1. POLICY
   1. This procedure establishes the process to conduct <Non-Committee Review>.
   2. This procedure begins when a <Designated Reviewer> has been notified to conduct a <Non-Committee Review>.
   3. This procedure ends when a <Designated Reviewer> has notified the HRPP staff member handling the submission of the completion of the review or that the study requires Committee Review.
2. POLICY
   1. <Designated Reviewers> are to review the materials described in “SOP: IRB Member Review Expectations (HRP-020).”
   2. <Designated Reviewers> for non-committee review may not disapprove research.
   3. Non-exempt research that does not undergo continuing review is considered open until closed by the investigator.
3. RESPONSIBILITY
   1. <Designated Reviewers> carry out these procedures.
4. PROCEDURE
   1. Consider whether you have a <Conflicting Interest>.
      1. If so, assign the review task to another <Designated Reviewer>.
      2. If the request is for study closure and the study meets closure criteria, close the study
   2. Consider whether you have sufficient expertise to review the submission. If you need additional expertise, notify the HRPO Director and follow “SOP: Consultation (HRP-110).” Sufficient expertise includes as applicable for the research:
      1. Scientific or scholarly expertise
      2. Knowledge of or experience working with vulnerable populations
      3. Qualification as a prisoner representative
      4. Knowledge of the country in which the research is conducted
      5. Medical licensure for FDA-regulated test articles
      6. Knowledge of federal agency requirements for DOD, DOE, DOJ, ED, EPA, or EPA research
      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
      8. Knowledge of community based participatory research
   3. If there is missing information, follow the procedures in “SOP: Regulatory Review (HRP-101).”
   4. Take one of the following actions:
      1. “Not Human Research”: The submission does not meet the definition of <Human Research> based on “WORKSHEET: Human Research Determination (HRP-421).”
      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).”
      3. “Exempt”: The submission meets the criteria in “WORKSHEET: Exemptions and Limited IRB Review (HRP-423)”;
      4. “Approve”: The submission meets one of the following:
         1. The criteria in “WORKSHEET: Expedited Review (HRP-424),” and “WORKSHEET: Criteria for Approval (HRP-400),” and other applicable worksheets and checklists as determined by the <Regulatory Review>; or
         2. For continuing review or review of modifications to previously approved HUD uses, the criteria in “WORKSHEET: Expedited Review (HRP-424),” and “WORKSHEET: Criteria for Approval HUD (HRP-450).”
      5. “Approve with Stipulations”: The submission with changes can be granted the action of “Approve.”
      6. “Acknowledge”: The IRB wants to confirm that the IRB has reviewed the materials, but an action of “Approve” is not applicable.
   5. If the determination is to “Approve” or “Conditionally Approve,” document your determination regarding the criteria for approval.
   6. Update <Regulatory Review> findings as needed.
   7. Document using Checklists in PRISM, and using supporting worksheets as needed
      1. If the action is “Exempt,” document the category or categories from “WORKSHEET: Exemption (HRP-423)” allowing the exemption.
      2. If the action is “Approve,” “Approve with Stipulations,”:
         1. Document the category or categories allowing review using the expedited procedure
         2. Document the period of approval (not to exceed one year) or that continuing review is not required.
         3. If the research is subject to <Revised Requirements> and you require continuing review even though it is not required by “WORKSHEET: Criteria for Approval (HRP-400)”, document the rationale for requiring continuing review.[[1]](#footnote-2)
   8. If you cannot apply any of the above actions, notify the HRPP staff member (or the HRPO Director if the HRPP staff member is the Designated Reviewer) handling the submission to update the review process to <Committee Review>.
   9. Notify the HRPP staff member handling the submission when the non-committee review checklist is completed.
   10. If the action is to “Approve with Stipulations”, the HRPO staff member will return the submission with required stipulations and once the submission is returned to the IRB, will verify with designated reviewer that the stipulations are adequately addressed.
   11. The HRPO staff member will issue the appropriate action letter.
5. REVISIONS FROM PREVIOUS VERSION
   1. 27 Mar 21: HRPO Director, Carley Emerson, originally created and approved
6. REFERENCES
   1. None

1. When research is FDA-regulated and subject to the <Revised Rule>, the IRB’s rationale for requiring continuing review is that the research is FDA-regulated. [↑](#footnote-ref-2)