



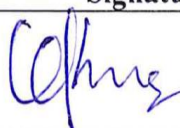
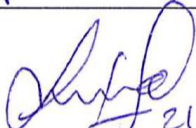
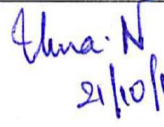
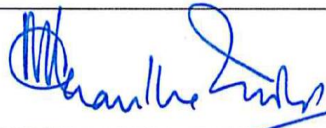




IHEC – MGMCRI SOPs
Procedures for allowing Guest/ Observer to visit
Institutional Human Ethics Committee or attend
IHEC meeting

SOP Code: SOP 05/V2
Effective from 21/10/2019

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

SOP Code: SOP 05/V2
Effective Date: 21-10-2019

SOP Constitution and Approval:

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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe procedures to be followed by Institutional Human Ethics Committee, MGMCRI and the Guest/ Observer visiting office of the IHEC, or attending IHEC 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 office of the IHEC and observe a meeting in progress.

3. Responsibility

- Member Secretary/Additional Member Secretary in consultation with Chairperson/Co-Chairperson decides on allowing a guest / observer to visit the IHEC Office or to attend IHEC meeting.
- Guests/observers intending to attend IHEC meeting should read, understand, accept and sign agreement contained in confidentiality form prior to visiting IHEC/ attending IHEC meeting.
- The Secretariat will ensure that the confidentiality form is duly signed and dated by the guest or observer for IHEC / IHEC meeting and will file it in IHEC records.

4. Detailed instructions

4.1 Receiving request from guest/observer to visit IHEC or attend IHEC meeting

- On receiving a written request from a guest regarding visiting the IHEC Office, Member Secretary/Additional Member Secretary will permit them on providing a valid explanation for the visit.
- On receiving a written request from a guest regarding observing the IHEC meeting the Member Secretary/Additional Member Secretary /Member Secretariat will obtain permission from Chairperson/Co - Chairperson.
- The date and time of the visit to IHEC or for IHEC meeting will be informed to the guest/ observer preferably in writing/email.
- The request letter/email will be filed in IHEC records by the secretariat.

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4.2 Filling up of Confidentiality Agreement Form

- Confidentiality Agreement Form (AX 01/SOP05/V2) 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/Additional 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 IHEC Chairperson on the Confidentiality / Agreement Form.
- The secretariat will provide guest or observer for IHEC a copy of the Confidentiality Agreement Form for their records (duly signed and dated by them and IHEC Chairperson) and acknowledge the receipt of agreement by their signature.
- The Secretariat will keep the original copy of the signed agreements at the IHEC 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/V2 - Confidentiality Agreement form for Guest/Observer to
IHEC /IHEC Meeting

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Annexure 1: AX 01/SOP 05/V2

Confidentiality Agreement Form for Guest/Observer Attendees to IHEC /IHEC Meeting

I, _____ (name), understand that I am being allowed to visit IHEC office facility / attend the IHEC meeting on _____ at _____ as a Guest. The venue of the IHEC meeting is _____. I may become aware of some confidential information during my visit to IHEC / during the course of the IHEC meeting. Upon signing this form, I ensure to take reasonable measures to keep the information as confidential.

Signature of the Guest:

Date:

Signature of the Chairperson (IHEC, MGMCRI):

Date:

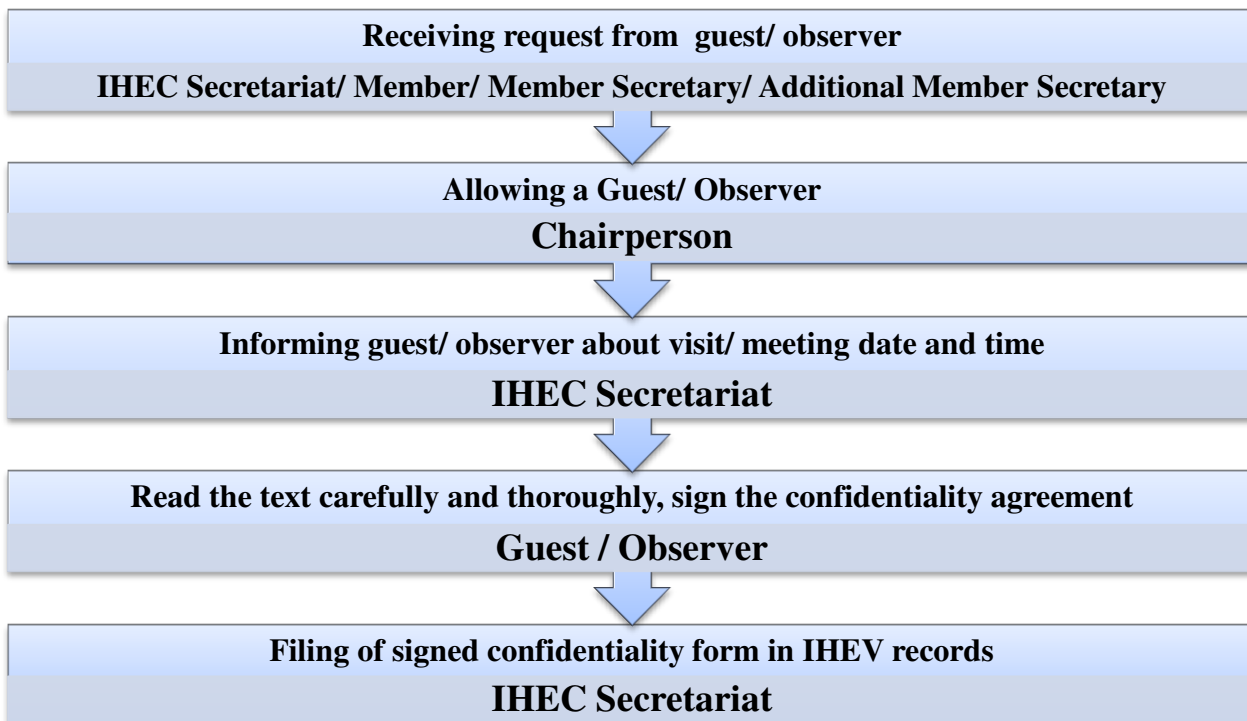
I, _____ (name) acknowledge that I have received a copy of this Agreement signed by the IHEC -Chairperson and me.

Signature of the Guest:

Date:

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6. Flow chart



7. References

- *Forum for Ethics review Committees in India (FERCI). Standard Operating Procedures of Institutional Ethics Committee (cited 5th October 2019). Available from: <http://www.ferci.org/sops/>*