

**SOP: 303B**  
**IRB MEETING ADMINISTRATION**

**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**

Copies of application materials described in SOP 301, Research Submission Requirements, are distributed 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 Files**

IRB files pertinent to the agenda items are available to IRB members during the meeting. The IRB files are also available to IRB members for review in the IRB office prior to the meeting. IRB members can request the IRB Administrator to obtain additional information. IRB members can request the

IRB Administrator to obtain the protocol file and relevant IRB minutes before or during the convened IRB meeting.

### **1.5 Minutes**

Minutes are recorded at each meeting, as described in SOP 303C, Meeting Minutes.

### **1.6 Tele-conferencing and Video-conferencing**

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.

#### **A. 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. The members who are not physically present are connected to the rest of the members via speakerphone. In this manner, all members are able to discuss all protocols, even though one or more members are not physically present.

#### **B. Meetings Conducted Via Tele-Conference Calls:**

On occasion, meetings may be convened via a telephone conference call where all or most members will participate via tele-conference call. A quorum (as defined in 1.1 above) must participate 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.

#### **C. Meetings conducted via Video-Conferencing Calls:**

IRB members from remote areas may choose to attend the IRB meeting via video-conference. 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 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**

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.

In order for a research project to be approved, it must receive approval from the majority of the IRB quorum. If an approval majority does not exist, the study is NOT approved.

Should an IRB member recuse him/herself, 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.

Following discussion of the research project, the IRB 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 they are 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.

#### Description of the Options for Motions:

**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.

**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, Amendments. 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:

- Indicate the number of participants to be enrolled
- Change the drug dosage to be consistent
- Indicate why children cannot be participants
- Provide additional details about the data monitoring plan.

All minor revisions must be submitted and reviewed by the IRB Chair or designated reviewer for final approval of the project before the study begins. The approval date will be the date that the IRB Chair 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.

**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 research project. The Investigator may submit the requested information to be reviewed at the next scheduled IRB meeting.

**Disapproved** – The magnitude and/or number of concerns, questions, or problems relating to the research project are such that a ‘contingently approved’ 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**

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

## **3. RESPONSIBILITY**

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

The HRPP and IRB staff are responsible for the IRB meeting procedural conduct and documentation.

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.

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

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.

The IRB Chair and/or IRB Vice Chair is responsible for the IRB meeting review conduct and leading discussion for all business which is addressed. The IRB Chair and/or IRB Vice Chair 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 study 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 11, 2002

OHRP Guidance on IRB Meetings Convened via Telephone Conference Call, March 28, 2000

Department of Veterans Affairs, VHA Handbook 1200.5, July 15, 2003

## **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, Amendments.

## **6. ATTACHMENTS**

203-A	New Study Reviewer Checklist – Full Board
203-D	VA Research Reviewer Checklist
203-E	Reviewer Checklist for Research Involving Pregnant Women, Fetuses or Neonates
203-F	Reviewer Checklist for Research Involving Prisoners
203-G	Reviewer Checklist for research Involving Children
203-H	Continuing Review Reviewer Checklist
203-I	Modification Reviewer Checklist
203-J	Waiver of Consent Checklist
303B-A	Board Meeting Checklist
303B-B	Sign-In Sheets-OKC
303B-B-1	Sign-In Sheets-Norman
303B-C	Email from George Pospisil, OSOPHS, DHHS.

## **7. PROCESS OVERVIEW**

### **7.1 Meeting Attendance**

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

### **7.2 Primary Reviewers**

The Chair, Vice-Chair or 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 IRB staff sends all IRB members study 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 staff prepares the meeting agenda and distributes it to IRB members prior to each meeting. A copy of the agenda is maintained on file with the meeting minutes. 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 receive:

- Application for New Research Project (Health Sciences Campus) or Institutional Review Board Application (Norman Campus)
- Proposed consent documents and scripts
- Full investigator or sponsor protocol
- Recruitment materials

In addition, Primary Reviewers also receive:

- Any relevant grant applications
- The investigator's brochure (when one exists)
- Copies of letters of assurance or cooperation with 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. A copy of the grant application or proposal is retained by the IRB Office and 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 amendments 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 a copy of the NIH-approved sample informed consent document and the full NIH-approved Investigator's protocol as a condition for review and 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:

- Appropriate reviewer checklist(s)

7.3.3 For Continuing Review by a convened IRB, all IRB members receive:

- Application for Continuing Review (Health Sciences Campus) or Continuing Review of Approved Research (Norman Campus)
- The complete protocol including any 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:

- Appropriate reviewer checklist(s)
- 7.3.4 For review of modifications to previously approved research, all IRB members receive:
- Protocol Modification Form (Health Sciences Campus) or Request for Modification of Approved Research (Norman campus)
  - Copies of all modified documents
- In addition, primary members receive:
- Appropriate reviewer checklist(s)
- 7.3.5 For expedited review of new research applications, continuing review, or review of modifications, at least one 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 study is excused from IRB deliberations and must not vote on the study.
- 7.5.3 A member who is excused from IRB deliberations cannot be counted towards the quorum.
- 7.5.4 No proxy votes are permitted.

**APPROVED BY:** \_\_\_\_\_

**DATE:** 09/01/2009

**NEXT ESTABLISHED REVIEW DATE:** MAY 2012