

TAGORE MEDICAL COLLEGE AND HOSPITAL 	Procedure for Research Participant's Request or Complaint		Institutional Ethics Committee
			TMCH/IEC/SOP/21
Amendment No: 00	Issue No: 01	Issue Date: 02/11/2020	PAGE 1 OF 5

Procedure for Research Participant's Request or Complaint

For Institutional Ethics Committee

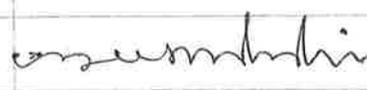
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Issue No : 01
Issue Date : 02.11.2020
Copy No : 01/10
**Copy Holder Name
and Designation** : Dr. R. Geetha, Member Secretary, IEC

Prepared By	Reviewed By	Approved By
		
Dr. R. Geetha Member secretary of IEC	Dr. I. Kannan Member of IEC	Dr. S. Seethalakshmi Chairperson of IEC

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1. Purpose

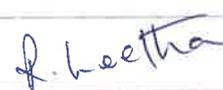
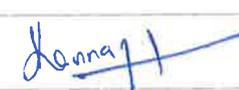
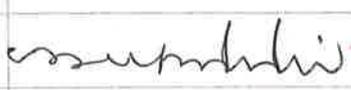
The purpose of this SOP is to describe procedures for dealing with requests for information by research participants regarding their rights as a participant or to resolve their complaint/s that is/are related to their participation in research approved by the Institutional Ethics Committee (IEC).

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 IEC.

3. Responsibility

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

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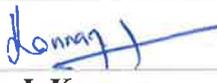
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4. Flow chart

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

5. 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 Participant's Request/ Complaint Record Form.
- The Member Secretary may receive a request, complaint or query directly from the participant. He/she 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 himself / herself or will designate one or more IEC member(s) to provide such information.

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- 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

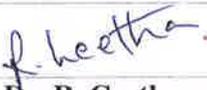
Member Secretary to:

- o Appoint a subcommittee of two or more IEC members for enquiry in order to resolve the matter.
- o Call an emergency meeting of two or more IEC members for discussion or
- o Consider the matter for discussion at the next full board meeting
- o The 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.
- o 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 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 and the form is signed and dated.
- 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 minutes.
- The Secretariat will place all documents in the relevant study file.

6. References

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, (Geneva 2000)-
<https://www.who.int/tdr/publications/documents/ethics.pdf> (last accessed 22nd October 2020).

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2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996-<http://www.ich.org/LOB/media/MEDIA482.pdf> (last accessed 22nd October 2020).
3. National Ethical Guidelines for Biomedical and Health Research involving Human Participants, ICMR 2017.

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