

	Peregrine Eye and Laser Institute Institutional Review Board
PELI-IRB SOP #25	SOP 25 Conduct of Meeting
Version No. 5	
Approval Date: July 16, 2022	
Effective Date: July 16, 2022	
Supersedes: Previous SOPs of the PELI-IRB	

SOP 25 Conduct of Meeting

1. Purpose

To provide an opportunity for the IRB to arrive at collegial decisions regarding study protocols and IRB operations and to be informed of pertinent administrative matters.

2. Scope

The SOP on the Conduct of Meeting covers all activities required for an effective and efficient conduct of a meeting such as IRB activities from the time the meeting is called to order and quorum is declared to the time the meeting is adjourned. This SOP begins with the distribution of meeting materials and ends with the collection, storage, and disposal of meeting materials.

3. Responsibility

Meetings shall be presided by the Chair or designated substitute, shall proceed only when quorum is declared, and shall be guided by the approved agenda. The presence of a conflict of interest among the members shall be disclosed prior to the discussion of protocols for review.

IRB meetings are not public meetings. Guests such as independent consultants and principal investigators can attend only upon the invitation of the Chair. The IRB reserves the right to invite investigators to attend meetings to give clarifications on their proposed studies. Except for the technical reviewers, all others are excused at the time of deliberation and decision making.

4. Process Flow/Steps

STEP	ACTIVITY	PERSON RESPONSIBLE
1	Call to order	Chair
2	Declare quorum	Member Secretary
3	Approve the provisional agenda	IRB members
4	Declare conflict of interest (COI)	IRB Members (who have COI)
5	Approve minutes of the previous meeting	IRB Members
6	Discuss "Business arising from the minutes"	IRB Members

7	Review protocols and protocol-related submissions	Chair and IRB Members
8	Report results of expedited and exempted reviews	Designated Reviewers
9	Review and discuss post approval submissions if there are any: <ul style="list-style-type: none"> • SAEs and SUSARs • Amendments • Progress/final report • Deviations • Queries/complaints • Appeals • Site visits • Early protocol termination • Suspension or termination of IRB approval • Continuing review 	Chair and IRB Members
10	Discuss operations-related matters	Chair and IRB Members
11	Adjourn meeting	Chair
12	Collect, store, and dispose meeting materials	Staff Secretary

5. Detailed Instructions

Step 1 The Chair calls the meeting to order.

Step 2 The Member Secretary declares the quorum. For a quorum to be reached, at least 50% plus 1 of the members must be present including a non-scientific member and a non-affiliated member. Quorum should be maintained throughout the meeting.

Step 3 The Chair invites the members to examine the provisional agenda and to propose addition or deletion of items after which the IRB members approve it.

Step 4 The IRB member may declare conflict of interest early in the meeting so that the Chair will note it and implement the policy on conflict of interest management (e.g. conflicted member stepping out of the room or non-participation in the decision making process of the protocol involved.)

Step 5 The IRB members review the minutes of the previous meeting by conforming, correcting or deleting certain declarations. Opinions and actions included in the minutes are understood to be collective and need not be attributed to specific members unless in the case of administrative or operational queries from members who require follow-up information or action.

Step 6 The term Business Arising from the Minutes means any matter which have come up as a result of approving the minutes. It can be a report on an action which is a result of a decision made in the last meeting. The Chair asks the IRB members if there is business arising from the minutes and declares none if IRB members say so.

Step 7 The primary reviewers should be guided by the assessment forms in their presentations. The sequence of review should follow this order: technical issues, ethical issues and informed consent process/form issues. The IRB does not require researchers/principal investigators to make a presentation but they may be invited for a clarificatory interview. The primary reviewers may initiate the interview and invite other IRB members to ask questions too. (Refer to SOP 10- Full Board Review)

The decision making process starts with the Chair reiterating the discussions and decisions of the primary reviewers and invites the IRB members by raising their hands if they concur with the decision of the primary reviewers. All IRB members present in the meeting and technical reviewers if invited by the Chair to attend the meeting are expected to vote. Independent consultants cannot vote. If a member abstains from voting, that abstention will not be counted as a „no“ vote and the member’s presence will not count towards quorum. An IRB member cannot vote if he has a conflict of interest in the study or arrived after discussion of the study has been done.

Step 8 The designated reviewer of the protocol for expedited review reports his review, recommendations and decision. (Refer to SOP 9-Expedited Review)

Step 9 The Chair and IRB members review and discuss the following post approval submissions if there are any: (see SOPs 13-22; SOP 24)

- SAEs and SUSARs
- Amendments
- Progress/final report
- Deviations
- Queries/complaints
- Appeals
- Site visits
- Early protocol termination
- Suspension or termination of IRB approval
- Continuing review

Step 10 Operations-related matters are matters not directly related to any protocol under review. Examples are : staff matters, operational manuals, legal matters and meeting schedules. The Chair asks the IRB members if there are operations-related matters to be discussed and declares none if the IRB members say so.

Step 11 Meetings must be adjourned after all items in the agenda have been discussed and/or resolved. A member must move for the adjournment of the meeting, and seconded, for it to be declared.

Step 12 The Staff Secretary confirms real time documentation done in each agenda and have the Chair and the Member Secretary sign the the minutes upon adjournment.