

Institutional Review Board, Tata Memorial Centre (IRB,TMC)

**Title: Dealing with participants/patients requests and
 complaints**

SOP Code: SOP 16/V1 Date : 05/09/2012 Pages: 1 to 5

16.1 Purpose

The IRB considers protection of the rights and welfare of the human subjects participating in a clinical research approved by the IRB as its primary responsibility. Informed Consent documents reviewed by the IRB inform the study participant that queries regarding their rights as a participant in the study may be addressed to the IRB, Member secretary, and the IRB address and phone number are provided.

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

16.2 Scope

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

16.3 Responsibility

It is the responsibility of the IRB Member Secretary to provide the required information to the research participants/ research participant's representatives/patient, in the case of queries received.

It is the responsibility of the Member Secretary/Chairperson to initiate a process of giving information to the participants or identifying and addressing any injustice that has occurred, if complaints are received from research participants.

16.4 Detailed instructions

When the IRB member/ administrative staff receive an inquiry or request from a research participant/ research participant's representatives/patient:

- The request and information will be recorded in the request record form (Form AX1- V1/SOP 16/V1)
- The Member Secretary will inform the Chairperson about the query/complaint received.
- The Chairperson / Members designated by the Chairperson will provide the information required by the research participant.
- In case of a complaint received from a research participant, the Chairperson will initiate 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 a full board meeting or to call an emergency meeting of 2 or more IRB members for discussion or to appoint a subcommittee of 2 or more IRB members for enquiry in order to resolve the matter.
- The Chairperson/ Member Secretary/ designated IRB members will assess the

situation and will mediate a dialogue between the research participant and the investigator in an attempt to resolve the matter.

- The IRB will insist on factual details to determine the reality between the truth and individual perception.
- 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 AX1- V1/SOP 16/V1 and the form will be signed and dated.
- The IRB members will be informed about the action taken and the outcome in the forthcoming IRB meeting.

16.5 Filing the request document

- The record form will be filed in the “response” file by the Member Secretary / Administrative staff.
- A copy of the same will be kept in the study file.
- The file will be stored in a secure place.

Reference

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| <ol style="list-style-type: none">1. Kathleen J. Motil, Janet Allen and Addison Taylor, “When a Research Subject Calls with a Complaint, What Will the Institutional Review Board do?” <i>IRB: Ethics and Human Research</i> 26, no.1(January –February 2004):9-13 |
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AX1- V1/SOP 16/V1

Request Record Form	
Date Received:	
Received by :	
Request from :	<div><input type="checkbox"/> Telephone call No.....</div> <div><input type="checkbox"/> Fax No.....</div> <div><input type="checkbox"/> Letter / Date.....</div> <div><input type="checkbox"/> E-mail / Date.....</div> <div><input type="checkbox"/> Walk-in / Date / Time.....</div> <div><input type="checkbox"/> Other, specify</div>
Participant's Name:	
Contact Address:	
Phone:	
Title of the Study :	
Starting date of participation :	
Request:	
Action taken:	
Outcome:	

Name of the Chairperson/ Member Secretary- -----

Signature of the Chairperson/ Member Secretary ----- Date- -----

Flow Chart

