

| | | |
|--|--|--|
| SOP: FO 303 Version No.: 04 Effective Date: 12/2/10 | ADMINISTRATIVE REVIEW AND DISTRIBUTION OF MEETING MATERIALS | Supersedes Document Dated: 7/1/08 |
|--|--|--|

Steering Committee approved 4/6/11

1. POLICY

The efficiency and effectiveness of the IRB is achieved by adherence to 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.

Specific Policies

Terms used in this policy, but not defined herein shall have the meanings set forth in the Glossary.

1.1. Exemptions

See Policy FO 302 for process.

1.2. Administrative Review

The Research Compliance Analyst assigned to review the submission application may request minor revisions to the informed consent document and may clarify with the Investigator (or his/her representative) any issues or discrepancies between the submitted protocol, submission application, and informed consent document. These revisions and clarifications will be included in the submission materials sent to the Primary Reviewer and IRB members prior to the IRB meeting.

1.3. Incomplete Submissions

Incomplete submissions will not be scheduled for IRB review until the investigator has provided all necessary materials. RSP staff will notify the submitting investigator (or his/her representative) of any outstanding documentation or additional information needed before the application is scheduled for review (see Policy FO 301).

1.4. Scheduling for Review.

Complete applications that appear to meet qualifications for expedited review as determined by the Research Compliance Analyst will be submitted to the Senior IRB Chair or his/her designee for review. If a submission meets expedited review requirements, the review will be performed as described in Policy RR 401. All other applications will be placed on the agenda for the earliest meeting possible for review by the full IRB as described in Policy FO 304.

| | | |
|--|--|--|
| SOP: FO 303 Version No.: 04 Effective Date: 12/2/10 | ADMINISTRATIVE REVIEW AND DISTRIBUTION OF MEETING MATERIALS | Supersedes Document Dated: 7/1/08 |
|--|--|--|

1.5. **Distribution of Meeting Materials to Members Prior to IRB Meetings**

Copies of meeting materials (as described in Policy FO 304, section 1.3 will be distributed to all IRB members by mail, generally no less than one week prior to the meeting. Each regular member of the IRB, or the alternate member attending the meeting in place of a regular member, and non-voting members will receive a copy of the submission materials. Consultants will receive copies of material that are relevant to their input at the IRB meeting.

The originals of all submitted materials will be retained in the RSPP office and will be available at the IRB meeting.

1.6. **Confidentiality of Meeting Materials**

All submitted materials received by the RSPP office will be considered confidential, and will be distributed only to those individuals who have a need to review them. Relevant submitted materials will be distributed to IRB meeting participants (regular or alternate members, non-voting members, and special consultants) for the purpose of review.

Materials will be collected after the meeting and disposed of in secure recycling bins designated for shredding. Members who retain meeting materials after the meeting will be cautioned to keep them in a secure location until no longer needed, and instructed to dispose of them in secure recycling bins designated for shredding. [See Aurora System Policies 94 (Confidentiality/ Privacy Information Policy) and 139 (Destruction of Protected Health Information).]

The originals of all submitted materials will be stored in an RSPP study file. Consultants and visitors to the IRB meeting will be expected to sign a Confidentiality Agreement (Form FO 303-A IRB Meeting Visitors/Consultants Confidentiality Agreement).

Meeting minutes are considered confidential. Requests for copies of meeting minutes must be approved by RSPP Manager or Senior IRB Chair.

2. **SCOPE**

These policies and procedures apply to all research submitted to the Aurora IRB.

3. **APPLICABLE REGULATIONS, GUIDELINES AND STANDARDS**

21 CFR 56.109

45 CFR 46.109

| | | |
|--|--|--|
| SOP: FO 303 Version No.: 04 Effective Date: 12/2/10 | ADMINISTRATIVE REVIEW AND DISTRIBUTION OF MEETING MATERIALS | Supersedes Document Dated: 7/1/08 |
|--|--|--|

OHRP Guidance on Written IRB Policies (January 15, 2007)

AAHRPP Element II.2.C.

4. REFERENCES TO OTHER APPLICABLE SOPS

SOP 301

SOP 302

SOP 304

SOP 401