Institutional Review Board
Malabar Cancer Centre (IRB, MCC)

Title: Dealing with patients/ study participants Requests or Complaints

Edited By : SOPs Development Team, Malabar Cancer Centre

Approved By

Chairperson **Member Secretary**

(Institutional Ethics Committee)

SOP 14/VER1 ***Pages: 1 to 6***

14.1 PURPOSES

The Institutional Review Board of the Malabar Cancer Centre takes care the protection of the rights and welfare of the human subjects participating in a clinical research approved by the committees under IRB, MCC, as its foremost responsibility. Informed Consent documents reviewed by the IEC inform the study participant that queries regarding their rights as a participant in the study may be addressed to the Member-Secretary, IEC and the IRB address and important phone numbers/ e-mail IDs are provided.

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

14.2 SCOPE

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

14.3 RESPONSIBILITY

It is the responsibility of the Member-Secretary, IEC, through a *Clinical Research Coordinator* (*CRC*) / *Clinical Research Manager* (*CRM*) or through a *Clinical Research Nurse (CRN)* 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 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.

14.4 DETAILED INSTRUCTIONS

When IRB member/ CRC/Research Nurse/Investigator/ 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 *ANX1-VER1/SOP 14/VER1*)
- The Member-Secretary, IEC will inform the Chairperson, IEC about the query/complaint received.
- The Member-Secretary / 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 Member-Secretary, IRB-IEC will initiate a process to identify and address any injustice that may have occurred.
- The Member-Secretary will consider the matter for discussion at a full board meeting or to call an emergency meeting of 2 or more IEC members for discussion or to appoint a subcommittee of 2 or more SRC members for enquiry in order to resolve the matter on an urgent basis.

- The Chairperson/ Member Secretary/ designated IEC 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 office of IRB, MCC.
- The information including any action taken or follow-up will be recorded in the form *ANX1- VER1/SOP 14/VER1* and the form will be signed and dated.
- The IRB members will be informed about the action taken and the outcome in the forthcoming SRC & IEC meetings.

14.5 REQUEST DOCUMENT FILLING UP

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.

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Reference

1. Kathleen J. Motil, Janet Allen and Addison Taylor, "When a Research Subject Calls with a Complaint, What Will the Institutional Review Board do?" *IRB: Ethics and Human Research* 26, no.1(January –February 2004):pp 9-13

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GLOSSARY

***Clinical Research Coordinator (CRC)*:** The Clinical Research Coordinator (CRC) is a specialized research professional working with and under the direction of the clinical Principal Investigator (PI). While the Principal Investigator is primarily responsible for the overall design, conduct, and management of the clinical trial, the CRC supports, facilitates and coordinates the daily clinical trial activities and plays a critical role in the conduct of the study. By performing these duties, the CRC works with the PI, department, sponsor, and institution to support and provide guidance on the administration of the compliance, financial, personnel and other related aspects of the clinical study.

The clinical research coordinator reports primarily to the Principal Investigator with associated responsibilities to the department head, division administrator or program administrator.

***Clinical Research Manager (CRM)*:** A Clinical Research Manager (CRM) for a study assumes overall responsibility for the preparation of protocols and Case Report Forms, finalization of monitoring and data management options (either in-house or contracted to a Contract Research Organization), Ethics committee approval, development of recruitment strategies to increase patient randomization into the trial, the provision of clinical trial materials, and management of the trial. A CRM coordinates the smooth monitoring of trials by identifying and managing qualified staff, establishing audit procedures and ensuring that cleaned data is entered into the database in a timely fashion.

***Clinical Research Nurse (CRN)*:** A Clinical Research Nurse works in a study team to assist team member in research projects. To coordinate the evaluation of subjects eligible for enrolment and to work with nurses, doctors and sponsoring agencies and their delegates regarding matters pertaining to the studies; coordinates with PI regarding giving doses of medicines/study drugs. Specifically to promote, coordinate, assist in study subject enrolment, and complete monitoring documentation and its database entry.

ANX1-VER1/SOP01/SOP1

Study Participant Request/ Complaint Record Form
Institutional Review Board (IRB)
Malabar Cancer Centre (MCC), Thalassery- 670103
India

Date of Receive: **Received By:**	
Request from:	* Telephone Call No. & Date:…… * Fax No. & Date : ……. * Letter & Date :……. * E-mail / Date :…….. * Walk-in/Date/Time :…… * Other, please specify:……..

Participant's Name :

Contact Address :

Contact No. :

Title of the Study/ PI Name :

Starting date of participation:

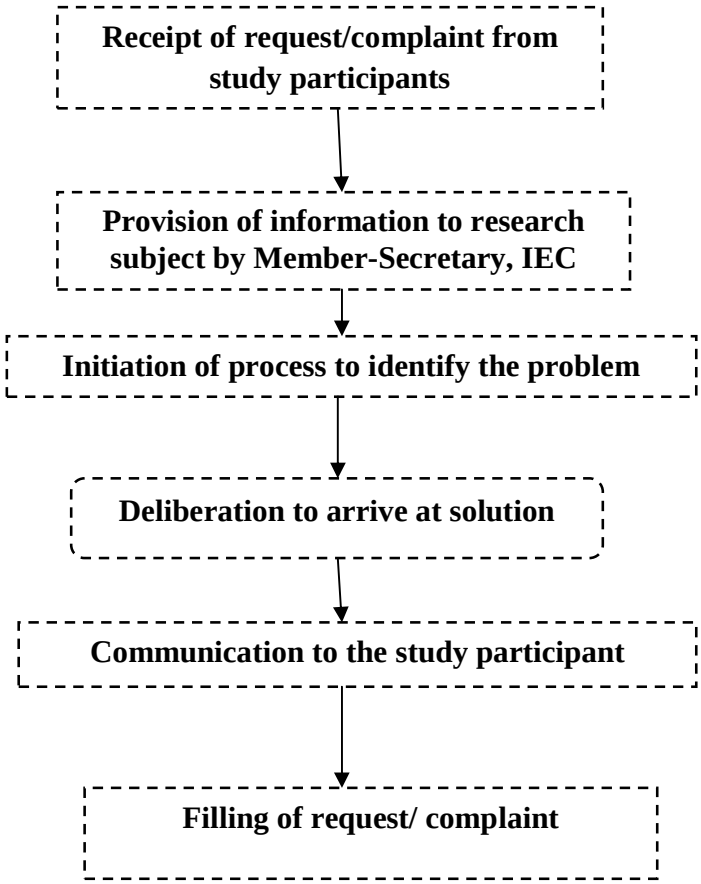
Request :

Action Taken :

Outcome :

……. …….
Name & Signature of the Member-Secretary, IEC, MCC Date

FLOW CHART


Receipt of request/complaint from study participants
Provision of information to research subject by Member-Secretary, IEC
Initiation of process to identify the problem
Deliberation to arrive at solution
Communication to the study participant
Filling of request/ complaint