**Statement of Policy**

Queries and complaints from clients, patients, or research participants shall be attended to promptly and appropriately while exercising due diligence. The nature of queries shall determine whether they can be answered by the REC staff or referred to the primary reviewers of the specific protocol. All complaints shall be referred to the Chair who shall determine the level of risk involved. Complaints of minimal risk shall be referred to the primary reviewers for resolution. Complaints of more than minimal risk shall be taken up in a special meeting within 48 hours for deliberation by the committee en banc with the primary reviewers leading the discussion.

**Objectives of the SOP**

Managing queries and complaints aims to promote public trust and confidence in the institution, especially in the REC and to ensure that the rights and well-being of participants are attended to.

**Scope/Applicability**

This SOP is limited to queries and complaints of research participants, or their families, in studies that have been issued an ethical approval by the REC. This SOP begins with the receipt, logging, and acknowledgement of queries and complaints and ends with the logging of the response and inclusion in the agenda of the REC meeting.

**Flowchart**

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| **ACTIVITY** | **RESPONSIBILITY** | **TIMELINE** |
| Step 1: Receipt, logging, and acknowledgement of queries and complaints (SOP on Managing REC Incoming and Outgoing Communications) | REC Staff | 1 day |
| Step 2: Referral of query or complaint to competent authority.2.1 Referral of protocol-related query to primary reviewers.2.2. Referral of all complaints to the REC Chair | REC Staff | 1-2 days |
| Step 3: Formulation of response3.1. Protocol-related queries3.2. Minimal-risk complaints3.3. More than minimal risk complaints : en-banc committee | Primary ReviewersPrimary ReviewersChair and REC members | 1-5 days |
| Step 4: Communication of response (SOP on Communicating REC Decisions (SOP# 21)) | Member SecretaryChair | 1-2 days |
| Step 5: Logging of the response (SOP on Managing REC Incoming and Outgoing Communications (SOP# 22)) and inclusion in the agenda of the REC meeting (SOP on Preparing the Meeting Agenda (SOP# 18)) | REC Staff | 1-2 days |

**Description of Procedures**

Step 1 - Receipt, logging, and acknowledgement of queries and complaints: Date, time, name of concerned party, specific study, nature of query or complaint.

Step 2 - Referral of query or complaint to competent authority:

2.1. The staff refers queries related to specific protocols approved by the REC to the primary reviewers.

2.2. On the other hand, the staff refers all complaints to the REC chair who determines the level of risk effected by the issue.

2.2.1. Minimal risk complaints are referred to the primary reviewers of the concerned protocol.

2.2.2. Complaints that involve more than minimal risk are referred to the Committee through a special meeting that shall be called within 48 hours. The staff notifies the concerned primary reviewers that they will lead the discussion such that pertinent materials are provided to them as reference.

Step 3 - Formulation of response:

3.1. For queries, the primary reviewers accomplish Form 032 on queries, notifications, and complaints.

3.2. For minimal risk complaints, the primary reviewers accomplish Form 032 on queries, notifications, and complaints.

3.3. For more than minimal risk, the committee may choose any of the following options:

3.3.1. Constitute a site visiting team to gather more information, verification and clarification regarding the source and cause/s of the complaint for its early resolution.

3.3.2. Designate the primary reviewers to meet with the complainants and the researcher (preferably separately) for clarification of issues and obtain suggestions for resolution.

3.3.3. Formulate recommendation if satisfied with the adequacy of information –

 - request for explanation/justification from researcher

- accept request/demand of participant

 - suspension of further recruitment

 - amendment of protocol and re-consent of participants

 - others

Step 4 - Communication of response: The communication of response is through an email or a letter. The Member Secretary prepares this. The Chair signs. See SOP on Communicating REC Decisions (SOP# 21).

Step 5 – Logging of the response and inclusion in the agenda of the REC meeting: The response would be documented and logged and included in the agenda of the REC meeting by the REC Staff. See SOPs on Managing REC Incoming/Outgoing Communications (SOP# 22) and Preparing the Meeting Agenda (SOP# 18).

**Forms:**

SOP 26 Form 032 Query, Notification and Complaint Form

Response Letter to Query / Complaint

 **History of SOP**

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| --- | --- | --- | --- |
| **Version No.** | **Date** | **Authors** | **Main Change** |
| 01 | 02/28/2017 |  |  |
| 02 | 06/21/2019 | krva | Revision of statements reflecting that complaints/ inquiry may come from the participants on their families |
| 03 | 09/26/2022 | krva | Revision of SOP |