



PCMC IR-EC SOP 24.0: Preparing for a Meeting

Supersedes:	PCMC IRB-EC SOP 01.0, V. 3.0
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Effective Date:	
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24.0 PREPARING FOR A MEETING

24.1 Policy Statement

The IR-EC shall include protocol-related and operations-related items during full board meeting. Protocol-related submissions shall be included in the agenda when received, at the latest, 7 working days before the scheduled meeting. Operations-related items may be included in the agenda as necessary.

24.2 Purpose of the Activity

To ensure efficient, orderly and smooth conduct of meetings and inclusiveness of topics to be taken up during the meeting. And to provide for adequate time for the Primary Reviewers to submit their evaluation.

24.3 Scope

This SOP includes the procedures for preparing for a meeting that begins from the preparing and finalizing the meeting agenda and ends with filing of a copy of the agenda after the meeting.

24.4 Process Flow/Steps for Preparing a Meeting

NO.	ACTIVITY	PERSON/S RESPONSIBLE
1	Preparing and finalizing the Meeting Agenda	IR-EC Secretariat Chair/Designated Member
2	Making arrangements for the meeting	IR-EC Secretariat
3	Distributing the Notice of Meeting	IR-EC Secretariat
4	Filing a copy of the agenda after the meeting	IR-EC Secretariat

24.5 Detailed Instructions

24.5.1 Preparing and finalizing the Meeting Agenda

24.5.1.1 The Secretariat shall collect all documents submitted to the PCMC IR-EC within a given period and put them in the full board meeting agenda for discussion or information of the PCMC IR-EC members.

24.5.1.2 The IR-EC Staff shall use the Meeting Agenda template to classify the items for review. The standard notice of meeting or agenda contains the following:

- a. Date of preparation



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- b. Date, time and venue of meeting
- c. Agenda items
- d. Protocols for Full board review: Initial Review and for Re-evaluation
- e. SAE reports
- f. Protocol violation/ deviation.
- g. Amendments
- h. Progress reports
- i. Final reports
- j. Participant queries
- k. Reports (expedited meeting results, etc.)
- l. Site Visit
- m. Other matters

24.5.1.2 The Secretariat shall refer the agenda items to the PCMC IR-EC Chair/ Designated Member for approval.

24.5.1.3 The Chair / Designated Member shall review the draft meeting agenda and shall make changes, if needed then this shall be approved by the Chair and it shall become the provisional meeting agenda. The provisional meeting agenda shall be presented at the beginning of the full board meeting and IR-EC Members shall be given the chance to suggest additional items to finalize the meeting agenda

24.5.2 Making arrangements for the meeting

24.5.2.1 The IR-EC Secretariat shall contact the IR-EC members to check who will be available to attend the meeting to ensure quorum.

24.5.2.2 The Secretariat shall inform the investigators about the meeting schedule. The time slot for their appearance at the PCMC IR-EC meeting shall be communicated to them.

24.5.2.3 The IR-EC Secretariat shall arrange the venue and other logistics for the meeting at least one week before the scheduled meeting.

24.5.2.4 The IR-EC Secretariat shall prepare relevant documents to be distributed to IR-EC members who confirmed to attend the meeting.

24.5.3 Distributing the Notice of Meeting

24.5.3.1 The IR-EC Secretariat shall distribute the Notice of Meeting (with the provisional meeting agenda) together with the relevant documents for review during the meeting of IR-EC members within five (5) days prior to the meeting date.

24.5.4 Filing a copy of the agenda after the meeting

24.5.4.1 The Secretariat shall take note of changes in the provisional meeting agenda after this is presented for approval to the IR-EC. If there are no



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changes, the provisional meeting agenda shall become the final meeting agenda.

- 24.5.4.2** The Secretariat shall file a copy of the agenda in the Agenda and Minutes folder.

24.6 Forms

Form 26.1 V.2.0 Notice of the Meeting Form

24.7 Glossary