1. PURPOSE

1.1. This procedure establishes the process to conduct an IRB meeting.
1.2. This procedure begins when the meeting is called to order.
1.3. This procedure ends when the meeting is adjourned.

2. POLICY

2.1. The Meeting Chair is responsible for:

   2.1.1. Leading the IRB meeting
   2.1.2. Facilitating IRB review
   2.1.3. Ensuring this Policy is followed
   2.1.4. Monitoring the IRB's decisions for consistency
   2.1.5. Ensuring that IRB decisions are consistent with federal regulations, state laws and local policies
   2.1.6. Ensuring that IRB members are free to participate in discussions
   2.1.7. Ensuring that IRB members attending by teleconference can actively and equally participate in all discussions
   2.1.8. Ensuring that a quorum is present when voting, and that a proper vote is taken for all appropriate items

2.2. All board members are supplied a laptop computer to access all meeting materials.

2.3. IRB members are to know the definition of Conflict of Interest and self-identify any Conflicts of Interest regarding any item on the agenda, to the meeting chair.

2.4. All IRB members or their designated alternates (including the IRB Chair and Vice Chairs) without Conflict of Interest who are part of quorum may vote.

2.5. Absent IRB members may submit written comments, but may not vote.

2.6. Consultants may not vote.

2.7. Observers may attend meetings, but:

   2.7.1. May not participate in IRB deliberations unless requested by the IRB to answer questions or serve as a consultant
   2.7.2. May not vote
   2.7.3. Are asked to maintain the confidentiality of the IRB proceedings

2.8. Investigators and study staff may attend the meeting, they must:

   2.8.1. Sign in to the meeting as guests, disclosing the agenda item(s) they are representing
   2.8.2. Not participate in the IRB proceedings unless called upon to clarify issues raised by the Board
   2.8.3. Leave the meeting room when asked by the meeting chair to do so, for the final deliberation and vote of the Board. However, per Florida State law, if they choose to stay, they are not allowed to participate any further.

3. RESPONSIBILITY

3.1. Meeting Chairs carry out these procedures.

4. PROCEDURE

4.1. Call the meeting to order, ask for a vote on any outstanding meeting minutes.

4.2. All known conflicts of interest will be disclosed on the meeting agenda.

4.3. For each study review:

   4.3.1. If there are individuals (either IRB members or consultants) with a Conflict of Interest related to an agenda item:
4.3.1.1. IRB members may ask questions of those individuals.
4.3.1.2. If physically present, ask those individuals to leave the room. Florida State law permits conflicted individuals to remain present, although they may not participate in the deliberation or vote.
4.3.1.3. If present by teleconference, set the conference equipment to block communications.

4.3.2. If the study is eligible for Non-Full Board Review, the IRB can choose to take no action and have the item reviewed by an Executive Reviewer.

4.3.3. Take no action on the item when quorum requirements are not met\(^1\) or when there is insufficient time to complete the review.
   - 4.3.3.1. Complete the review when proper quorum is reestablished.
   - 4.3.3.2. Move the item to another meeting.

4.3.4. For research involving prisoners reviewed by the convened IRB:
   - 4.3.4.1. The prisoner representative must be a voting member of the IRB.
     - 4.3.4.1.1. The prisoner representative may be listed as an alternative member who becomes a voting member when needed.
   - 4.3.4.2. The prisoner representative must review research involving prisoners, focusing on the requirements in Subpart C or equivalent protections.
     - 4.3.4.2.1. The prisoner representative must receive all review materials pertaining to the research (same as primary reviewer).
   - 4.3.4.3. The prisoner representative must be present at a convened meeting when the research involving prisoners is reviewed. If the prisoner representative is not present, research involving prisoners cannot be reviewed or approved.
     - 4.3.4.3.1. The prisoner representative may attend the meeting by phone, video-conference, or webinar, as long as the representative is able to participate in the meeting as if they were present in person at the meeting.
   - 4.3.4.4. The prisoner representative must present his/her review either orally or in writing at the convened meeting of the IRB when the research involving prisoners is reviewed.
   - 4.3.4.5. Minor modifications to research may be reviewed using the expedited procedure described below, using either of the two procedures described based on the type of modification.
   - 4.3.4.6. Modifications involving more than a minor change reviewed by the convened IRB – must use the same procedures for initial review including the responsibility of the prisoner representative to review the modification and participate in the meeting (as described above).
   - 4.3.4.7. Continuing review – must use the same procedures for initial review including the responsibility of the prisoner representative to review the continuing review materials and participate in the meeting (as described above).

\(^1\) If quorum is lost during a meeting, the IRB cannot take votes until the quorum is restored. If required members (e.g. non-scientific) leave the room and quorum is lost votes cannot be taken until the quorum is restored, even if half of the members are still present.
4.3.4.7.1. If no subjects have been enrolled, the research may receive continuing review using the expedited procedure under expedited category #8.

4.3.5. If one or more consultants are involved:

4.3.5.1. Inform the IRB members of any Conflict of Interest.

4.3.5.2. Have those consultants present at the meetings discuss their findings.

4.3.6. Have the primary reviewer:

4.3.6.1. Summarize the submission, including study objectives and procedures, and risk and benefits to subjects. Any regulatory or study designed concerns are presented to the Board.

4.3.6.2. Summarize their review of an Unanticipated Problem Involving Risks to Subjects or Others, Serious Noncompliance, Continuing Noncompliance, Suspension of IRB Approval, or Termination of IRB approval.

4.3.6.3. Summarize the IRB's consensus.

4.3.7. Make a motion for one of the following:

4.3.7.1. "Approve": When the IRB determines that the initial, continuing, or revision submission meets the criteria for approval.

4.3.7.1.1. For initial and continuing review, the period of approval is for one year unless a shorter period is specified, and the level of risk (minimal risk or greater than minimal risk).

4.3.7.2. "Approve with Contingencies": When the IRB determines that the initial, continuing, or revision submission will meet the criteria for approval with minor or prescriptive changes or requirements that can be verified without considering the criteria for approval.²

4.3.7.2.1. For initial and continuing review, the period of approval is for one year unless a shorter period is specified, and the level of risk (minimal risk or greater than minimal risk).

4.3.7.2.2. Summarize the IRB's required modifications and reasons.

4.3.7.3. "Tabled": When the IRB determines that the initial, continuing, or revision submission does not meet the criteria for approval and also does not meet the criteria for "Approve with Contingencies" or "Disapproval".

4.3.7.3.1. Summarize the IRB's reasons and recommendations, if any.

4.3.7.4. "Disapprove": The initial, continuing, or revision submission does not meet the criteria for approval and/or the IRB considers the research to have extensive deficiencies.

² Substantive changes or requirements, requests for more information for IRB consideration, and other issues related to the criteria for approval require review and approval by the convened IRB.
4.3.7.4.1. Summarize the IRB's reasons and recommendations, if any.

4.3.7.5. “Suspend Study”: When the IRB determines that based on new information the previously approved research no longer meets the criteria for approval.

4.3.7.5.1. If study was emergently suspended by the IRB Chair, the IRB Chair will present his/her reason for taking this action.

4.3.7.5.2. Include in the motion: Which research activities must stop or be modified.

4.3.7.5.3. If the research in its entirety no longer meets the regulatory criteria for approval, include in the motion: Stop all research procedures (except as noted below) and stop enrollment.

4.3.7.5.4. If stopping research will adversely affect the best interests of currently enrolled subjects, include in the motion: Which subjects can continue and what procedures can be performed.

4.3.7.5.5. Summarize the IRB’s reasons and recommendations.

4.3.7.6. “Suspend Study Enrollment”: When the IRB determines that based on new information no further study subjects may be enrolled in the protocol, however current subjects may continue on study procedures.

4.3.7.6.1. If study enrollment was emergently suspended by the IRB Chair, the IRB Chair will present his/her reason for taking this action.

4.3.7.6.2. Summarize the IRB's reasons.

4.3.7.7. “Terminate”: When the IRB determines that based on new information the previously research no longer meets the criteria for approval and the IRB has no recommendations to make the research approvable.

4.3.7.7.1. Summarize the IRB’s reasons.

4.3.7.8. “Lift Suspension”: When the IRB determines that based on a revised submission or new information the previously suspended study or suspended study enrollment meets the criteria for approval.

4.3.8. Ensure that the IRB staff member taking minutes has recorded the IRB’s actions, required modifications, reasons, recommendations, determinations, and findings.

4.3.9. Call for a vote of IRB members “For,” “Against,” or “Abstaining.” If more than half the IRB members present votes “For,” the motion is approved.

4.3.9.1. Any votes that result in a tie will be recorded but not passed. A new motion will need to be made and a new vote taken.

4.3.10. Have individuals with a Conflicts of Interest rejoin the meeting.

4.4. Adjourn the meeting when there is no further business or when notified by an IRB staff member that quorum for all remaining agenda items cannot be met.

4.4.1. If there are remaining agenda items, move them to another meeting.

5. REFERENCES
5.1. 21 CFR §56.109
5.2. 45 CFR §46.109
5.3. OHRP Guidance on IRB Approval of Research with Conditions