

**INSTITUTIONAL REVIEW BOARD**  
**SOP 304: ADMINISTRATIVE REVIEW AND DISTRIBUTION OF MATERIALS**

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**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 patient 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 prior to 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. Confidentiality**

4.1 All submissions received by the IRB will be considered confidential and will be accessible only by meeting participants (regular members, alternate members and ad hoc consultants) for the purpose of review.

**SCOPE**

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