1. POLICY

Except when an expedited review procedure is used, the IRB will review proposed research at convened meetings at which a quorum is present. Each IRB will meet monthly, or at some other frequency determined by the IRB Chair and the HRPP Director for each campus.

Specific Policies

1.1 Quorum

The IRB meeting cannot begin until quorum exists. Should the quorum fail during the meeting, the IRB may not take further actions or votes until the quorum is restored.

1.1.1 A quorum is defined as more than one half of the number of members.

1.1.2 A quorum consists of members or their alternates and includes at least one member whose expertise is in a scientific area, one member whose expertise is in a nonscientific area, and one member who is not otherwise affiliated with the University.

1.1.3 For research involving an FDA-regulated article, a licensed physician must be included in the quorum.

1.1.4 An alternate member may attend in the place of an absent member in order to meet the quorum requirements outlined above.

1.1.5 A special consultant(s) may not be used to establish a quorum.

1.1.6 Even if a member abstains from voting, the member may be used to establish a quorum.

1.2 Conflict of Interest for IRB members

IRB members shall not review their own studies. See SOP 104B: Conflict of Interest-IRB Members, for information concerning conflicts of interest for IRB members.

1.3 Meeting Materials Sent Prior to IRB Meetings

The meeting agenda and submission materials described in SOP 301: Research Submission Requirements, are provided to all IRB members the week prior to the regularly scheduled IRB meeting. The process for compiling meeting materials for review by IRB members is described in Section 7.3 below.

1.4 IRB Research Project Files

The IRB research project files are available to IRB members for their review in the IRB’s electronic information system. IRB members may request the IRB Administrator to obtain additional information. IRB members may request the IRB Administrator for assistance in obtaining the protocol file and relevant IRB minutes before or during the convened IRB meeting.
1.5 Minutes

Minutes shall be recorded at each meeting, as described in SOP 303C: Meeting Minutes.

1.6 Meeting Materials and Equipment

1.6.1 All IRB members shall have access to a laptop computer in order to participate in the review during the meeting. The University provides support for this technology.

1.6.2 IRB meetings are conducted electronically. The IRB has access to a projector to display the agenda items via the IRB electronic information system.

1.6.3 Circumstances sometimes warrant conducting IRB meetings via telephone conference call and/or video-conference call, provided that each participating IRB member (i) has received all pertinent material prior to the meeting, and (ii) can actively and equally participate in the discussion of all protocols. Minutes of such meetings must clearly document that these two conditions have been satisfied.

1.6.3.1 Convened Meeting Using Speakerphone:

Should one or more members not be able to be physically present during a convened meeting, but be available by telephone, the meeting may be convened using a speakerphone or similar device. The members who are not physically present are connected with the meeting via speakerphone or similar device. In this manner, all members are able to discuss all protocols, even though one or more members are not physically present.

1.6.3.2 Meetings Conducted Via Teleconference Calls:

On occasion, meetings may be convened via a telephone conference call where all or most members will participate via teleconference call. A quorum (as defined in 1.1 above) must be on line or present for the conference call meeting to be convened. To allow for appropriate discussion to take place, all members must be connected simultaneously for a conference call to take place -- "telephone polling" (where members are contacted individually) will not be accepted as a conference call.

1.6.3.3 Meetings conducted via Videoconferencing Calls:

IRB members from remote areas may choose to attend the IRB meeting via videoconference or similar method. These members have the same responsibilities and voting privileges as the rest of the IRB.

1.7 Unscheduled Meetings

It may be necessary to hold unscheduled IRB meetings in order to review studies. Typically, these meetings are held to review studies to provide treatment for participants more quickly than scheduled meetings; for example, HUD protocols, Treatment IND protocols, or studies that have a limited time for enrollment.
1.8 Voting

1.8.1 Members of the IRB vote according to the criteria for approval (SOP 403: Initial Review-Criteria for IRB Approval, and SOP 404: Continuing Review). Members also determine level of risk, the frequency of review for each protocol, monitoring requirements of the investigative site, and whether third party assessment and follow-up will be needed.

1.8.2 In order for a human research project to be approved, it must receive approval from the majority of the members present at the meeting. If an approval majority does not exist, the human research project is NOT approved.

1.8.3 Should an IRB member recuse him/herself during a meeting, that member is not counted toward the quorum. If quorum is lost due to the recusal, any further discussion/deliberation regarding the project must cease until quorum can be re-established. This may result in a deferral.

1.8.4 Following discussion of the research project, the IRB Chair/Vice-Chair shall call for a vote on one of the following motions: approve, contingently-approve, defer, disapprove, or abstain. An IRB member can abstain from voting if he/she is undecided as to how to vote. That individual is still counted toward the quorum count; however, the abstention is not counted as an approval. For example: If a protocol is being voted on by seven Board members and one abstains, a majority of the remaining six must vote “for” the protocol in order to receive approval; i.e., at least four must vote in favor of approval. In addition, if the community member abstains from voting, that person is still counted toward the quorum and also fulfills the regulatory requirements as having a community member present, but the abstention does not count in favor of approval; a majority of the remaining members must still vote in favor before approval can be granted.

1.8.5 Description of the Options for Motions:

A. **Approved** – The research project has been approved by the convened IRB as submitted and the investigator is not requested to revise any aspect of the project. The approval date is the date of the IRB meeting.

B. **Contingently Approved** – The convened IRB imposes specific revisions that require simple concurrence requests from the Investigator or requires modifications that are minor as defined in SOP 405: Modifications. Research cannot be contingently approved if the IRB requests clarifications, additional information, or changes that are more than minor. Examples of revisions that cannot be contingently approved are:

   o Indicate the number of participants to be enrolled
   o Change the drug dosage to be consistent
   o Indicate why children cannot be participants
   o Provide additional details about the data monitoring plan.
All minor revisions must be submitted and reviewed by the IRB Chair or IRB reviewer for final approval of the project before the research project begins. The approval date will be the date that the IRB Chair or IRB Chair's designee reviews and approves the requested revisions. If there are revisions that require judgment(s) not allowable under expedited review procedures, these revisions must be presented to the IRB at the next convened meeting.

C. **Deferred** – The convened Board requires significant additional information and/or a risk/benefit assessment could not be made with the information provided to make a determination regarding the human research project. The Investigator may submit the requested information to be reviewed at the next scheduled IRB meeting.

D. **Disapproved** – The magnitude and/or number of concerns, questions, or problems relating to the human research project are such that a 'contingently approved' or a “deferred” determination cannot be made. The Investigator has an opportunity to respond in writing or in person regarding the determination. The Investigator can resubmit the research project; it undergoes review again by the convened IRB. Disapproved protocols cannot be approved by University administration.

2. **SCOPE**

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

3. **RESPONSIBILITY**

3.1 The HRPP Director or designee will attend all IRB meetings to provide consistency in applying the federal regulations, state law, and University and HRPP policies.

3.2 The HRPP and IRB staff are responsible for ensuring that the IRB meets procedural conduct and documentation requirements.

3.3 The HRPP and IRB staff are responsible to monitor the members present at the convened meeting and determine that meetings are appropriately convened and held, such as ensuring quorum is maintained and that there are no IRB members with a conflict of interest present at the meeting.

3.4 Primary and Secondary Reviewers are responsible to conduct an in-depth review of all materials.

3.5 All other IRB members are responsible to review all provided materials in enough depth to be prepared to discuss the information at the convened meeting.

3.6 The IRB Chair or IRB Chair's designee is responsible for the IRB meeting reviewer conduct and leading discussion for all business that is addressed. The IRB Chair or IRB Chair's designee directs the proceedings of the meeting and requires that any member who has a conflict of interest does not vote or participate in the IRB's consideration of the research project for determination, except as requested by the IRB.
4. **APPLICABLE REGULATIONS AND GUIDELINES**

45 CFR 46.103, 46.108  
21 CFR 56.108  
FDA Information Sheet, Guidance for IRB’s and Clinical Investigators, 1998 Update  
OHRP Guidance on Written IRB Procedures, July 1, 2011  
OHRP Guidance on IRB Meetings Convened via Telephone Conference Call, March 28, 2000  
Department of Veterans Affairs, VHA Handbook 1200.5, October 15, 2010

5. **REFERENCES TO OTHER APPLICABLE SOPS**

SOP 104B: Conflict of Interest – IRB Members  
SOP 203: Duties of IRB Members  
SOP 301: Research Submission Requirements  
SOP 303C: IRB Meeting Minutes  
SOP 403: Initial Review-Criteria for IRB Approval  
SOP 404: Continuing Review  
SOP 405: Modifications

6. **ATTACHMENTS**

203-A HSC Reviewer Checklist  
203-A-1 Norman Campus Reviewer Checklist  
303B-A Board Meeting Checklist  
303B-B Sign-In Sheets-OKC  
303B-B-1 Sign-In Sheets-Norman

7. **PROCESS OVERVIEW**

7.1 **Meeting Attendance**

IRB staff contacts IRB members to verify intended meeting attendance to ensure presence of a quorum at the IRB meeting.

7.2 **Primary Reviewers**

The IRB Chair or IRB Chair’s designee assigns primary reviewers for each research proposal. The primary and secondary reviewers’ duties are described in SOP 203: Duties of IRB Members.

7.3 **Meeting Materials Sent Prior to IRB Meetings**

7.3.1 The IRB Administrator provides all IRB members with research project documentation required for review the week prior to the regularly scheduled IRB meeting. These documents include:

- Agenda  
- Minutes from the previous IRB meeting
- **Reviewer materials**

The IRB Administrator finalizes the meeting agenda and provides it and all meeting materials to IRB members prior to each meeting. A copy of the agenda and meeting minutes are maintained electronically. IRB members review the agenda and meeting materials for any potential conflict of interest they may have so that they may recuse themselves from the discussion and vote of an item. The IRB minutes also specifically reflect such recusals as they occur during meetings. In addition to the items listed above, IRB members receive in their packages the following documents:

7.3.2 For initial review by a convened IRB, all IRB members have access to:

- Research project submission
- Proposed consent documents and verbal consent scripts
- Full investigator or sponsor protocol
- Recruitment materials
- Any relevant grant applications
- The investigator’s brochure (when one exists)
- Copies of letters of assurance or Memoranda of Understanding with human research sites
- Grant Application: The primary reviewers review the grant application, if any, to ensure that the research described in the IRB proposal is consistent with the grant application. The grant application is not reviewed by every IRB member. An electronic version of the grant application or proposal is made available to any IRB member who may wish to review it. The IRB may require the Investigator(s) to: (i) summarize, and cross-reference to the application, specific information contained in the grant application; (ii) identify any IRB-approved protocols that describe the proposed research; and (iii) either certify that the application or proposal is consistent with any corresponding IRB protocol(s) or submit protocol modifications to reconcile any discrepancies.
- IRB Review of NIH-Approved Informed Consent Documents for NIH-Supported Multi-center Clinical Trials: If available, for NIH-supported multi-center clinical trials, the IRB receives and reviews an electronic copy of the NIH-approved sample informed consent document and the full NIH-approved Investigator’s protocol as a condition for approval of the local informed consent document. Any deletion or substantive modification of information concerning risks or alternative procedures contained in the sample informed consent document must be justified in writing by the Investigator, approved by the IRB, and reflected in the IRB minutes.

In addition, primary members receive a reviewer checklist.

7.3.3 For Continuing Review by a convened IRB, all IRB members receive:
• Continuing Review/Final Report form
• The complete protocol incorporating protocol modifications previously approved by the IRB
• Full investigator or sponsor protocol updated with any changes
• Current and proposed consent documents and scripts

In addition, primary members receive a reviewer checklist.

7.3.4 For review of modifications to previously approved research, all IRB members receive:
• Modification/Notification Form
• Modified documents

In addition, primary members receive a reviewer checklist.

7.3.5 For expedited review of new research submissions, continuing review, or review of modifications, the IRB reviewer will receive and review all information that the convened IRB would have received.

7.4 Minutes

For specific information regarding meeting minutes, refer to SOP 303C: Meeting Minutes.

7.5 Voting

Following discussion of each agenda item, the IRB Chair or IRB member makes a motion, another IRB member seconds the motion, the IRB members vote on the item, and the IRB staff counts and records all votes for, against, or abstaining from the motion.

7.5.1 A vote is considered official only when it takes place with a quorum present.

7.5.2 A member who is determined to have a conflict of interest on a research project is recused from IRB deliberations and must not vote on that research project.

7.5.3 A member who is recused from IRB deliberations cannot be counted towards the quorum.

7.5.4 No proxy votes are permitted.

APPROVED BY: ___________________________ DATE: 08/31/2014

NEXT ESTABLISHED REVIEW DATE: AUGUST 2016