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)."

3. RESPONSIBILITY

3.1. <Designated Reviewers> carry out these procedures.
3.2. <Designated Reviewers> may not disapprove research

4. PROCEDURE

4.1. Consider whether you have a <Conflicting Interest>. If not:

4.1.1. If the request is for study termination and the study meets termination criteria, terminate the study.
4.1.2. If the request is for study termination that does not meet termination criteria, communicate with the investigator.
   4.1.2.1. If the investigator withdraws the submission, stop processing.
   4.1.2.2. If the investigator will not withdraw the submission, return to the HRPP staff member handling the submission for <Committee Review>.
4.1.3. 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:
   4.1.3.1. Scientific or scholarly expertise
   4.1.3.2. Knowledge of or experience working with vulnerable populations
   4.1.3.3. Qualification as a prisoner representative
   4.1.3.4. Knowledge of the country in which the research is conducted
   4.1.3.5. Medical licensure for FDA-regulated test articles
   4.1.3.6. Knowledge of federal agency requirements for DOD, DOE, DOJ, ED, EPA, or EPA research
   4.1.3.7. 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
   4.1.3.8. Knowledge of community based participatory research
4.1.4. If the research involves anonymous, coded, or exempt genetic research, apply "WORKSHEET: Oregon Genetic Research Anon-Coded (HRP-461)"
4.1.5. If there is insufficient information, return for additional <Regulatory Review>.
4.1.6. Take one of the following actions:
   4.1.6.1. "Not Human Research": The submission does not meet the definition of <Human Research> based on "WORKSHEET: Human Research (HRP-421)."
4.1.6.2. “Human Research Not Engaged” the submission meets the definition of <Human Research> but does not engage the institution based on “WORKSHEET: Engagement (HRP-422).”

4.1.6.3. “Approve”: The initial, continuing, or modification submission meets either:

4.1.6.3.1. The criteria in “WORKSHEET: Exemption (HRP-423),” or.

4.1.6.3.2. The criteria in “WORKSHEET: Expedited (HRP-424),” “WORKSHEET: Criteria for Approval (HRP-400),” and other applicable worksheets and checklists as determined by the <Regulatory Review>.

4.1.6.4. “Conditionally Determine Not Human Research”: The submission with changes can be determined “Not Human Research.”

4.1.6.5. “Conditionally Determine Human Research Not Engaged” The submission with changes can be determined “Human Research Not Engaged.”

4.1.6.6. “Conditionally Approve”: The submission with changes can be granted the action of “Approve.”

4.1.6.7. Refer to the HRPP staff member handling the submission for <Committee Review>.

4.1.7. Update <Regulatory Review> findings as needed.

4.1.8. Document using “FORM: Non-Committee Review (HRP-211)” or equivalent:

4.1.8.1. The action

4.1.8.2. If the action is “Approve” or “Conditionally Approve,” document whether the approval level was “Exempt” or “Expedited.”

4.1.8.2.1. For “Exempt,” document the category or categories allowing the exemption in “WORKSHEET: Exemption (HRP-423)” and document the period of approval (not to exceed three years).

4.1.8.2.2. 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).

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