# Site Monitoring Visit

**For Institutional Ethics Committee**

## Tagore Medical College and Hospital

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## 1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide the procedures to select a site for monitoring and how the site will be monitored.

## 2. Scope

This SOP applies to any visit and/or monitoring of any study sites as stated in the Institutional Ethics Committee (IEC) approved study protocols.

## 3. Responsibility

It is the responsibility of the designated IEC member(s) or designated qualified agent to perform on-site inspection of selected study site(s) of relevant projects it has approved. The IEC members or Secretariat in consultation with the Chairperson may initiate an on-site evaluation of a study site for a routine audit.

## 4. Flow chart

| No. | Activity | Responsibility |
|---|---|---|
| 1 | Selection of study sites and Identification of monitors for site monitoring | IEC members / Chairperson |
| 2 | Before the visit | IEC members / representative, Secretariat |
| 3 | During the visit | IEC members / representative |
| 4 | After the visit | IEC members /representative, Secretariat |

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## 5. Detailed instructions

### *5.1 Selection of study sites and Identification of monitors for site monitoring*

• IEC will identify the site(s) for routine monitoring at the time of approval of the project depending upon the reason provided by any IEC member or later after the start of the project can be for cause monitoring. This decision will be recorded in the IEC Decision Form.
• The Chairperson will identify and designate one or more IEC members or independent monitor to carry out routine monitoring of the study site.
• The reason for identifying a particular site for 'monitoring' will be provided to an IEC member. This cause could include any one or more of the following:

- Routine monitoring
- High number of protocol violations, or
- Large number of studies carried out at the study site or by the investigator, or
- Remarkable number of SAE reports, or
- High recruitment rate, or
- Non-compliance, or
- Suspicious conduct, or
- Complaints received from participants, or
- Any other cause as decided by IEC.

• After discussion at an IEC meeting, decision regarding conducting 'monitoring' will be taken. The Chairperson will identify and select one or more IEC members or independent monitor who along with IEC members will conduct monitoring of a site.

### *5.2 Before the visit*

• The IEC Chairperson will designate an IEC member or appoint an Independent monitor who along with IEC members will perform the task of monitoring. The selected member or independent monitor will be provided with an appointment letter in this regard. A copy of the appointment letter along with the agenda for monitoring will be forwarded to the Principal Investigator of the site to be monitored. The IEC members and independent monitor (if

designated) will sign a Confidentiality/ Conflict of Interest Agreement Form prior to accessing documents related to study and visiting the study site.

• The Secretariat will inform the Principal Investigator in writing about the date/time of monitoring visit and request for confirmation from the Principal Investigator or Co-investigator to be available for the monitoring visit.

• The IEC member(s)/ Independent monitor along with IEC members will:

contact the site to notify them that they will be visiting them. At that time, the monitor and the site will coordinate the time for the site evaluation visit.

review the IEC project files for the study and site profile and make appropriate notes.

be provided with relevant reference material/ documents related to the project that may have to be referred to during the study visits and collect the Site Monitoring Visit Report Form from the Secretariat.

### *5.3 During the visit*

• The IEC member/Independent monitor along with IEC members will-

- Check the log of delegation of responsibilities of study team
- Check if the site is using latest IEC approved versions of the protocol, informed consent documents, case record forms, diaries, advertisements, etc.
- Review the informed consent document to make sure that the site is using the most recent version,
- Observe the informed consent process or audio visual consent or audio consent , if possible, Review randomly selected participants files to ensure that participants are signing the correct informed consent,
- Observe laboratory and other facilities necessary for the study at the site, if possible.
- Review the project files of the study to ensure that documentation is filed appropriately.
- Review the source documents for their completeness.
- Collect views of the study participants, if possible.
- Fill the Site Monitoring Visit Report Form sign and date it.

### *5.4 After the visit*

• The IEC member/ Independent monitor will submit the completed Site Monitoring Visit Report Form *to* the IEC secretariat within *14 days* of conducting a site monitoring visit.
• The report should describe the findings of the monitoring visit. The member-secretary will present the monitoring report at the next full board IEC meeting and the concerned IEC member/ independent monitor will provide additional details/ clarifications to members, as required.
• 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:

- Continuation of the project with or without changes,
- Restrictions on enrollment,
- Recommendations for additional training,
- Recruiting additional members in the study team,
- Revising/ providing qualifications/ experience criteria for members of the study team,
- termination of the study,
- Suspension of the study, etc.

• The final decision taken at the full board IEC meeting by the Chairperson is recorded in the Site Monitoring Visit Report Form
• The Secretariat will convey the decision to the Principal Investigator in writing within 14 days of the meeting.
• The Secretariat will place the copy of the report in the protocol file.

## 6. References


1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, (Geneva 2000)- *https://www.who.int/tdr/publications/documents/ethics.pdf* (last accessed 22nd October 2020).


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2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996-*http://www.ich.org/LOB/media/MEDIA482.pdf* (last accessed 22nd October 2020).
3. National Ethical Guidelines for Biomedical and Health Research involving Human Participants, ICMR 2017


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