

	Institutional Ethics Committee Title: Procedures for allowing Guest/ Observer to visit IEC office or attend IEC meeting	SOP 05/V1 Effective from September 2019 Valid till September 2022
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5.1. 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.

5.2. Scope

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

5.3. 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/observer(s) 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.

5.4. Detailed instructions

5.4.1 Receiving request from guest/observer to visit IEC office or attend IEC meeting

- On receiving a written or verbal request the IEC Member/Member Secretary/ Secretariat will obtain permission from Chairperson.
- The date and time of the visit will be informed to the guest/ observer in writing/email.
- The request letter/email will be filed in IEC records by the secretariat.

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5.4.2 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 fill the details in the form.

5.4.3 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.

5.4.4 Signing of Confidentiality Agreement Form

- The guest /observer will sign and date the document before a member of the Secretariat.
- She/he 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 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 controlled access.

5.4.5 Keep the Agreement in mind

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

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5.5. Annexure

Annexure 1

AX 01/SOP 05/V1 - Confidentiality Agreement for Guest /Observer visiting IEC office or attending an IEC Meeting

or AX02/SOP 03/ V1 - COI

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Annexure 1: AX 01/SOP 05/V1

Confidentiality Agreement Form

For Guest / Observer visiting IEC office or attending an IEC meeting

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 confidential.

_____ Signature of the Guest	_____ Date
_____ Chairperson of IEC	_____ 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

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6. Flow chart

No.	Activity	Responsibility
1.	Receiving request from guest/ observer	IEC Secretariat/ Member/ Member Secretary
2.	Allowing a guest/ observer	Chairperson
3.	Informing guest/ observer about visit/ meeting date and time	IEC Secretariat
4.	Read the text carefully and thoroughly, sign the confidentiality agreement	Guest/observer
5.	Filing of signed confidentiality form in IEC records	IEC Secretariat