PERELI-IRB SOP 17/05-0-2022	**Peregrine Eye and Laser Institute** **Institutional Review Board**
Version No. 5	**SOP 17** **Responding to Participant Queries and Complaints**
Approval Date: July 16, 2022	
Effective Date: July 16, 2022	
Supersedes: Previous SOPs of the PELI-IRB	

SOP 17 Responding to Participant Queries and Complaints

1. **Purpose**

   To describe the IRB process in reviewing and addressing participants' queries and complaints.

2. **Scope**

   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 IRB. It begins with the receipt and recording of the query or complaint and ends with the logging of the response and inclusion in the agenda of the REC meeting.

3. **Responsibility**

   The IRB is responsible for attending to queries and complaints from clients, patients, or research participants promptly and appropriately while exercising due diligence. The nature of queries shall determine whether they can be answered by the IRB staff or referred to the primary reviewers of the specific protocol. All complaints must 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.

2. **Process Flow/ Steps**

STEP	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Receive and record queries and complaints	Staff Secretary	same day of participant's query/complaint
2	Refer query or complaint to competent authority.	Staff Secretary	1 day upon receipt
3	Formulate a response	Primary Reviewers Chair	1 week upon receipt of forwarded query/complaint

4	Include in the agenda of the next full board meeting	Staff Secretary and Chair	Not applicable
5	Summarize actions taken and Communicate response	Staff Secretary and Chair	1-3 days after decision was made

3. Detailed Instructions

Step 1 The Staff Secretary receives the query or complaint, records it in **Form 3.6** Query/Complaint Record including date, time, name and contact details of concerned party, specific study, starting date of participation, and concerns of the participant.

Step 2 The Staff Secretary receives the query/complaint from the refers queries related to specific protocols approved by the IRB to the primary reviewers and all complaints to the REC chair who determines the level of risk affected by the issue. Minimal risk complaints are referred to the primary reviewers of the concerned protocol. Complaints that involve more than minimal risk are referred to the full board 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 If study protocol-related query or complaint, accomplished Form 3.6 should be reviewed and signed by primary reviewer. For more than minimal risk, the committee may choose any of the following options:

i. 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.
ii. Designate the primary reviewers to meet with the complainants and the researcher (preferably separately) for clarification of issues and obtain suggestions for resolution.
iii. Formulate recommendation if satisfied with the adequacy of information. Possible recommendations are :
    - Request for explanation/justification from researcher
    - Accept request/demand of participant
    - Suspension of further recruitment
    - Amendment of protocol
    - Re-consent of participants
    - Others

Step 4 Complaints that involve more than minimal risk are included in the agenda of the next regular meeting. See SOP 10 Full Review.

Step 5 The Staff Secretary summarizes the actions taken and outcome of the query/complaint in **Form 3.6** Query/Complaint Record signed by the Chair and communicates the response. See SOP 28 Communicating IRB Decisions.