STANDARD OPERATING PROCEDURE [SOP]

MONITORIING OF RESEARCH PROJECTS

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1. Purpose

The purpose of this standard operating procedure (SOP) is to describe the procedures for continuous monitoring of an Institutional Ethics Committees (IEC) approved research project.

2. Scope

This SOP applies to all IEC approved studies for which a routine or for-cause on-site monitoring may be undertaken by the IEC.

3. Monitoring participant's rights, safety and wellbeing

It will be the responsibility of the Full Committee to decide and conduct continuous monitoring of an approved research project. It will be further the responsibility of the designated IEC member(s) to perform on-site monitoring of selected study site(s).

A. Selection of study sites

Routine monitoring for a site may be decided at the time of approval of the project by the full committee. This may be recorded in the IEC decision and in the IEC minutes of the meeting.

B. Before the visit

Irrespective of the cause for conducting monitoring, the following procedure will be followed:

a. The Chairperson will identify and select one or more IEC members (henceforth referred to as monitors) to conduct monitoring of a site.

b. The agenda of monitoring will be decided by the identified monitors in consultation with the

Member Secretary and Chairperson

c. The Member Secretary will decide the date of the monitoring in consultation with the monitors and the PI.
d. The final date will be communicated to the PI (with a request to be available) and monitors.
e. The Member Secretary will provide Monitors with relevant reference material / documents related to the project for review.
f. Monitors will carry with them Site Monitoring Visit Report Forms from IEC Office for documentation of the monitoring findings.

C. During the visit

The Monitor will follow the check list and during the monitoring will:

a. check the log of delegation of responsibilities of study team, check if the site is using latest IEC approved current versions of the protocol, informed consent documents, case record forms, diaries, advertisements, etc.
b. check investigational product accountability is adequately controlled and documented throughout the product flow at the study site (arrival, dispensing, use, return from the subject and return/destruction after the study),
c. check for storage times, conditions and expiry dates to be acceptable and sufficient supplies available, wherever applicable,
d. verify that the investigator follows the approved protocol and all approved amendment(s), if any,
e. ensure that the investigator and the investigator's trial staff are adequately informed about the trial,
f. verify that the investigator and the investigator's trial staff are performing the specified study functions, in accordance with the approved protocol and any other written agreement between the sponsor and the investigator/institution, and have not delegated these functions to unauthorized individuals,
g. verify that the investigator is enrolling only eligible subjects, [1st as well as subsequent ones from recruitment log],
h. determine whether all SAEs are appropriately reported within the time as per the applicable regulatory requirement(s). Case record forms would be checked to review the safety data i.e. Adverse Events (AEs) and SAEs for the volume or severity of adverse events,
i. review the project files of the study to ensure that documentation is filed appropriately,
j. review the source documents for their completeness,

k. check for unreported protocol deviations or violations,

The Monitor will fill the Site Monitoring Visit Report Form, sign and date it.

[Annexure 10, 22, 23]

4. Ensuring adequacy and continuity of consent process

The monitor will:

a. observe the informed consent process, if possible,

b. review randomly selected participant's files to ensure that participants are signing the correct informed consent

c. may even interview, if participant is available

[Annexure 10.1]

5. Conduct of For-cause assessments following non-compliance and/or complaints for the trials approved by the ethics committee

"For-cause monitoring" will be performed at sites for reasons identified by any member of the IEC, after approval by the Chairperson. The reasons for identifying a particular site for "for-cause monitoring" could include any one or more of the following:

a. High number of protocol deviations/ violations

b. Repeated Serious Adverse Events (SAE) reports in a trial

c. Too many SAEs for a particular investigator over a period

d. High recruitment rate

e. High number of instances requiring active observation

f. Complaints received from participants or any other person

g. Frequent failure to submit the required documents

h. Any other cause as decided by IEC

6. Identifying opportunities for improvement and actions to be initiated

After the on- site visit by the monitor

i. The Monitor will submit the completed Site Monitoring Visit Report Form to the IEC Member Secretary within 7 working days of conducting a site monitoring visit or at the time of full board meeting (whichever is earlier).

ii. The report should describe the findings of the monitoring visit.

iii. The Member-Secretary will present the monitoring report at the next full board IEC meeting and the concerned Monitor will provide additional details/ clarifications to members, as required.

iv. The IEC will discuss the findings of the monitoring process and take appropriate specific action by voting or combination of actions, some of which are listed below:

1. Continuation of the project with or without changes,
2. Restrictions on enrollment
3. Recommendations for additional training
4. Recruiting additional members in the study team
5. Revising/ providing qualifications/ experience criteria for members of the study team, termination of the study, suspension of the study, etc.

v. If the Monitor has findings that impact on safety of the participant the Monitor will inform the Member Secretary on the same day. The Member Secretary will discuss with the Chairperson to decide on the suitable action to be taken.

vi. The final decision taken at the full board IEC meeting by the Chairperson will be recorded in the Site Monitoring Visit Report Form

vii. The Member Secretary will convey the decision to the Principal Investigator in writing within 14 working days of the meeting.

viii. The Member Secretary will place the copy of the report in the protocol file.

Measures apart from active monitoring

The Committee can call for and discuss information on any relevant aspect (s) of the project with the investigator (s) at any time. In particular, the Committee may require investigators to provide interim reports on stipulated dates and a final report at completion of the study.

1. The Committee may ask for the following information in the report:
   - Progress to date, outcome/ results and publications/ presentations in the case of completed research
   - Maintenance, security, confidentiality and integrity of records and data
   - Compliance with the approved protocol
   - Compliance with any conditions of approval
   - Changes to the protocol or conduct of the research
   - Changes to the personnel of the PI /other investigators and
   - Serious Adverse events or complaints relating to the project
2. The Committee will require, as a condition of approval of each project, that investigators immediately report anything which might warrant review of ethical approval of the protocol, including:

- proposed changes in the protocol
- any unforeseen events that might affect continued ethical acceptability of the project new information from other published or unpublished studies which may have an impact on the continued ethical acceptability of the trial, or which may indicate the need for amendments to the trial protocol.

3. The Committee will also require, as a condition of approval of each project, that investigators inform the IEC, giving reasons, if the research project is discontinued before the expected date of completion, and that the investigators comply with the approved protocol.
4. The Committee will ensure that adequate information with regards to rights and responsibilities of research participants are displayed at relevant sites too.
5. At the end of each financial year, before preparing its report to the Appointing Authority, the Committee will require all investigator [s], whose projects have been approved in the preceding year, to declare to the Committee, in writing the status of their ongoing research projects.