

SOP: 302
ADMINISTRATIVE REVIEW AND DISTRIBUTION OF MATERIALS

1. POLICY

The efficiency and effectiveness of the IRB is supported by administrative procedures that allow IRB members to have adequate time for a thorough assessment of each proposed research project.

Specific Policies

1.1 Submissions: Upon receipt of a new submission to the IRB, the IRB staff assesses the documents for assignment to the appropriate IRB by determining the campus affiliation of the Investigator, study site, type of research, scope of the research, date received, deadline submission, and volume of research assigned to each IRB.

1.1.1 Research submitted to the HSC IRB office will be assigned to one of the five IRBs. Typically, HSC IRBs review the following:

- IRB 1 reviews Medical/Behavioral protocols
- IRB 2 reviews Medical/Oncology/Surgical/Radiotherapy protocols
- IRB 3 reviews Medical/Pediatric protocols
- IRB 4 reviews Medical/Behavioral/Pediatric protocols
- IRB 5 reviews Medical protocols

1.1.2 Typically, OU Norman IRBs review social behavioral research and some Medical studies. The two OU Norman IRBs are equivalent in the scope of research reviewed. For OU Norman studies with biomedical applications, see SOP 602G, Reciprocal Review Policy (Norman – HSC Campuses).

- Board 1 reviews Social Behavioral/Medical research
- Board 2 reviews Social Behavioral/Medical research

1.1.3 Submissions of ongoing research: Upon receipt of a submission of ongoing research to the IRB, the IRB staff assesses the documents for assignment to the currently assigned IRB for the project. This includes continuing reviews, modifications, unanticipated problems involving risks to participants or others, and miscellaneous items.

1.1.4 The IRB responsible for the initial protocol review will generally be the IRB responsible for subsequent reviews (e.g., continuing review applications, protocol modifications, unanticipated problems involving risks to participants or others).

1.2 Administrative Assessment: The IRB staff shall conduct an administrative assessment of all study submissions received from Investigators to verify the submission of required documentation is complete. This is not an official determination of the IRB. The IRB Administrator shall conduct this assessment of submissions and may seek guidance from the HRPP Director or HRPP Assistant Director as necessary.

- 1.2.1 As part of the administrative assessment, the IRB Administrator makes a determination as to the type of review (Full Board, Expedited, or Exempt) required for the particular submission. Assignments are determined according to the scope of research, with consideration given to date received and deadline for submission.

1.3 Incomplete Submissions

Incomplete applications are not presented for review until the Investigator provides all necessary materials, as determined by the IRB Administrator. The IRB Administrator shall notify the submitting Investigator of any outstanding documentation or additional information needed before the application is scheduled for review.

The IRB Administrator shall return applications that require substantial revision or additional information to the Investigator.

1.4 Review Assignment

Complete applications that appear to meet the requirements for review by the convened IRB are added to the agenda for the next appropriate meeting, as described in SOP 303B, IRB Meeting Administration.

Complete applications that appear to meet the requirements for Expedited or Exempt review are presented to the IRB Chair or designee. If a submission meets the Exempt or Expedited review requirements, the review is conducted as described in SOP 401, Research Exempt from IRB Review, and SOP 402, Expedited Review.

1.5 Distribution to Members Prior to IRB Meetings

Copies of application materials described in SOP 301, Research Submission Requirements, are distributed to all IRB members the week prior to the regularly schedule IRB meeting. Each member of the IRB, and any alternate member, if applicable, receives a copy of the initial application material. Consultants receive copies only of material that pertains to their requested review assignment.

The original submission materials are retained in the IRB Office and are available at the IRB meeting.

1.6 Confidentiality

All material received by the IRB is considered confidential and is distributed only to meeting participants (members, alternate members and consultants) for the purpose of review. All application materials are stored in an IRB study file with access limited to IRB members and staff. Consultants and visitors are expected to sign Confidentiality Agreements.

2. SCOPE

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

3. RESPONSIBILITY

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

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

The IRB Support Staff assemble and deliver IRB member packages and send pertinent protocols to consultants invited to the meeting.

The HRPP Director or designee is responsible for IRB assignment of new research protocols, based on the scope of the research, applicable meeting submission deadline dates, and current IRB agenda volume.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.109

45 CFR 46.109

OHRP Guidance on Written IRB Procedures, July 11, 2002

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 301, Research Submission Requirements

SOP 303B, IRB Meeting Administration

SOP 401, Research Exempt from IRB Review

SOP 402, Expedited Review

SOP 602G, Reciprocal Review Policy (Norman – HSC Campuses).

6. ATTACHMENTS

202-E IRB Guest Confidentiality Agreement

7. PROCESS OVERVIEW

The following process overview describes the system for receiving and distributing the materials submitted by Investigators. This overview includes the requirements for pre-review and distribution of documents before IRB review.

7.1 The IRB staff assesses applications submitted to the IRB per 1.1 above. The HRPP Director or designee provides guidance and oversight for the distribution of applications when needed.

7.1.1 The IRB Administrator reviews New Study Applications, Applications for Continuing Review, Protocol Modification Forms, Unanticipated Problem Report Forms, and Miscellaneous items.

7.1.2 The IRB Administrator conducts an initial assessment of all study submissions received from Investigators to ascertain completeness and make a preliminary determination as to the type of review.

7.1.3 The IRB Chair or designee makes the final determination as to the type of review.

7.1.4 Incomplete applications are not presented for review to the convened IRB until the Investigator provides all necessary materials. The IRB Administrator may seek guidance regarding incomplete applications that require substantial revisions. If deficiencies are noted, the IRB Administrator contacts the Investigator for resolution.

7.2 Complete applications that appear to meet the qualifications for review by the convened IRB are added to the agenda for the next appropriate meeting, as described in SOP 303B, IRB Meeting Administration.

Complete applications that appear to meet the requirements for Expedited or Exempt review are presented to the IRB Chair or designee. If a submission meets the Exempt or Expedited review requirements, the review is conducted as described in SOP 401, Research Exempt from IRB Review; and SOP 402, Expedited Review.

7.3 Copies of application materials described in SOP 301, Research Submission Requirements, are distributed to all IRB members before the meeting. The IRB staff is responsible for distribution of meeting materials.

7.4 Application materials are distributed to each member of the IRB and any alternate members attending the meeting. Consultants receive material that pertains to their requested assignment of review.

Original submission materials are retained in the IRB Office and are available at the IRB meeting.

7.5 All materials received by the IRB are considered confidential and are distributed only to meeting participants (regular members, alternate members, and consultants) for the purpose of review. All application materials are stored in an IRB study file with access limited to IRB members and staff. The IRB Administrator is responsible for providing Confidentiality Agreements to guests, such as consultants, for signature.

APPROVED BY: _____ **DATE:** 09/01/2009

NEXT ESTABLISHED REVIEW DATE: MAY 2012