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 human 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, research project site, type of research, scope of the research, date received, deadline submission, and volume of research assigned to each IRB. The IRB staff may seek guidance from the HRPP Director or HRPP Assistant Director as necessary.

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

- IRB 1 reviews Medical/Behavioral research projects
- IRB 2 reviews Medical/Oncology/Surgical/Radiotherapy research projects
- IRB 3 reviews Medical/Pediatric research projects
- IRB 4 reviews Medical/Behavioral/Pediatric research projects
- IRB 5 reviews Medical research projects on an as needed basis, except for VA studies

1.1.2 Typically, OU Norman IRBs review social behavioral research. The two OU Norman IRBs are equivalent in the scope of research reviewed. For OU Norman studies with biomedical interventions, see SOP 602G: IRB of Record.

- Board 1 reviews Social Behavioral research projects
- Board 2 reviews Social Behavioral research projects

1.1.3 Submissions of ongoing research: Upon receipt of any submission of ongoing research to the IRB, the IRB staff assesses the documents for assignment to the appropriate IRB for the project.

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

1.2 Administrative Assessment: The IRB staff shall conduct an administrative assessment of all research project 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 submissions are not presented for review. The Investigator must provide 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 submission is scheduled for review.

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

1.4 Review Assignment

Complete submissions 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 submissions that appear to meet the requirements for Expedited or Exempt review are presented to the IRB Chair or IRB Chair 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 Materials Provided to Members Prior to IRB Meetings

Submission materials described in SOP 301: Research Submission Requirements, are provided to all IRB members the week prior to the regularly scheduled IRB meeting. Each member of the IRB, and any alternate member, if applicable, is provided the initial submission materials via the IRB’s electronic information system. Consultants are provided access only to material that pertains to their requested review assignment.

The original paper submission materials are retained in the IRB Office and are available at the IRB meeting. The original electronic submission materials are retained in the IRB’s electronic information system.

1.6 Confidentiality

All material provided by the IRB is considered confidential and is made accessible via the IRB’s password-protected electronic information system only to IRB staff and meeting participants (members, alternate members and consultants) for the purpose of review. Consultants and guests who have access to confidential IRB material are expected to sign IRB Guest Confidentiality Agreements prior to receiving any material.

2. SCOPE

This SOP applies to all human research submitted to the IRB.
3. RESPONSIBILITY

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

3.2 The IRB office is responsible for providing complete review material to IRB members and other relevant parties, via the IRB’s electronic information system.

3.3 The HRPP Director or designee is responsible for IRB assignment of new human research projects, 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 1, 2011

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: IRB of Record.

6. ATTACHMENTS

202-E IRB Guest Confidentiality Agreement

7. PROCESS OVERVIEW

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

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


7.1.2 The IRB Administrator conducts an initial assessment of all research project 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 IRB designee makes the final determination as to the type of review.

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

7.2 Complete submissions 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 submissions that appear to meet the requirements for Expedited or Exempt review are presented to the IRB Chair or IRB Chair’s 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 Submission materials described in SOP 301: Research Submission Requirements, are provided to all IRB members and alternate members if applicable, before the meeting. The IRB staff is responsible for verifying that all meeting materials are available to the IRB members.

7.4 Submission materials are provided to each member of the IRB and any alternate members attending the meeting. Consultants are provided access only to material that pertains to their requested assignment of review.

The original paper submission materials are retained in the IRB Office and are available in the IRB meeting. The original electronic submission materials are retained in the IRB’s electronic information system.

7.5 All materials received by the IRB are considered confidential and are provided to IRB staff and meeting participants (regular members, alternate members, and consultants) only for the purpose of review. The IRB Administrator is responsible for providing IRB Guest Confidentiality Agreements for signature to guests and consultants prior to giving them access to confidential IRB materials or information.

APPROVED BY:________________________ DATE: 08/31/2014

NEXT ESTABLISHED REVIEW DATE: AUGUST 2016