

SOP: FO 304 Version No: 1 Effective Date: 03/27/06	ADMINISTRATIVE REVIEW AND DISTRIBUTION OF MATERIALS	Supersedes Document Dated: 05/01/04
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1. 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.

Specific Policies

1.1 Exemptions

The IRB Administrator will review Claims for Exemption submitted by Investigators in consultation with the IRB Chairperson, or his/her designee. The IRB has chosen to require continued monitoring for select studies designated as Exempt from IRB review. In these instances, the determination will be included in the Agenda and Minutes under the Announcement section. Such Claims of Exemption will be logged in the IRB tracking database and filed.

1.2 Incomplete Submissions

Incomplete applications will not be accepted for review until the Investigator has provided all necessary materials as determined by IRB Administrative staff. The IRB Administrative staff will contact the submitting Investigator to obtain any outstanding documentation or additional information before the application is scheduled for review.

1.3 Scheduling for Review

Complete applications that appear to meet qualifications for expedited status will be submitted to the Chairperson or his/her designee for review. If a submission meets expedited review requirements, the review will be performed as described in SOP RR 401 (Expedited Review). All other applications will be placed on the agenda for the earliest meeting possible for review by the full IRB as described in SOP FO 303 (IRB Meeting Administration).

1.4 Distribution to Members Prior to IRB Meetings

Copies of application materials described in SOP FO 301 (Research Submission Requirements) will be distributed to all IRB members, generally at least ten (10) days prior to the meeting. Each regular member of the IRB, and any alternate members attending the meeting in place of a regular member, will receive a copy of the initial application material. Consultants will receive only copies of material that pertain to their requested input.

The original documents submitted will be retained in the IRB Office.

1.5 Confidentiality

All material received by the IRB will be considered confidential and will be distributed only to meeting participants (regular members, alternate members and special consultants) for the purpose of review. All application materials will be stored in an IRB study file with access limited to IRB members and IRB Administrative staff. IRB members will be expected to sign confidentiality agreements (OR 202-D IRB Member Confidentiality Agreement) upon joining the

IRB and every two years thereafter upon re-appointment. Consultants and visitors will be expected to sign a confidentiality agreement (OR 202-E Acknowledgement of Confidentiality) at the outset of the meeting. Copies of the signed confidentiality agreements will be kept on file in the OROC.

2. SCOPE

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

3. RESPONSIBILITY

IRB Administrator is responsible for conducting appropriate assessment of submissions for triage purposes.

IRB Administrator is responsible for providing complete review material packets to IRB members and other relevant parties.

IRB Chairperson (or designee) is responsible for supporting and assisting the IRB Manager in submission triage activities.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.109

45 CFR 46.109

5. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

6. ATTACHMENTS

None

7. PROCESS OVERVIEW

Investigators are required to submit application and all documentation three (3) weeks prior to the IRB meeting. Investigators are also to provide sufficient copies (noted on application checklist) to OROC staff. Packets are distributed to the IRB members by OROC staff at least 10 days prior to the IRB meeting.

8. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task	Tool
<i>IRB Administrator</i> <i>IRB Chairperson</i>	Conduct preliminary assessment of submissions claiming exemption from IRB review.	See also SOP FO 302
<i>IRB Administrator</i>	Conduct assessment of submission adequacy and contact Investigators for any missing elements.	See also SOP FO 301
<i>IRB Coordinator</i>	Assemble reviewers' packets. Send to all regular members of the IRB. Send pertinent protocols to consultants invited to the meeting.	