

	<p style="text-align: center;">Institutional Ethics Committee</p> <p style="text-align: center;">Title: Dealing with Participants' Requests and/or Complaints</p>	<p style="text-align: center;">SOP 17/V1 Effective from September 2019 Valid till September 2022</p>
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17.1. 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 Ethics Committee (IEC).

17.2. Scope

This SOP applies to the 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 IEC.

17.3. Responsibility

It is the responsibility of the IEC Secretariat and Chairperson/ 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.

17.4 Detailed instructions

- A request, complaint or query, from a research participant will be accepted by the Secretariat and forwarded to the IEC Member Secretary after entering into the request record form.
- The Member Secretary may receive a request, complaint or query directly from the participant. She/he will record it in the request record form and notify the Secretariat.
- 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 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 herself/himself or will designate one or more IEC member(s) to provide such information.
- In case of a complaint received from a research participant:

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- The 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 to:
 - Appoint a subcommittee of two or more IEC members for enquiry in order to resolve the matter.
 - Call an emergency meeting of two or more IEC members for discussion or
 - Consider the matter for discussion at the next full committee meeting
- The Chairperson/ Member Secretary/ designated IEC members will assess the situation and mediate a dialogue between the research participant and PI in an attempt to resolve the matter.
- The IEC will insist on factual details to determine gap, if any, between truth and individual perception.
- Opportunity will be given to complainant and the accused to make submissions
- If the matter is serious it will be brought to the attention of the Head of the institution who in consultation with the Chairperson will make a decision. For this the Chairperson will provide the following:
 - a. the complaint;
 - b. material reviewed in the Chairperson's investigation;
 - c. the results of the Chairperson's investigation; and
 - d. Any other relevant documentation.
- If the Head of the institution feels that the matter needs further investigation she/he could set up a panel for that purpose.
- The possible procedures include the following:
 - a. Noting on the file about the occurrence of the matter;
 - b. Requirement for amendments to the project, including increased monitoring by the IEC;
 - c. Suspension of the project;
 - d. Termination of the project; or
 - e. Other action to resolve the complaint.

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- If the complainant is not satisfied with the outcome of the Chairperson's investigation, then he/she can refer the complaint to the Dean or his/her nominee, or request that the Chairperson do so. The final decision will be taken based on the recommendation of any one of the above by the Member Secretary in consultation with the Chairperson 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 and signed with date.
- The IEC members will be informed about the action taken and the outcomes in the forthcoming IEC meeting and minuted.
- The Secretariat will place all documents in the relevant study file.

17.5 Annexure

Annexure 1 AXO1/SOP 17/V1- Request/ Complaint Form

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Annexure 1: AX 01/SOP 17/V1

Request / Complaint Form

Date:	
Received by :	
Request/ Complaint received through:	<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 _____
Participant's Name:	
Contact details Address & Phone:	
IEC Project no.	
Title of the Project	
Starting date of participation :	
Information requested/ complaint/query	_____ _____ _____
Action taken:	_____ _____

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Reviewed by	_____
Final Decision	_____
Date of IEC meeting (if applicable)	_____

Name & Signature of Member Secretary

Date

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17.6 Flowchart

No.	Activity	Responsibility
1.	Receiving the request/ query/complaint from research participant	IEC Member Secretary/ Member
3.	Initiating process to identify the problem	IEC Chairperson/ Member Secretary
4.	Deliberations to arrive at solution	IEC Chairperson/ Member Secretary/ Members
5.	Communication with the research participant	IEC Secretariat
6.	File the request document	IEC Secretariat