Title: Procedures for allowing Guest/ Observer to visit Institutional Ethics Committee or attend IEC meeting

SOP Code: SOP 05/V1

Effective Date: aa/bb/cccc

[The IEC members (author/s, reviewer/s) and Chairperson will sign and date the SOP on this first page]

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1. Purpose
The purpose of this Standard Operating Procedure (SOP) is to describe procedures to be followed by Institutional Ethics Committee (IEC) and the Guest/Observer whenever he/she visits the IEC Office or attends an IEC full board meeting. The SOP is needed to ensure adequate protection of confidentiality of information related to research studies.

2. Scope
This SOP covers the procedures for allowing guest/observer to visit the IEC Office and observe a meeting in progress.

3. Responsibility
- It is the responsibility of Member Secretary in consultation with Chairperson to decide whether a guest/observer may be allowed to visit the IEC Office or attend an IEC meeting.
- It is the responsibility of the guest/observers intending to attend an IEC meeting to read, understand, accept and sign the agreement contained in the Confidentiality form prior to visiting IEC/attending an IEC meeting.
- The Secretariat will ensure that the Confidentiality Form is duly signed and dated by the guest or observer for IEC/IEC meeting and will file it in IEC records.

4. Detailed instructions
4.1 Receiving request from guest/observer to visit IEC or attend IEC meeting
- On receiving a written or verbal request from a guest regarding visiting the IEC Office or to observe an IEC meeting, the IEC member/Member Secretary/Secretariat will obtain permission from Chairperson.
The date and time of the visit to IEC or for IEC meeting will be informed to the guest/observer preferably in writing/email.

The request letter/email will be filed in IEC records by the secretariat.

4.2 Filling up of Confidentiality Agreement Form

- Confidentiality Agreement Form (AX 01/SOP 05/V1) will be provided to the guest attendee/observer on the day of visit/at the time of meeting.
- The guest/observer will read the form carefully before visit/or before commencement of the meeting and follow it.
- He/she will fill up the details in the form.

4.3 Ask questions, if any

- If there are any doubts, the guest/observer will seek clarifications or additional information from the Secretariat. The Member Secretary will provide explanations, additional information and/or clarifications.

4.4 Signing of Confidentiality Agreement Form

- The guest/observer will sign and date the document before a member of the Secretariat.
- He/she will return the signed form to the Secretariat.
- The Secretariat will obtain the signature of the IEC Chairperson on the Confidentiality/Agreement Form.
- The secretariat will provide guest or observer for IEC a photocopy of the Confidentiality Agreement Form for their records (duly signed and dated by them and IEC Chairperson) and acknowledge the receipt of agreement by their signature.
The Secretariat will keep the original copy of the signed Agreements at the IEC office in the files entitled ‘Confidentiality Agreement file for guests/observers, Independent Consultants (IC)’.

The Secretariat will store the file in a secure cabinet with limited and named access.

4.5 Keep the Agreement in mind

The guests /observer must implement the clauses of the signed Confidentiality Agreement Form.

5. Annexures

Annexure 1  AX 01/SOP 05/V1  Confidentiality Agreement for Guest/Observer to IEC /IEC Meeting

Annexure 1: AX 01/SOP 05/V1

Confidentiality Agreement Form

For Guest / Observer Attendees to IEC/ IEC Meetings

I, ___________________________________________ (name), understand that I am being allowed to visit IEC office facility / attend the IEC meeting on __________ at _______am as a Guest. The venue of the IEC meeting will be _____________________.

I may become aware of some confidential information during my visit to IEC / during the course of the IEC meeting. Upon signing this form, I ensure to take reasonable measures to keep the information as confidential.

____________________________
Signature of the Guest

__________________________
Date
I, ____________________________________________ (name) acknowledge that I have received a copy of this Agreement signed by the IEC -Chairperson and me.

__________________________  __________________________
Signature of the Guest      Date

6. Flow chart

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<td>Informing guest/ observer about visit/ meeting date and time</td>
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<td>4.</td>
<td>Read the text carefully and thoroughly, sign the confidentiality agreement</td>
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