



**IHEC – MGMCRI SOPs**  
**Dealing with Participant's Requests and/or**  
**Complaints to Institutional Human Ethics**  
**Committee**



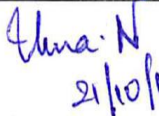

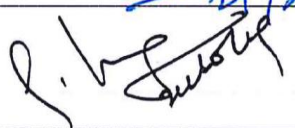
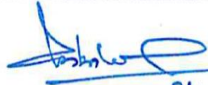


**SOP Code: SOP 17/V2**  
**Effective from 21/10/2019**

**Title: Dealing with Participant's Requests and/or Complaints to Institutional Human Ethics Committee (IHEC)**

**SOP Code: SOP 17/V2**

**Effective Date: 21-10-2019**

**SOP Constitution and Approval:**

<b>Prepared by:</b>	<b>Signature and Date:</b>
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Dr. Uma Narayanamurthy, Additional Member Secretary, IHEC	 21/10/19
<b>Reviewed by:</b>	<b>Signature and Date:</b>
Dr. Ananthakrishnan. N, IHEC Member	 21/10/19
Dr. Sivagnanam G, IHEC Co-Chairperson	 21/10/19
<b>Approved by:</b>	<b>Signature and Date:</b>
Dr. Jambulingam, P IHEC Chairperson	 21.10.19
Dr. Adithan C, Dean Research, SBV	 21/10/19
Dr. Ravishankar M, Dean, MGMCRI	 21/10



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## **1. Purpose**

The purpose of this SOP is to describe procedures for dealing with requests for information by research participants regarding their rights as a participant or to resolve their complaint/s that is/are related to their participation in research approved by the Institutional Human Ethics Committee (IHEC).

## **2. Scope**

This SOP applies to handling of requests for information/ complaints made by participants concerning the rights and well-being of the research participants participating in research studies by the IHEC.

## **3. Responsibility**

It is the responsibility of the IHEC Secretariat and Chairperson/Member Secretary/Additional Member Secretary to initiate the process of giving information asked by research participants or to address any injustice that has occurred, if any complaints are received.

## **4. Detailed instructions**

- A request, complaint or query, from a research participant will be accepted by the Secretariat and forwarded to the IHEC Member Secretary/Additional Member Secretary after entering into the request record form AX 01/SOP 17/V2.
- The Member Secretary will additionally ascertain details of the request/ complaint by examining any relevant documents and by interviewing the participant if necessary. If required, the Member Secretary/Additional Member Secretary will call for additional relevant information and documents from the Principal Investigator (PI).
- The Secretariat will inform the Chairperson about the request, query or complaint received from the research participant.
- In case of a request for additional information or clarification, the Member Secretary in consultation with the Chairperson will provide the information himself / herself or will designate one or more IHEC member(s) to provide such information.
- In case of a complaint received from a research participant:

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- The Member Secretary/Additional Member Secretary, in consultation with the Chairperson will initiate a process to address any injustice that may have occurred. Depending on the seriousness of the matter, the Chairperson will direct the Member Secretary/Additional Member Secretary to:
  - ✓ Appoint a subcommittee of two or more IHEC members for enquiry in order to resolve the matter.
  - ✓ Call an emergency meeting of two or more IHEC members for discussion or
  - ✓ Consider the matter for discussion at the next full board meeting.
- The Chairperson/Member Secretary/ designated IHEC members will assess the situation and mediate a dialogue between the research participant and PI in an attempt to resolve the matter.
- The IHEC will insist on factual details to determine gap, if any, between truth and individual perception.
- The final decision will be taken by the Member Secretary/Additional Member Secretary in consultation with the Chairperson based on the recommendation of any one of the above and it will be informed to the research participant and the PI by the Secretariat.
- The information including any action taken or follow-up and final decision will be recorded in the form AX 01/SOP 17/V2 and the form is signed and dated.
- The IHEC members will be informed about the action taken and the outcomes in the forthcoming IHEC meeting (in case of requests/ complaints not discussed in full board meeting) and minuted.
- The Secretariat will place all documents in the relevant study file.

## 5. Annexure

Annexure 1: AX 01/SOP 17/V2 – Request/ Complaint Form



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*Annexure 1: AX 01/SOP 17/V2  
Request / Complaint Form*

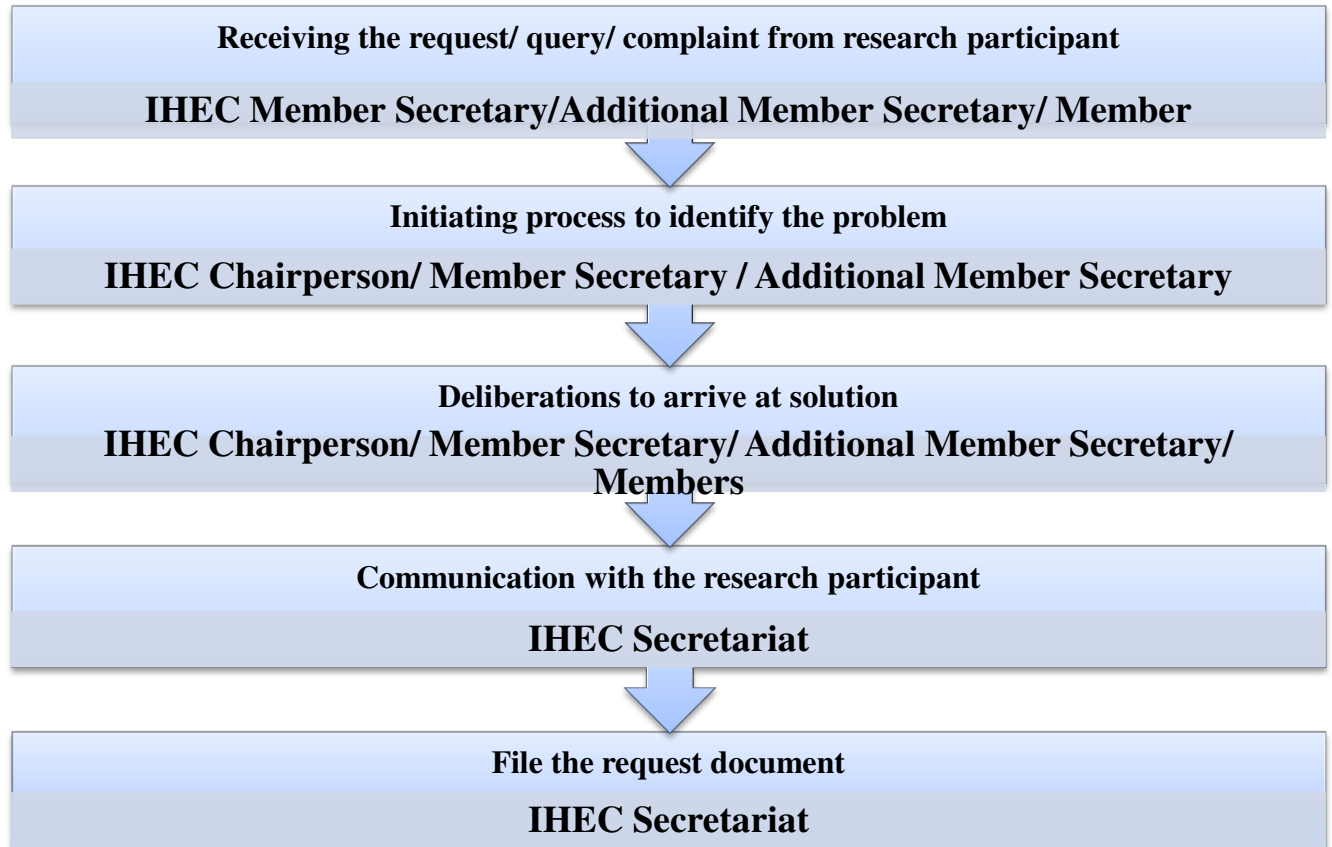
<b>Date:</b>	
<b>Received by:</b>	
<b>Request / Complaint Received through:</b>	<input type="checkbox"/> Telephone No.: _____ <input type="checkbox"/> Fax No.: _____ <input type="checkbox"/> Letter / Date _____ <input type="checkbox"/> E-mail / Date: _____ <input type="checkbox"/> Walk-in / Date / Time: _____ <input type="checkbox"/> Other, specify _____
<b>Participant’s Name:</b>	
<b>Contact details Address &amp; Phone:</b>	
<b>IHEC Project No.:</b>	
<b>Title of the Project</b>	
<b>Starting date of participation:</b>	
<b>Information requested/ complaint/query</b>	_____ _____
<b>Action taken:</b>	_____ _____
<b>Reviewed by:</b>	_____ _____
<b>Final Decision</b>	_____ _____
<b>Date of IHEC meeting (if applicable)</b>	_____

\_\_\_\_\_  
Name & Signature of Member Secretary

\_\_\_\_\_  
Date



## 6. Flowchart



## 7. References

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