Title: Dealing with Participants' Requests and/or Complaints to Institutional Ethics Committee

SOP Code: KIMS/SOP-18/V2

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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 (IHEC).

2.

3. 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 IHEC.

4. Responsibility

It is the responsibility of the IHEC 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.

5. Detailed instructions

- A request, complaint or query, from a research participant will be accepted by the Secretariat and forwarded to the IHEC Member Secretary after entering into the request record form *AXN - 01*/KIMS*/SOP-18/V2*.
- The Member Secretary may receive a request, complaint or query directly from the participant. He/she will record it in the request record form AXN-01/KIMS/SOP-18/V2 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 IHEC member(s) to provide such information.

- 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:
        - Appoint a subcommittee of two or more IHEC members for enquiry in order to resolve the matter.
        - Call an emergency meeting of two or more IHEC members for discussion or
        - Consider the matter for discussion at the next full board meeting
    - The Chairperson/ Member Secretary/ designated IHEC members will assess the situation and mediate a dialogue between the research participant and PI in an attempt to resolve the matter.
    - The IHEC 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 *AXN- 01*/KIMS*/SOP 17/V2* and the form is signed and dated.
- The IHEC members will be informed about the action taken and the outcomes in the forthcoming IHEC meeting (in case of requests/ complaints not discussed in full board meeting) and minuted.
- The Secretariat will place all documents in the relevant study file.
- Patient rights and responsibilities will be displayed in the patient recruitment area.

6. Glossary

Patient rights:

Rights as a Research Participant

- To have enough time to decide whether or not to be in the research study, and to make that decision without any pressure from the people who are conducting the research.
- To refuse to be in the study, or to stop participating at any time after you have joined the study. If you decide to stop participating in the study, you have a right to continue, necessary standard medical treatment.

- To be told what the study is trying to find out, what will happen to you, what drug/device will be used in the study, and what you will be asked to do if you are a participant in the study.
- To be told about the reasonable foreseeable risks of being in the study.
- To be told about the possible benefits of being in the study.
- To be told whether there are any costs associated with being a participant and whether you will be compensated for participating in the study.
- To be told who will have access to information collected about you and how your confidentiality will be protected.
- To be told whom to contact with questions about the research, about research-related injury, and about your rights as a research subject.
- If the study involves treatment or therapy:
    - to be told about treatment choices you have other than the treatment for participants in the study.
    - to be told where treatment is available if you have a research-related injury, and who will pay for treatment for any study related injury treatment.
- To receive a copy of the consent form that you will sign.
- To ask any questions you may have.

Responsibilities as a Research Participant

- Completely read the consent form and ask the Principal Investigator (PI; the person in charge of the study) any questions you may have. You should understand what will happen to you during the study before you agree to participate.
- Know the dates when your study participation starts and ends.
- Carefully weigh the possible benefits (if any) and risks of being in the study.
- Talk to the Principal Investigator if you want to stop being part of the research study.
- Contact the PI and/or the KIMS Institutional Review Board (IRB) with complaints or concerns about your participation in the study.
- Report immediately to the PI immediately any and all problems you may be having with the study drug/procedure/device.
- Fulfil the responsibilities of participation as described in the consent form unless you are stopping your participation in the study.
- Tell the PI or the person you are working with in the study on receipt of compensation you were promised for participating in the study.
- Ask for the results of the study, if you want them.
- Keep a copy of the signed consent form for your records.

7. Annexure

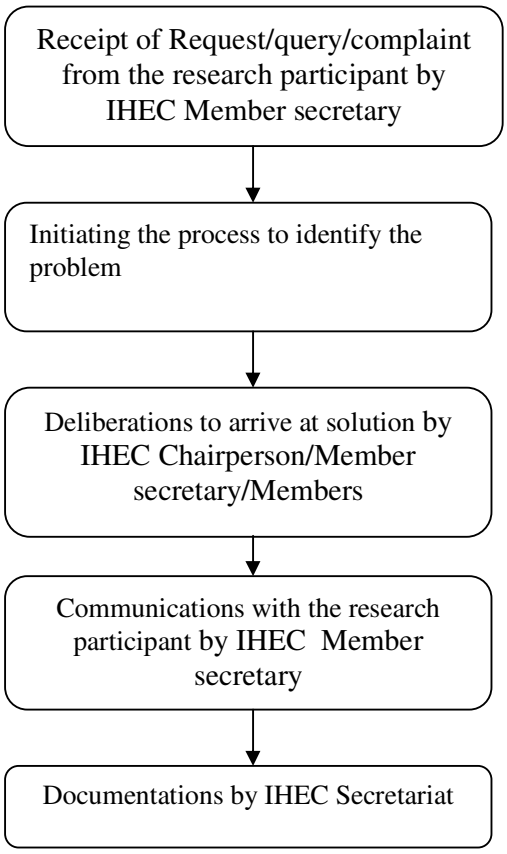
Annexure 1 *AXN- 01*/KIMS*/SOP 17/V2* – Request/ Complaint Form

Annexure 1: AXN- 01/KIMS*/SOP 17/V2 Request / Complaint Form*

Date:	
Received by :	
Request/ Complaint received through:	❑ Telephone No.
	❑ FAXN- No.
	❑ Letter / Date
	❑ E-mail / Date
	❑ Walk-in / Date / Time
	❑ Other, specify _____
Participant's Name:	
Contact details Address & Phone:	
IHEC Project no.	
Title of the Project	
Starting date of participation :	
Information requested/ complaint/query	_____ _____ _____ _____
Action taken:	_____
Reviewed by	_____
Final Decision	_____
Date of IHEC meeting (if applicable)	_____

Name & Signature of Member Secretary _____ **Date** _____

8. FLOW CHART


Receipt of Request/query/complaint from the research participant by IHEC Member secretary
Initiating the process to identify the problem
Deliberations to arrive at solution by IHEC Chairperson/Member secretary/Members
Communications with the research participant by IHEC Member secretary
Documentations by IHEC Secretariat