centre (IRB, TMC)

Title: Review of study completion reports

SOP Code: SOP 12/V1 Date:05/09/2012 Pages: 1 to6

12.1 Purpose

The purpose of this SOP is to provide instructions on the review of Study Completion Report for every study previously approved by the IRB.

12.2 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.

Although IRB provides a Study Completion Report Form (*AX1-V1/SOP12/V1*) to the investigator, additional information (letter format, form provided by the Sponsor, etc.) may be submitted to provide adequate and sufficient information.

12.3 Responsibility

It is the responsibility of the IRB members to review the study completion report and notify it or request for further information, if necessary.

12.4 Detailed instructions

12.4.1 Before each board meeting

- The secretariat will receive 20 hard copies or 5 hard copies + soft copy of Study Completion Reports from the PI.
- The Secretariat will follow instructions as in SOP 03/V1 (Management of Research study 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.
- The Member Secretary should keep the study completion reports on the agenda for IRB meeting. (Procedures for Agenda preparation, Meeting procedures and recording of Minutes- SOP 05/V1)

12.4.2 Before and during board meeting

- IRB member(s) should review a copy of the completion report.
- The members will discuss the report in the IRB meeting.
- If appropriate to the discussions, the chairperson may call for consensus to accept it or request further information or take any other action.

12.4.3 After the board meeting

- The secretariat will note the decision in the meeting minutes and the study will be

considered as closed if the document is accepted.

- The IRB decision is communicated to the investigator. In case, further information / action is requested, the same should be followed by the PI and communicated to the IRB office within 30 days. This update will be tabled in the full board meeting of IRB.

- Once the report is accepted by IRB, the Secretariat will file the report in the study master file.

- The IRB secretariat will archive the entire study as per SOP 10/V1 section 10.4 and the report for a period of 3 years from the date of completion of the project, if the report is accepted.

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)

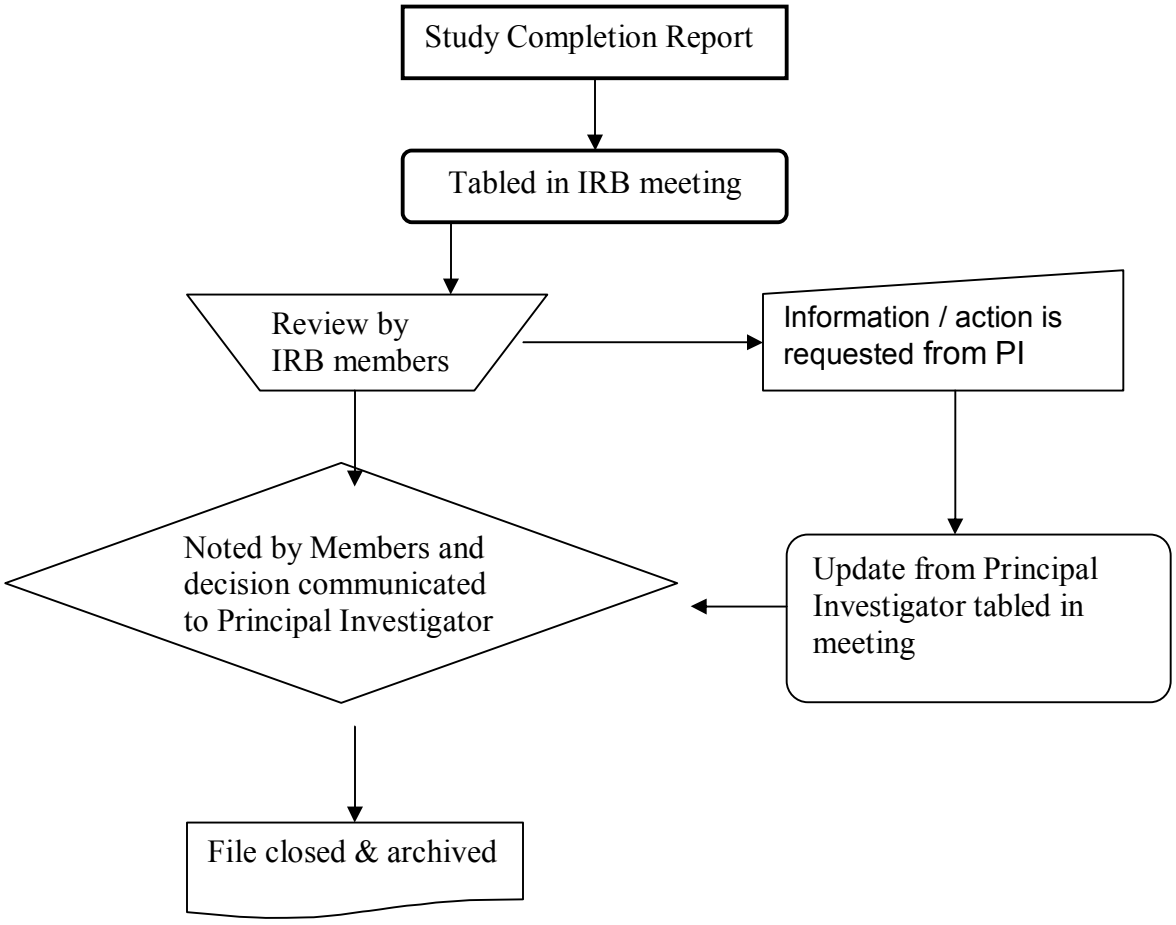
Annexure

AX1-V1/SOP12/V1

Study Completion Report Form
TMC Project No. Study Title: Principal Investigator:
Sponsor
Duration of the study
Study Start Date Completion Date
Summary of Protocol participants: o Target accrual of trial (entire study) _____ o Total patients to be recruited at TMH (IRB ceiling)_____ o Screened: _____ o Screen failures: _____ o Enrolled: _____ o Consent Withdrawn: _____Reason: (Attach in format below) o Withdrawn by PI: _____Reason: (Attach in format below) o Active on treatment: _____ o Completed treatment : _____ o Patients on Follow-up: _____ o Patients lost to follow up: _____ o Any other: _____ o Any Impaired participants • None_____ • Physically _____ • Cognitively _____ • Both _____

TMH Case No& Reason for withdrawal
No. of study arms :-
Objectives:-
Results (brief) (use extra blank sheets, if more space is required)
Presentation/publication related to the data generated in this trial
SAEs at our center (Total number and type)
Whether all SAEs were intimated to the IRB (Yes/No)
Protocol deviations/violations (Number and nature)
Conclusion
Please specify if the raw data was submitted to TMC- Research Administrative Council (TRAC) (applicable only for investigator initiated studies supported by intramural funding).
Signature of PI Date:

Flow Chart


Study Completion Report
Tabled in IRB meeting
Review by IRB members
Information / action is requested from PI
Noted by Members and decision communicated to Principal Investigator
Update from Principal Investigator tabled in meeting
File closed & archived