Standard Operating Procedures

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<th>SOP #103.6 Revision 6</th>
<th>TITLE: IRB Meeting Conduct</th>
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<td>Approved By: OIRB Director</td>
<td>Signature</td>
<td>Date 8/25/16</td>
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<td>Approved By: IRB Chair</td>
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PURPOSE
To define policies and procedures for conducting full board meetings of the Institutional Review Board (IRB) in accordance with federal regulations.

REVISIONS FROM PREVIOUS VERSION
Addition of minimum attendance requirement for non-affiliated members, prisoner rep requirements and clarification regarding approval date of projects approved with conditions.

POLICY
All regular members who are in attendance at a convened board meeting and who are not recused are entitled to one vote on each and all motions presented to the board for vote. An alternate member of the board may vote on motions affecting protocol approvals only in place of any regular member who is absent. All alternate members in attendance may vote along with regular members on all other motions presented to the board for vote. IRB chairs are regular members of the board with full voting privileges.

Prior to initiating any protocol review at a meeting of the full board, the chair shall establish and the meeting minutes shall reflect that a quorum is present and the voting members, alternates, and consultants collectively constitute sufficient and appropriate expertise to review the full range of protocols under review at that meeting. Care will be taken to ensure that the agenda items are limited to ensure adequate time is allotted for quality review. IRB members are provided copies of their completed reviewer checklists and access to study documents via IRBNet. Meetings are held once monthly; ad hoc meetings may be conducted if needed, if adequate quorum can be obtained.

As noted in the federal regulations subparts 108, 109 and 110, disapproval of a proposed protocol requires a majority of the voting members of the full board at a convened meeting at which a quorum has been established.

All subject matter of board meetings that is related to protocols, including discussion involving researchers or participants, or is otherwise of a sensitive nature, shall be treated as confidential information.

RESPONSIBILITIES
Execution of SOP: OIRB Director, OIRB Staff, IRB, IRB Chairs.
PROCEDURE

Meeting Preparation
The agenda is closed and published in IRBNet one week prior to the scheduled meeting. Members are notified of the published agenda and their review assignments through the IRBNet system. Reviewers are requested to upload their completed reviews into IRBNet no later than two days prior to the scheduled meeting. In exceptional circumstances, a submission may be added to the agenda after it closes, in which case all members will be immediately notified.

Primary Review System
Unless a submission to the IRB is determined to be exempt, qualifies for expedited review, or otherwise does not require full board review, it is scheduled for, presented at, and voted on at a convened IRB meeting. Submissions requiring full board review are assigned to at least one primary reviewer (usually two reviewers are assigned to new projects) based on the IRB member’s educational background and expertise as applicable.

Board members are provided all documents submitted by the investigator. Additional information may be requested from investigators to resolve questions prior to the meeting. Researchers may be asked to attend the meeting to answer questions, but will not be present for the board’s discussion or vote. Faculty advisors (as PI of record) will be required to attend to answer questions along with the student investigator if the research is a student project.

The primary reviewer is responsible for:
- Comparing the detailed grant application or industry/DHHS approved protocol with the IRB application, when applicable;
- Informing the full IRB of any discrepancies between the detailed protocol and the summary application materials;
- Determining whether the project involves a DHHS approved protocol (e.g., NIH cooperative group trial) and, if so, comparing the “Risks” and “Alternatives” sections of the DHHS approved sample informed consent document with the UNM proposed form to ensure that the DHHS and UNM sections of the consent are consistent; and
- Conducting an in-depth review.

Primary reviewers may request the use of an outside consultant if they feel additional expertise is needed to evaluate a study’s scientific merit, risk/benefit ratio or other identified concern. The reviewer may contact OIRB staff to arrange for the consultant review prior to the study being presented at a convened meeting or the primary reviewer may initiate the contact for verbal information from an outside consultant. In either case, the person who initiates the contact with the outside consultant, will ask the person if they or a family member have a potential COI with the study (in accordance with SOP 201) before proceeding with any exchange of information.

All IRB members review all information in the agenda packet in advance of the meeting (including those protocols for which the IRB member is not the primary reviewer) in enough depth to be familiar with the
protocol, to be prepared to discuss the protocol at the meeting, and to be prepared to determine whether the research meets the regulatory criteria for approval.

Primary reviewer(s) will present the submission to the IRB members at the convened meeting, after which the board will discuss the project and vote. At the discretion of the IRB, an outside consultant may be asked to review a study for additional assessment of an identified concern. If so, the decision regarding approval will be deferred until information is reviewed at a convened meeting. If an outside consultant review has been obtained, all IRB members will receive the consultant’s review and any supporting documents. A Chair or primary reviewer will present the consultant review to the board. The consultant may be asked to attend the meeting or be available for audio conferencing at the discretion of the reviewer.

Alternates
Alternate members are appointed to the board in general and do not serve as alternates to specific individual board members. In the event a regular member is absent and an alternate member is eligible to vote, the eligible member shall be notified by the chair of his or her voting privileges when the alternate member arrives to the meeting.

Quorum
A quorum is established when a simple majority of members, including the chair or a vice-chair acting as chair, are in attendance and able to vote (e.g. not disqualified from voting due to conflict of interest). A quorum shall be calculated as follows:

- At least one non-scientist is in attendance (see SOP 101 Composition and Membership of the IRB).
- At least one non-affiliated/community member is in attendance for at least 9 of the 12 meetings per year.
- Quorum requires a simple majority of the total number of regular members as reported to the federal Office for Human Research Protections (OHRP).
- If the research involves categories of human subjects vulnerable to coercion or undue influence, OIRB staff ensure that adequate representation is present for discussions.

Quorum is required for the IRB to take any approval-related actions on protocol submissions that require full board review. A majority of the quorum must vote in favor of a motion for the motion to be approved. Discussion on motions may proceed with fewer members present than a quorum, but no votes may be cast or counted until a quorum is present. If at any time a quorum is temporarily lost no votes on motions requiring a quorum may be made until a quorum is restored.

If a protocol or policy affects prisoners involved in research the IRB prisoner representative, who is a voting member must be present at the meeting and will be assigned as a primary reviewer.

Abstentions
An abstention is a refusal to vote either for or against a motion and does not affect the total members required to establish a quorum. Only members who are eligible to vote on the motion may abstain from voting. Members are not required to state a reason for their abstention.

Recusals
Any board member with a conflict of interest must recuse him/herself from the discussion and voting on any motion pertaining to the conflict. Recused members must leave the room in which the discussion and voting take place. Such recusals will be noted in the minutes. A recusal constitutes an absence and absent members may not be counted toward establishing or maintaining a quorum. The board may, at its discretion, invite a member with a conflict of interest to stay for the discussion only to answer questions about the research.

Virtual Attendance via Electronic Means
If a board member is unable to be physically present at a convened meeting, attendance may be established by electronic means. Members participating by electronic connection count toward a quorum and may participate as voting members. For purposes of establishing and recording voting privileges, any board member who attends the meeting by electronic connection shall be considered in attendance as long as the connection stays open throughout the meeting. Temporary disconnections that are quickly re-established shall not affect the member’s attendance status.

The electronic equipment utilized must adequately allow the member to hear the discussions and be heard by all others in attendance, and may utilize speaker-phone, teleconferencing, internet-based virtual meeting software, or another means that meet the requirements stated in this section and are secure. Methods of virtual attendance relying on electronic connections should allow the member(s) to participate in real-time. Meeting minutes should indicate the specific electronic method of attendance used by these members, including connection and disconnection times. A member in virtual attendance who is recused from participating in discussion and voting on a matter presented to the board must electronically disconnect from that portion of the meeting. The connection, disconnection and reconnection times should be noted in the meeting minutes.

For matters requiring a vote, a member in virtual attendance must have received documents made available to all other board members and had sufficient time to review such materials. Members may not simply phone in votes or otherwise participate only in the voting for approval of research protocol, but must also be present for the majority of the related discussion.

IRB Review
During discussion, the IRB members raise only those issues that the board determines do not meet the federal criteria for approval as specified in 45 CFR 46.111 and 21 CFR 56.111. In addition, the IRB determines the risk level and provides protocol specific examples as appropriate. Also, the IRB considers whether the PI’s preliminary assessment of federally mandated specific findings requirements (e.g., request for waiver of informed consent) are acceptable with respect to meeting federal requirements.

An IRB member makes a motion and then the convened IRB votes for or against or abstains from one of the following four actions:
1. **APPROVED**: IRB approval - A vote for approval indicates that the IRB has concluded that the research and consent/assent forms meet the federal criteria for approval. IRB approval verifies that the IRB agrees with the assessment of the protocol and/or specific findings as described by the PI in the application. OIRB staff send the investigator an approval letter accompanied by an informed consent/assent document (if applicable) with the affixed "IRB Approval" validation stamp, which includes valid dates of IRB approval.

2. **APPROVED WITH CONDITIONS**: A vote of approve with conditions indicates that the IRB has approved the protocol pending submission of minor modifications and that the IRB has given the individual chairing the meeting (and/or other IRB member with appropriate expertise or qualifications) the authority to approve the minor modifications. A vote of approve with conditions can only be made if any requested clarifications or modifications are not relevant to the determinations required by the IRB under the Common Rule or its Subparts (if applicable). If substantive clarifications or modifications regarding the protocol or informed consent documents are required as a condition of approval, approval must be deferred pending subsequent review of responsive material by the convened IRB.

OIRB staff send the researcher a letter describing the modifications requested by the IRB. The PI responds to the IRB’s suggested revisions in writing and sends the response and any supporting documents to OIRB staff, who verify whether the requested modifications are complete via administrative review. OIRB staff may forward the responses to the Chair or IRB for additional review, if appropriate.

3. **DEFERRED (TABLED)**: A vote of deferred indicates that the IRB withholds approval pending submission of major revisions/additional information. OIRB staff send the researcher a letter that lists the reasons for tabling and includes a description of the revisions or additional information requested. For some studies, the IRB may appoint one or more members of the IRB to discuss the reasons with the researcher. If the vote is for a deferral, OIRB staff schedule the PI’s response to the requested revisions for review by the full board; the IRB may or may not require the PI to attend.

4. **DISAPPROVED**: If the vote is for disapproval, OIRB staff send the investigator a letter describing the reasons for disapproving the protocol. Disapproval of a protocol usually occurs when the IRB determines that the risk of the procedures outweighs any benefit to be gained or if the proposed research does not meet the federal criteria for IRB approval. A disapproval may be appealed to the IRB.

During the convened meeting, the IRB determines the approval period, as appropriate to the degree of risk but not less frequently than once per year (two year approvals may be granted for unfunded minimal risk faculty research). The IRB may set a shorter approval period for high risk protocols or protocols with high risk/low potential benefit ratios.

When a protocol receives final approval, the OIRB assigns the start of the approval period as the date of the convened IRB meeting. If a protocol has received a conditional approval and the PI completes the
revisions, the date conditions are met is the approval date and the approval period start from the meeting date of the convened IRB on which the IRB initially reviewed the protocol. Should there be serious concerns or a lack of significant information requiring the convened IRB to complete its review and issue approval of the study at a subsequent meeting, the approval period starts with the date of the subsequent convened IRB meeting.

*Recording Board Actions in the Minutes*
All motions made by any board member for consideration by the full board shall be summarized and recorded in the meeting minutes. The summary shall be in sufficient detail to reflect the meeting attendance, summary of any controverted issues, any changes made to the motion and their outcome, and the total number of votes on the motion including votes for, against, and abstaining. Documentation of the minutes shall be retained as stated in SOP 104.

**REFERENCES**
45 CFR 46.108(b)
21 CFR 56.108