1. PURPOSE

1.1. This policy establishes for the review of Human Research the expectations of IRB members in advance of a meeting or when serving as an Executive Reviewer.

2. POLICY

2.1. In this policy, “all IRB members” refers to all members of the committee who have completed training and have been officially appointed to the Board by the [Institutional Official] and counts toward the quorum for an IRB meeting.

2.1.1. For review using the expedited procedure, the Executive Reviewer fulfills the roles described for all IRB members, which includes the role of the primary reviewer, and the scientific/scholarly reviewer, or obtains consultation for these roles.

2.2. All IRB members are to treat all oral and written information obtained as part of the review process as confidential. IRB members must not disclose or use confidential information without prior authorization.

2.3. All IRB members must consider if they have a Conflict of Interest with a protocol they are reviewing or voting on.

2.3.1. No IRB member may participate in any review (including deliberation or voting) in which he or she has a Conflict of Interest, except to provide information requested by the IRB.

2.3.2. When reviewing an item each IRB member is to consider whether he or she has a Conflict of Interest and if so, self-identify that Conflict of Interest to the IRB staff or Chair.

2.4. All IRB members have access to review the Pre - Review findings for each submission, if any.

2.5. All IRB members are to consider the criteria in all applicable IRB Guidance Documents.

2.5.1. The primary reviewer for each submission is expected to complete applicable MyIRB reviewer checklists with preliminary judgments as to whether each criterion is met and provide preliminary study-specific findings justifying determinations.

2.5.2. The primary reviewer leads the discussion.

2.5.3. IRB members who are not the primary reviewer for a submission but are designated to review the submission for that IRB meeting should also complete the reviewer checklist and finalize their review within myIRB.

2.6. For initial review: In advance of the meeting, all IRB members will have access to review the following materials within myIRB in order to determine whether the criteria in applicable IRB Guidance Documents are met:

2.6.1. Initial myIRB application and form(s)

2.6.2. The protocol

2.6.3. Consent document(s) and script(s), when they exist

2.6.4. Recruitment materials, when they exist

2.7. For review of a revision: In advance of the meeting, all IRB members will have access to review the submitted revision(s) within myIRB, determine which criteria in applicable IRB Guidance Documents are affected, and review the following materials as necessary to a depth sufficient to determine whether affected criteria are met:

2.7.1. Protocol

2.7.2. Previously approved revisions not reflected in the current protocol, or a summary thereof

2.7.3. Consent document(s) and script(s), when they exist

2.7.4. Recruitment materials, when they exist
2.8. For continuing review: In advance of the meeting, all IRB members will have access to review the continuing review progress report and attachments within myIRB, determine which criteria in applicable IRB Guidance Documents are affected, and review the following materials as necessary to a depth sufficient to determine whether affected criteria are met:

2.8.1. Protocol
2.8.2. Previously approved revisions not reflected in the current protocol, or a summary thereof
2.8.3. Consent document(s) and script(s), when they exist
2.8.4. New consent document(s) and script(s), when they exist
2.8.5. Recruitment materials, when they exist

2.9. For review of reportable events: In advance of the meeting, all IRB members will have access to review the reportable events and attachments within myIRB, determine which criteria in applicable IRB Guidance Documents are affected, and review the relevant sections of the following materials to a depth sufficient to determine as necessary whether affected criteria are met:

2.9.1. Protocol
2.9.2. Previously submitted revisions or a summary thereof
2.9.3. Consent document(s) and script(s), when they exist
2.9.4. Written reports of consultants, when they exist

2.10. The assigned reviewers review all submitted materials for consistency, including the following when they exist:

2.10.1. The complete protocol including any previously approved protocol revisions
2.10.2. Investigator brochure

2.11. If the research involves prisoners as subjects and is federally funded, if no other IRB that contains a prisoner advocate has reviewed this protocol, then the prisoner representative reviews the submitted information to determine whether the criteria to include prisoners have been met. The prisoner representative must be present when the research is reviewed and provide a review either orally or in writing, if applicable.

2.11.1. For research that involves prisoners as subjects but is not federally funded, the IRB will apply protections equivalent to Sub-Part C.
2.11.2. “IRB REGULATORY GUIDANCE: Federally Funded Research Involving Prisoners (HRP-308)” can be used for guidance.

2.12. All IRB members have access to review written reports of consultants, if any.
2.13. Any IRB member who needs to access minutes or other information in the IRB record accesses that information directly or contacts an IRB staff member for assistance.

3. REFERENCES

3.1. None