1. **Policy Statement**

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 IREB staff, secretary, the Chair 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.

1. **Objective/s of the Activity**

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

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

1. **Scope**

This SOP described the process in managing queries and complaints and is limited to queries and complaints of research participants, or their families, in studies that have been issued an ethical approval by the IREB. 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 IREB meeting.

1. **Workflow**

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| **ACTIVITY** | **RESPONSIBILITY** |
| 1: Receipt, logging, and acknowledgement of queries and complaints (SOP on Managing IREB Incoming and Outgoing Communications) | IREB Staff |
| 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 IREB Chair | IREB Staff |
| 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 IREB members |
| 4: Communication of response (SOP on Communicating IREB Decisions (SOP #21) | IREB Staff |
| 5: Logging of the response (SOP on Managing IREB Incoming and Outgoing Communications (SOP#22) and inclusion in the agenda of the IREB meeting (SOP on Preparing the Meeting Agenda (SOP#18)) | IREB Staff |

1. **Description of Procedures**

**5.1 - Receipt, logging, and acknowledgement of queries and complaints:**  The staff should immediately log received queries and complaints based on date, time, name of concerned party, specific study, nature of query or complaint.

**5.2 - Referral of query or complaint to competent authority**:

5.2.1. The staff refers queries related to specific protocols approved by the IREB to the primary reviewers.

5.2.2. The staff refers all complaints to the IREB 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.

**5.3 - Formulation of response**:

5.3.1. For queries, the primary reviewers accomplish the Form ## Query Reply.

5.3.2. For minimal risk complaints, the primary reviewers accomplish Form ## Complaints Resolution.

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

5.3.3.1. 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.

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

5.3.3.3. 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

**5.4 - Communication of response**: The member secretary or the Chair shall sign responses to queries and complaints.

**5.5 – Logging of the response and inclusion in the agenda of the IREB meeting**:

1. **Glossary**

**Query** – the act of asking for information or clarification about a study.

**Complaint** – the act of expressing discontent or unease about certain events or arrangements in connection with a study.

**Regular Meeting**– a periodically scheduled assembly of the IREB.

**Special Meeting** - an assembly of the Committee outside of the regular schedule of meetings for a specific purpose.

**Competent Authority** –designated officer or member of the IREB with the authority to respond to queries and complaints regarding studies approved by the IREB.

**Primary Reviewers**– are members of the Institutional Research Ethics Board (usually a scientist and a non-scientist) assigned to do an in-depth evaluation of the research-related documents using technical and ethical criteria established by the committee.

**Site Visiting Team**– members/staff of the IREB (2-4 members) assigned by the IREB Chair to formally go to the research site, meet with the research team and evaluate compliance with the approved protocol and Informed Consent Form and Process, including other related research procedures to ensure promotion of the rights, dignity and well-being of participants and protection of integrity of data.

1. **Forms***:*

*Form 26A Query/Complaint Form*

*Form 26B Query/Complaint Response Form*

1. **History of SOP**:

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| --- | --- | --- | --- |
| ***Version No.*** | ***Date*** | ***Authors*** | ***Main Change*** |
| *0* |  |  | *First draft* |

1. **References**

*WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011*

*CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*National Ethical Guidelines for Research Involving Human Participants 2022*

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