

SOP: Non-Committee Review Conduct

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1. POLICY

- 1.1. This procedure establishes the process to conduct <Non-Committee Review>.
- 1.2. This procedure begins when a <Designated Reviewer> has been notified to conduct a <Non-Committee Review>.
- 1.3. This procedure ends when a <Designated Reviewer> has notified the HRPP staff member handling the submission of the completion of the review.

2. POLICY

- 2.1. <Designated Reviewers> are to review the materials described in "POLICY: IRB Member Review Expectations (HRP-020)."
- 2.2. <Designated Reviewers> may not disapprove research

3. RESPONSIBILITY

- 3.1. <Designated Reviewers> carry out these procedures.

4. PROCEDURE

- 4.1. Consider whether you have a <Conflicting Interest>. If not:
 - 4.1.1. If the request is for study closure that does not meet "WORKSHEET: Closure Criteria (HRP-413)", communicate with the investigator.
 - 4.1.1.1. If the investigator withdraws the submission, stop processing.
 - 4.1.1.2. If the investigator will not withdraw the submission, return to the HRPP staff member handling the submission for <Committee Review>.
 - 4.1.2. Consider whether you have sufficient expertise to review the submission. If you need additional expertise, follow "SOP: Consultation (HRP-110)". Sufficient expertise includes as applicable for the research:
 - 4.1.2.1. Scientific or scholarly expertise
 - 4.1.2.2. Knowledge of or experience working with vulnerable populations
 - 4.1.2.3. Qualification as a prisoner representative
 - 4.1.2.4. Knowledge of the country in which the research is conducted
 - 4.1.2.5. Medical licensure for FDA-regulated test articles
 - 4.1.2.6. Knowledge of federal agency requirements for DOD, DOE, DOJ, ED, EPA, or EPA research
 - 4.1.2.7. Concern with the welfare of children with disabilities or individuals with mental disabilities as subjects, if the research is funded by the National Institute on Disability and Rehabilitation Research and purposefully requires inclusion of these subjects
 - 4.1.2.8. Knowledge of community based participatory research
 - 4.1.3. If there is missing information, follow the procedures in "SOP: Pre-Review (HRP-101)."
 - 4.1.4. Take one of the following actions:
 - 4.1.4.1. "Not Human Research": The submission does not meet the definition of <Human Research> based on "WORKSHEET: Human Research (HRP-421)."
 - 4.1.4.2. "Human Research Not Engaged" the submission meets the definition of <Human Research> but does not engage the institution based on "WORKSHEET: Engagement (HRP-422)."
 - 4.1.4.3. "Approve": The initial, continuing, or modification submission meets either:

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- 4.1.4.3.1. The criteria in "WORKSHEET: Exemption (HRP-423)", or.
- 4.1.4.3.2. The criteria in "WORKSHEET: Expedited (HRP-424)," "WORKSHEET: Criteria for Approval (HRP-400)," and other applicable worksheets and checklists as determined by the <Pre-Review>.
- 4.1.4.4. "Modifications Required to Secure Determination of Not Human Research": The submission with changes can be determined "Not Human Research."
- 4.1.4.5. "Modifications Required to Secure Determination of Human Research Not Engaged" The submission with changes can be determined "Human Research Not Engaged."
- 4.1.4.6. "Modifications Required to Secure Approval": The submission with changes can be granted the action of "Approve."
- 4.1.4.7. "Close": The submission meets "WORKSHEET: Closure Criteria (HRP-413)".
- 4.1.4.8. Refer to the HRPP staff member handling the submission for <Committee Review>.
- 4.1.5. Document using "FORM: Non-Committee Review (HRP-211)" or equivalent:
 - 4.1.5.1. The action
 - 4.1.5.2. If the action is "Approve" or "Modifications Required to Secure Approval," document whether the approval level was "Exempt" or "Expedited."
 - 4.1.5.2.1. For "Exempt," document the category or categories allowing the exemption in "WORKSHEET: Exemption (HRP-423)."
 - 4.1.5.2.2. For "Expedited," document the category or categories allowing review using the expedited procedure in "WORKSHEET: Expedited (HRP-424)" and document the period of approval (not to exceed one year for regulated research, and not to exceed three years for all others).
- 4.1.6. Update <Pre-Review> findings as needed.
- 4.2. Notify the HRPP staff member handling the submission when done.
- 4.3. Return any materials that are part of the permanent record.
- 4.4. Destroy or return any temporary copies of materials.

5. REFERENCES

- 5.1. None