

INSTITUTIONAL REVIEW BOARD SOP 303: MEETING PREPARATION

POLICY

The efficiency and effectiveness of the IRB is supported by administrative procedures that ensure that IRB members not only have adequate time for thorough assessment of each proposed study, but that the documentation they receive is complete and clear enough to allow for an adequate assessment of study design, procedures, and conditions, and also to consider the subject's rights, welfare and safety.

PROCEDURES

1. Pre-Review

- 1.1 An administrative review of all new studies, amendments, and continuing reviews will be conducted by the IRB administrator.
 - 1.1.1 The IRB administrator may attach documentation to incomplete submissions that have already been posted to the IRB agenda provided that the review has not been completed by the primary reviewer.
- 1.2 The IRB administrator will also review all consent forms prior to IRB submission.

2. Primary Reviewers

- 2.1 The IRB administrator will designate primary reviewers for amendments and continuing reviews requiring review at a convened meeting. Complexity of the protocol is always a consideration when the assignments are made.
 - 2.1.1 A physician will generally be assigned to all humanitarian use device protocols.
 - 2.1.2 Unanticipated problems will be assigned to a scientific member.

3. Meeting Materials

- 3.1 The meeting agenda along with the minutes from the previous month will be distributed electronically to the IRB members sufficiently in advance of each meeting.
 - 3.1.1 It is the responsibility of the IRB administrator to maintain a copy of the IRB agenda and meeting minutes for each month.
- 3.2 The IRB members will have complete access to all IRB submissions.

4. Meeting Invite

4.1 A Microsoft Teams meeting invite will be emailed to the IRB members and Principal Investigator, if applicable, the week of IRB.

5. Confidentiality

5.1 All meetings materials received by the IRB members are considered confidential.

SCOPE

This SOP applies to all IRB members and the IRB administrator.