Independent
Ethics Committee
(Clinical Research) India

# Standard Operating Procedures

# (SOP -11/01)

For

## Review of Study Completion Reports

**Independent Ethics Committee (Clinical Research) India**

## 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 Independent 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.

Although IEC provides a Study Completion Report Form (*AF/01/01-SOP11/01*) to the investigator, any mechanism (letter format, form provided by the Sponsor, etc.) may be used, provided that the information submitted is sufficient.

## 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 | Before each Board meeting | IEC Secretariat |
| 2 | During the Board meeting | IEC Secretariat/ IEC Members/ Chairperson |
| 3 | After the Board meeting | IEC Secretariat |

## 5. Detailed instructions

### *5.1 Before each Board meeting*

- The Secretariat will receive 3 copies of Study Completion Report from the Principal Investigator.
- The Secretariat will follow instructions as in SOP 05/01 (Management of Protocol Submission) for receiving and checking the report packages.

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- It is the responsibility of the IEC Secretariat to review the report for completeness before submission for the Board meeting.
- The Secretariat verifies the submitted Study Completion Report along with Study Completion Report Form *AF/01/01-SOP11/01* and couriers it to the Chairperson.
- Prior to sending the Study Completion Report to the Chairperson, the Administrative Officer will prepare the Study Completion statement i.e. *AF/02/01-SOP11/01* and attach this also to the packet sent to the Chairperson.
- The Chairperson will review the report, Study Completion Report Form and Study Completion statement and notify it or the Chairperson can designate two other IEC members to review the Study report and related documents.
- The Secretariat will courier the Study Completion Report Form *AF/01/01-SOP11/01* and Study Completion statement *AF/02/01-SOP11/01* to the designated IEC members.
- The Secretariat notes this in the agenda for IEC members as per SOP 16/01 (Procedures for Agenda preparation, Meeting procedures and recording of Minutes).

### *5.2 During the Board meeting*

- The Secretariat requests the IEC member(s) designated the task to review a copy of the Final Report to present his/her comments.
- The Chairman or designee entertains any discussion of the study.
- If appropriate to the discussions, the Chairperson may call for consensus to notify it 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 is considered as closed if decision is noted
- The IEC decision is notified to the investigator as noted, request further information / action in writing to be submitted in the IEC office within 30 days.
- The Secretariat will accept and file the Final Report and get a copy of the Study Completion Report Form *AF/01/01-SOP11/01* signed by the Chairperson or the designee and file it.
- The Administrative Officer will archive the entire study protocol and the report for a period of 5 years from the date of completion of the project if the decision is noted and closed.

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## 6. References

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, (Geneva 2000)- *www.who.int/tdr/publications/publications/* (lastaccessed 24 March 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 March 2008)

## 7. Annexure

| | | |
|---|---|---|
| ANNEX 1 | AF/01/01-SOP11/01 | Study Completion Report Form |
| ANNEX 2 | AF/02/01-SOP11/01 | Study Completion Statement |

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**Annex 1**
AF/01/01-SOP11/01

**Study Completion Report Form**
(Filled by Principal Investigator)

| | |
|---|---|
| Protocol No | **Assigned No FFF / FF-FF** |
| Protocol Title | |
| Principal Investigator | |
| Phone Number | E mail address :- |
| Sponsor | |
| address | |
| phone | E mail :- |
| Study site(s) | |
| Total no of study participants | No of study arms :- |
| Study materials | |
| Treatments form | |
| Study dose(s) :- | |
| Duration of the study | |
| Objectives:- | |
| Results( brief) ( use extra blank paper, if more space is required. | |
| SAE (Total number) | |
| Whether SAEs intimated to the IEC (Yes/No) | |
| No of patients withdrawn | |
| conclusion | |
| Signature of P.I | Date :- |
| Assessment | |
| Reviewer Name | Sign & date |
| Comments(if any) | |
| Decision :- a) noted b) requires more information | |

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**Annex 2**
AF/02/01-SOP11/01

**Study Completion Statement**

Project title:

Principal Investigator:

Site:

Date of project approval:

| | | | |
|---|---|---|---|
| Status report received | | | |
| Date of meeting | | | |
| Date(s) of extension approval | | | |

Documents approved after the first approval:
1.
2.

SAE details

| Sr. No. | Date | SAE |
|---|---|---|
| | | |
| | | |