	<p><b><u>FERCI MODEL SOPs</u></b></p> <p><b><u>Procedures for allowing Guest/ Observer to visit Institutional Ethics Committee or attend IEC meeting</u></b></p>	<p><b><u>SOP 05/V1</u></b></p> <p><b><u>Effective Date: aa/bb/cccc</u></b></p>
--	--	--

**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]*

**Prepared by:**

Dr. Padmaja Marathe, FERICI Member	(Signature with Date)
------------------------------------	-----------------------

**Reviewed by:**


Dr. U. M. Thatte, FERICI Secretary	(Signature with Date)
Dr. S. K. Kamat, FERICI Treasurer	(Signature with Date)

**Approved by:**

Dr. Vasantha Muthuswamy, FERICI President	(Signature with Date)
Dr. Nandini Kumar, FERICI Vice President	(Signature with Date)

**Table of Contents:**

No.	Contents	Page No.
1	Purpose	2
2	Scope	2
3	Responsibility	2
4	Detailed Instructions	2
5	Annexures	4
6	Flowchart	5

 <p>FORUM FOR ETHICS REVIEW COMMITTEES FERCI</p>	<p style="text-align: center;"><b><u>FERCI MODEL SOPs</u></b></p> <p style="text-align: center;"><b><u>Procedures for allowing Guest/ Observer to visit Institutional Ethics Committee or attend IEC meeting</u></b></p>	<p style="text-align: center;"><b><u>SOP 05/V1</u></b></p> <p style="text-align: center;"><b><u>Effective Date: aa/bb/cccc</u></b></p>
--	--	--

## **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 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.

	<p><b><u>FERCI MODEL SOPs</u></b></p> <p><b><u>Procedures for allowing Guest/ Observer to visit Institutional Ethics Committee or attend IEC meeting</u></b></p>	<p><b><u>SOP 05/V1</u></b></p> <p><b><u>Effective Date: aa/bb/cccc</u></b></p>
--	--	--

- 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.

	<p><b><u>FERCI MODEL SOPs</u></b></p> <p><b><u>Procedures for allowing Guest/ Observer to visit Institutional Ethics Committee or attend IEC meeting</u></b></p>	<p><b><u>SOP 05/V1</u></b></p> <p><b><u>Effective Date: aa/bb/cccc</u></b></p>
--	--	--

- 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
---------------------------------	---------------

	<p><b><u>FERCI MODEL SOPs</u></b></p> <p><b><u>Procedures for allowing Guest/ Observer to visit Institutional Ethics Committee or attend IEC meeting</u></b></p>	<p><b><u>SOP 05/V1</u></b></p> <p><b><u>Effective Date: aa/bb/cccc</u></b></p>
--	--	--

<p>_____</p> <p>Chairperson of IEC</p>	<p>_____</p> <p>Date</p>
--	--------------------------

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

<p>_____</p> <p>Signature of the Guest</p>	<p>_____</p> <p>Date</p>
--	--------------------------

## 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