1. POLICY

Except when an exempt or expedited review procedure is used, the Institutional Review Board (IRB) will review proposed research at convened meetings at which a quorum is present. The IRB will meet regularly, and on other occasions as warranted by events and determined by IRB Chair in consultation with the IRB Manager.

Specific Procedures

1.1 Quorum

1.1.1 A quorum is defined as the minimum number of IRB members that must be present at meetings to approve research and to make meeting proceedings valid. A quorum is one half of the number of primary IRB members appointed to the Board plus one.
1.1.2 A quorum consists of primary members and alternate members who are standing in for absent primary members and includes: at least one member whose principal concerns are in nonscientific areas.
1.1.3 An alternate member may attend in the place of his/her designated, absent primary member in order to meet the quorum requirements outlined above.
1.1.4 Consultants will not be used to establish a quorum.
1.1.5 Even if a member abstains from voting, the member may be used to establish a quorum.
1.1.6 If a member recuses him/herself from deliberations and voting, the member may not be used to establish quorum for the duration of review of the item from which the member is recused. A member experiencing a conflict of interest (COI) must recuse him/herself.

1.2 Primary Reviewers

Prior to convened meetings, the IRB Manager, in consultation with the IRB Chair, will designate a primary reviewer for each research proposal slated for review at the upcoming meeting. The primary reviewer's duties are described in IRB SOP RR404, Initial Full Board Review.

1.3 Meeting Materials Sent Prior to IRB Meetings

Members receive meeting materials prior to meetings via a dedicated member website. Meeting materials are made available well in advance of the meeting in order to allow time for adequate review. These include:
1.3.1 Agenda
A meeting agenda will be prepared by the IRB Manager and posted on the IRB member website prior to the meeting. A copy of the agenda and attached materials will be maintained on file with the meeting minutes. The meeting agenda will remind members to declare any potential COI they may have with research that is about to be reviewed at the outset of each meeting. The chair will ask for a declaration of such COI, and the declaration will be incorporated in the minutes of the meeting. The IRB minutes will also specifically reflect recusals as they occur during meetings.

1.3.2 Application Review Materials
All IRB members will receive an electronic file containing; a transmittal letter with the scheduled meeting date, a list of the protocols to be reviewed and the name of the primary reviewer of each protocol, a complete copy of the protocol application, and the appropriate IRB Review Sheet(s) that will be used to document the member’s approval decision and review comments.

1.3.3 Monthly Approved Application Reports
A report of all IRB protocol applications reviewed and approved at the exempt and expedited levels since the previous Board meeting will be prepared by the IRB Coordinator and posted on the IRB member website prior to each meeting.

1.3.4 Monthly Summary Reports of Incidents of NonCompliance and Adverse Events/Unanticipated Problems Involving Risks to Subjects and Others
A report summarizing any adverse events, unanticipated problems, or incidents of non compliance, with the IRB’s response and recommendations will be prepared by the IRB Manager and posted on the IRB member website prior to the meeting.

1.4 Minutes
The Federal regulations for the protection of human subjects [45 CFR 46.115(a)(2)] require that "Minutes of IRB meetings… shall be in sufficient detail to show attendance at the meeting; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution." The OSU IRB’s minutes will adhere to this regulatory standard.

1.4.1 Recording
The IRB Coordinator, or designee, will take minutes of each convened meeting. Minutes will be written in sufficient detail to show the following:

- Meeting attendance including; status of each attendee (primary member, alternate member, consultant, guest, etc.), and COIs, if any;
- Actions taken by the IRB on each agenda item requiring full IRB action including the basis for requiring changes in or disapproving proposed research;
- Summary of the discussion of controverted issues and resolution;
- Voting results including the number for, against, abstaining, and members who recused themselves with the reason for recusal noted.

1.4.2 Approval
Draft minutes will be distributed to members prior to the next scheduled IRB meeting for review and consideration of approval at the meeting. Corrections requested by the IRB will be made by the IRB Manager, or designee, and the minutes will be printed in final form and made available to members upon request. The IRB Coordinator will maintain copies of the minutes, as well as the agenda and pertinent materials on
file in the Office of University Research Compliance. A copy of the approved minutes of each meeting and any attachments to the minutes will be shared with the Institutional Official (IO).

1.5 Telephone/Video Call Use

1.5.1 Convened meeting using speaker phone or video call:
Should a member not be able to be physically present during a convened meeting, but is available by telephone or video call, the meeting can be convened using a speakerphone or internet connection. The member who is not physically present will be connected to the rest of the members via speakerphone or video. In this manner, all members will be able to discuss the protocol even though one member is not physically present. Members participating by speakerphone or video call may vote, provided they have had an opportunity to review all the material the other members have reviewed.

1.5.2 Meetings Conducted Via Telephone Conference Calls:
On occasion, meetings may be convened via a telephone conference call. A quorum (as defined 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. Members not present at the convened meeting, nor participating in the conference call, may not vote on an issue discussed during a convened meeting (no voting by proxy will be permitted).

1.6 Voting

Convened members of the IRB will vote on the recommendations made during review of each protocol application according to the criteria for approval. Members also will determine the level of risk, the frequency of review for each protocol, appropriate monitoring of the investigative site, and whether third party assessment and follow-up will be needed. A majority of members must vote in favor of an action for that action to be accepted by the IRB. Only primary members and alternate members who are acting in place of their respective, designated, absent, primary members may vote. The vote will be recorded in the minutes. Members with a COI will recuse themselves from the discussion and voting and this information will be noted in the minutes.

2. SCOPE

This policy and procedure applies to all research submitted to the IRB.

3. RESPONSIBILITY

The IRB Manager is responsible for IRB meeting procedural conduct and documentation. The IRB Chair is responsible for IRB meeting review conduct and leadership.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.103, 46.108
21 CFR 56.108, 56.109
FDA Information Sheets, 1998

5. REFERENCES TO OTHER APPLICABLE SOPS

This SOP affects all other SOPs.
7. IMPLEMENTATION OF PROCEDURES

8. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

<table>
<thead>
<tr>
<th>Who</th>
<th>Task</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>IRB Coordinator</strong></td>
<td>Prepare monthly report of Approved Applications.</td>
</tr>
<tr>
<td><strong>IRB Manager</strong></td>
<td><em>Complete agenda</em>, prepare monthly Summary Report of Incidents of Noncompliance and Adverse Events/Unanticipated Problems. Distribute approved minutes and attachments to IO. Assemble reviewers' materials for electronic distribution and/or posting to the IRB member website.</td>
</tr>
<tr>
<td><strong>IRB Coordinator</strong></td>
<td>Attend meetings of the IRB. Record proceedings of each meeting. Maintain meeting records.</td>
</tr>
<tr>
<td><strong>IRB Chair</strong></td>
<td>Chair meeting. Ensure that all business is addressed, that proceedings are recorded, and that any member who has a conflict of interest does not participate in the IRB's review and vote of the study or issue, except to respond to questions as requested by the IRB.</td>
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<tr>
<td><strong>IRB Manager</strong></td>
<td>Complete draft minutes in time to include in the members' packets for the next meeting.</td>
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