

POLICY: MEMBER REVIEW EXPECTATIONS

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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 a <Designated Reviewer>.

2. POLICY

- 2.1. In this policy, “all IRB members” refers to all members of the committee who will be present with voting status.
 - 2.1.1. For review using the expedited procedure, the <Designated Reviewer> fulfills the roles described for all IRB members, the primary presenter, 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 are to know the definition of <Conflicting Interest>.
 - 2.3.1. No IRB member may participate in any review (including discussion or voting) in which he or she has a <Conflicting 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 <Conflicting Interest> and if so, self-identify that <Conflicting Interest>.
- 2.4. All IRB members review the <Pre-Review> findings for each submission, if any.
- 2.5. All IRB members consider the criteria in all applicable worksheets and checklists.
 - 2.5.1. The primary presenter for each submission is expected to fill out applicable checklists with preliminary judgments as to whether each criterion is met and provide preliminary study-specific findings justifying determinations marked with “ⓘ.”
 - 2.5.2. The primary presenter leads the discussion.
 - 2.5.3. IRB members who are not the primary presenter for a submission do not need to complete any checklists.
- 2.6. For initial review: In advance of the meeting, all IRB members review the following materials to a depth sufficient to determine whether the criteria in applicable worksheets and checklists are met:
 - 2.6.1. Initial application form(s)
 - 2.6.2. Sections of the protocol relevant to the criteria.
 - 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 modification: In advance of the meeting, all IRB members review the modification, determine which criteria in applicable worksheets and checklists 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 modifications not reflected in the current protocol, or a summary thereof
 - 2.7.3. Consent document(s) and script(s), when they exist

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- 2.7.4. Recruitment materials, when they exist
- 2.8. For continuing review: In advance of the meeting, all IRB members review continuing review progress report and attachments, determine which criteria in applicable worksheets and checklists 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 modifications 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 new information¹: In advance of the meeting, all IRB members review the new information and attachments, determine which criteria in applicable worksheets and checklists 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 modifications 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 primary presenter reviews all submitted materials for consistency with the materials reviewed by all IRB members, including the following when they exist:
 - 2.10.1. The complete protocol including any previously approved protocol modifications
 - 2.10.2. Investigator brochure
 - 2.10.3. HHS grant application
 - 2.10.4. HHS-approved protocol
 - 2.10.5. HHS-approved template consent document
- 2.11. If the research involves prisoners as subjects, the prisoner representative reviews the submitted information, be present when the research is reviewed, and provide a review either orally or in writing.
- 2.12. IRB members or consultants with scientific or scholarly expertise review the submitted information in enough depth to answer any questions they might have.
- 2.13. All IRB members review written reports of consultants, if any.
- 2.14. Any IRB member who needs to access minutes or other information in the IRB record accesses that information directly or contacts an HRPP staff member for assistance.

3. REFERENCES

- 3.1. None