


SOP 17	 Sri MANAKULA VINAYAGAR Medical college and Hospital	
SOP code: SOP 17/ V3	Dealing with Participants' Requests and/or Complaints to Institutional Ethics Committee	Effective Date: 31.12.2021

Title: Dealing with participants requests and/or Complaints to Institutional Ethics Committee

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 (EC).

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 EC.

3. Responsibility

It is the responsibility of the EC Secretariat and Chairman/ 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 EC Member Secretary after entering into the request record form *AX 01/SOP 17/V3*.
- The Member Secretary may receive a request, complaint or query directly from the participant. He/she will record it in the request record form *AX 01/SOP 17/V3* 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).

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- The Secretariat will inform the Chairman 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 Chairman will provide the information himself / herself or will designate one or more EC member(s) to provide such information.
- In case of a complaint received from a research participant:
 - The Member Secretary, in consultation with the Chairman will initiate a process to address any injustice that may have occurred. Depending on the seriousness of the matter, the Chairman will direct the Member Secretary to:
 - Appoint a subcommittee of two or more EC members for enquiry in order to resolve the matter.
 - Call an emergency meeting of two or more EC members for discussion or
 - Consider the matter for discussion at the next full board meeting
 - The Chairman/ Member Secretary/ designated EC members will assess the situation and mediate a dialogue between the research participant and PI in an attempt to resolve the matter.
 - The EC 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 in consultation with the Chairman 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/V3* and the form is signed and dated.
- The EC members will be informed about the action taken and the outcomes in the forthcoming EC meeting (in case of requests/ complaints not discussed in full board meeting) and record in minutes of the meeting.
- The Secretariat will place all documents in the relevant study file.

5. Reference to other applicable SOP: NIL

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6. Annexure

Annexure 1 AX 01/SOP 17/V3 – Request/ Complaint Form

Annexure 1: AX 01/SOP 17/V3

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:	
EC Project no.	

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Title of the Project	
Starting date of participation :	
Information requested/ complaint/query	
Action taken:	
Reviewed by	
Final Decision	
Date of EC meeting (if applicable)	

Name & Signature of Member Secretary

Date

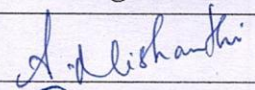
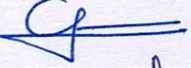
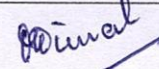
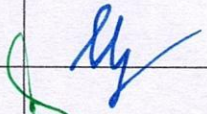
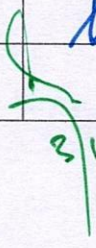
7. Flowchart

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

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8. References

1. Forum for Ethics review Committees in India (FERCI). Standard Operating Procedures of Institutional Ethics Committee (cited 22nd October 2018). Available from: [http:// www.ferci.org/sops/](http://www.ferci.org/sops/)
2. Ministry of Health and Family Welfare. New Drugs and Clinical Trials Rules, 2019. Available from: [https://cdsco.gov.in/opencms/export/sites/CDSCO WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf](https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf)

	Name	Designation	Signature
Prepared	Dr. Nishanthi. A	Member	
	Dr. Ganesh. R	Member	
Reviewed	Dr. Vimal. M	Member Secretary	
Approved	Dr. T. Thiagarajan	Chairman	
Issued	Dr. R. N. Kagne	Dean	

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3. References

1. Form for Ethics review Committee in India (FERCI) - Standard Operating Procedures of Institutional Ethics Committee (dated 22nd October 2018). Available from: <http://www.erc.org.in/>
2. Ministry of Health and Family Welfare / New Drugs and Clinical Trials Rules, 2019. Available from: https://cdsco.gov.in/notifications/notifications/CDSO_WDR-PDR-2019.pdf

Signature	Designation	Name	
	Member	Dr. Nishant A.	Prepared
	Member	Dr. Ganesh R.	
	Member Secretary	Dr. Manish M.	Reviewed
	Chairman	Dr. T. Thiruganjan	Approved
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