

Title: Responding to Research Participant's Request or Complaint

SOP Code: SOP 21/V1 dated 18th February 2017

Table of Contents:

No.	Contents	Page No.
1	Purpose	2
2	Scope	2
3	Responsibility	2
4	Flow Chart	2
5	Detailed Instructions	2
6	Filing the request documents	4
7	References	4
8	Annexure	4

1. Purpose

The Institutional Ethics Committee (IEC) considers protection of the rights and welfare of the human subjects participating in a clinical investigation/ research approved by it, as its primary responsibility.

The purpose of this Standard Operating Procedure (SOP) is to provide guidelines for dealing with requests by research participants/ patients regarding their rights as a participant or to resolve their complaint(s) that is/ are related to their participation in research/ trial approved by IEC.

2. Scope:

This SOP applies to all requests/ complaints concerning the rights and well-being of the research participants participating in studies approved by the IEC.

3. Responsibility:

It is the responsibility of the IEC Secretariat for providing required information to the research participants in case of queries received from research participants.

It is the responsibility of the Chairperson to initiate a process to give information to the participants or to identify and address any injustice that has occurred if complaints are received from research participants.

4. Flow chart

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

5. Detailed instructions:

- After receiving a request, complaint or query, the IEC member or administrative staff will record it in the request record form AX 01/SOP 21/V1. The IEC member will forward the request to the Secretariat.

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- The Secretary will ascertain if the concerned individual has been approached to participate in the study or is already participating in the study based on documents available with. If required, the IEC will call for relevant information and documents from the Investigator, as required
 - 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 Chairperson will decide to provide the information himself / herself or will designate one or more IEC member to provide such information. The Secretariat will make all documents relevant to the request, available to the Chairperson/ designated member.
 - In case of complaint received from a research participant, the Chairperson initiates a process to identify and address any injustice that may have occurred. The Chairperson will direct the Member Secretary to:
 - Consider the matter for discussion at the next full board meeting or call an emergency meeting of two or more IEC members for discussion or appoint a subcommittee of two or more IEC members for enquiry in order to resolve the matter.
 - The Chairperson/ Member Secretary/ designated IEC members will assess the situation and mediate a dialogue between the research participant and the investigator in an attempt to resolve the matter.
 - The IEC will insist on factual details to determine gap, if any, between truth and individual perception.
 - The final decision will be taken by the Chairperson based on any one or a combination of processes listed below:
 - a) Discussions at the Full-Board meeting
 - b) Discussions at the meeting of selected/ designated IEC members
 - c) Report provided by the subcommittee appointed by the Chairperson
 - The final decision will be informed to the research participant by the Secretariat.
 - The information including any action taken or follow-up will be recorded in the form AX 01/SOP 21/V1 and the form is signed and dated.
 - The IEC members are informed about the action taken and the outcomes in the forthcoming IEC meeting.

6. Filing the request document

The Secretariat staff/ Secretary will place the request record form in the relevant study file.

7. Reference

Kathleen J. Motil, Janet Allen and Addison Taylor, "When a Research Subject Calls with a Complaint, What Will the Institutional Ethics Committee do?" *IEC: Ethics and Human Research* 26, no.1 (January –February 2004):9-13

8. Annexure

Annexure 1 *AX 01/SOP 21/V1* Request Record Form

Annexure 1

AX 01/SOP 21/V1

Request Record Form

Date	
Received by :	
Request received through:	<input type="checkbox"/> Telephone call 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 Address: Phone:	

Title of the Participating Study	
Starting date of participation :	
Information requested/ complaint/query	<hr/> <hr/>
Action taken:	<hr/> <hr/> <hr/>
Outcome:	<hr/> <hr/>

Signature of the IEC Chairperson

Date _____