

Standard Operating Procedures of Institutional Ethics Committee

ICMR – NIRRH Ethics Committee for Human Studies

Title: Response to Research Participant`s Requests/ queries/complaints

SOP Code: 20/V1.3

Dated: 8th November 2024

Page Nos: 238 to 243

20.1. Purpose:

Since the ICMR-NIRRH Ethics Committee for Human Studies considers protection of the rights and welfare of the human participants participating in a clinical investigation/research approved by the IEC as its primary responsibility, Informed Consent documents reviewed by the IEC may routinely contain the statement, “Questions regarding the rights of a participant/patient may be addressed to the Member Secretary with the ICMR-NIRRH Ethics Committee for Human Studies *address and/or phone number*. On some occasions, the first contact with the participant/patient would be the IEC Secretariat.

This procedure provides guidelines for dealing with and accommodating requests by participants/patients regarding their rights as a participant in any approved research study.

20.2. Scope

This SOP applies to all responses to requests from participant concerning their rights and well-being while participating in studies approved by the IEC.

20.3. Responsibility

The Institute’s policy designates the Member Secretary of the IEC as the person responsible for communicating with participants/patients regarding their rights as study participants. Delegation of this responsibility to another IEC member is acceptable as long as the delegation is documented (in writing). Delegation to non-IEC members is not permitted.

20.4. Flow chart

Sr. No.	Activity	Responsibility
1	Receive the request	IEC Member Secretary / Secretariat
2	Take action	IEC Member Secretary, Chairperson and IEC
3	File the request document	IEC Secretariat

20.5. Detailed instructions

20.5.1 Receive the request

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 Participant’s Request/ Complaint Record Form (AX 01/ SOP17/V1.3)

The Member Secretary/secretariat may receive a request, complaint or query directly from the participant. He/she will record it in the Request/complaint record form AX 01/SOP 17/V1.3 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.

- a. Communicate with the IEC about study participant rights for instruction (if required).
- b. Refer the inquiry to the IEC Chairperson in writing (if required).
- c. Staff of the institute may provide assistance in contacting the Member Secretary, but will not provide comments/opinions about the inquiry.

20.5.2 Take Action

In case of a request for additional information or clarification, the Member Secretary in consultation with the Chairperson will provide the information herself/himself.

In case of a complaint received from a research participant, 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:

- a. Appoint a subcommittee of two or more IEC members for enquiry in order to resolve the matter or
- b. Call an emergency meeting of two or more IEC members for discussion or
- c. Consider the matter for discussion at the next full board meeting.
- d. The Member Secretary will assess the situation and mediate a dialogue between the research participant and PI in an attempt to resolve the matter, within a period of one week.
- e. The IEC will insist on factual details to determine gap, if any, between truth and individual perception.
- f. The final decision will be taken by the 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.
- g. The information including any action taken or follow-up and final decision will be recorded in the form AF/01/20/V1.3 see ANNEX 1 and the form is signed and dated.
- h. The IEC members will be informed about the action taken and the outcomes in the forthcoming IEC meeting (in case of requests/ complaints not discussed in full board meeting) and will be minuted.
- i. The head of the institution will be apprised about the action taken by the Chairperson if the matter is of serious nature.
- j. The complainant will be given a copy of the decision taken.

- k. If the complainant is not satisfied with the decision, she/he can appeal to the Head of the institution who in consultation with the Chairperson will take action and communicate it to the complainant.
- l. The Secretariat will place all documents in the relevant study file.

20.5.3 File the request document

- a. Keep the record form in the “response” file.
- b. Keep a copy in the study file.
- c. Store the file in the appropriately labeled shelf.

20.6. ANNEX

ANNEX 1	AF/01/20/V1.3	Request Record Form
ANNEX 2	AF/02/20/V1.3	Document History

Request Record Form

Date Received:	
Received by :	
Request by :	<input type="checkbox"/> Telephone call No..... <input type="checkbox"/> Fax No..... <input type="checkbox"/> Mailed 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:	
What is the request?	
Action taken:	
Outcome:	

Signature of Member Secretary

Signature of the Chairperson

Document History

Author	Version	Date	Description of the Change
Dr. Ragini Kulkarni	Version 1.0	3 rd May 2013	First approved copy
Dr. Ragini Kulkarni	Version 1.1	24 th September 2014	SOP no. changed from 21 to 17
Dr. Beena Joshi	Version 1.2	3 rd May 2019	SOP no. changed from 17 to 20 Document History added
Dr. Vikrant Bhor	Version 1.3	8 th November 2024	Title of the SOP is modified All bullets are numbered. <ul style="list-style-type: none"> ● 20.5.1 Receive the request is modified ● 20.5.1 Take Action is modified