	SOP: Non-Committee Review Conduct			
	Document No.:	**Edition No.:**	**Effective Date:**	**Page:**
	HRP-104	**001**	**17 DEC 2018**	**Page 1 of 3**

CENTER FOR HEALTH SCIENCES

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.

2.3. Non-exempt research that does not undergo continuing review is considered open until closed by the investigator.

3. RESPONSIBILITY

3.1. <Designated Reviewers> carry out these procedures.

4. PROCEDURE

4.1. Consider whether you have a <Conflicting Interest>.

4.1.1. If so, assign the review task to another <Designated Reviewer>.

4.2. 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:

4.2.1. Scientific or scholarly expertise

4.2.2. Knowledge of or experience working with vulnerable populations

4.2.3. Qualification as a prisoner representative

4.2.4. Knowledge of the country in which the research is conducted

4.2.5. Medical licensure for FDA-regulated test articles

4.2.6. Knowledge of federal agency requirements for DOD, DOE, DOJ, ED, EPA, or EPA research

4.2.7. 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

4.2.8. Knowledge of community based participatory research

4.3. If there is missing information, follow the procedures in "SOP: Regulatory Review (HRP-101)."

4.4. Take one of the following actions:

4.4.1. "Not Human Research": The submission does not meet the definition of <Human Research> based on "WORKSHEET: Human Research (HRP-421)."

4.4.2. "Human Research Not Engaged" the submission meets the definition of <Human Research> but does not engage the institution based on "WORKSHEET: Engagement (HRP-422)."

4.4.3. "Approve": The submission meets one of the following:

4.4.3.1. The criteria in "WORKSHEET: Exemption (HRP-423)";

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

	SOP: Non-Committee Review Conduct			
	Document No.:	**Edition No.:**	**Effective Date:**	**Page:**
	HRP-104	**001**	**17 DEC 2018**	**Page 2 of 3**

CENTER FOR HEALTH SCIENCES

4.4.3.3. For continuing review or review of modifications to previously approved HUD uses, the criteria in "WORKSHEET: Expedited Review (HRP-424)," "WORKSHEET: Criteria for Approval HUD (HRP-450)."

4.4.4. "Conditionally Determine Not Human Research": The submission with changes can be determined "Not Human Research."

4.4.5. "Conditionally Determine Human Research Not Engaged" The submission with changes can be determined "Human Research Not Engaged."

4.4.6. "Conditionally Approve": The submission with changes can be granted the action of "Approve."

4.4.7. "Withdraw Approval"/"Rescind Approval": A prior approval of a document, site, investigator, and so forth was incorrect and can be withdrawn. The research may continue as it did before the approval.

4.4.8. "Approve in Principle": When a federal funding agency requires IRB approval before the funding agency can release grant monies, and the investigator cannot submit a complete research proposal, the IRB may provide a preliminary opinion on the proposed research.

4.4.9. "Accept/Acknowledge": The IRB wants to confirm that the IRB has reviewed the materials, but an action of "Approve" is not applicable.

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

4.5. Update <Regulatory Review> findings as needed.

4.6. Document using "FORM: Non-Committee Review (HRP-211)" or equivalent:

4.6.1. The action

4.6.2. If the action is "Approve," "Conditionally Approve," or "Withdraw Approval"/"Rescind" Approval," document whether the approval level was "Exempt" or "Expedited."

4.6.2.1. For "Exempt," document the category or categories from "WORKSHEET: Exemption (HRP-423)" allowing the exemption.

4.6.2.2. For "Expedited":

4.6.2.2.1. Document the category or categories in "WORKSHEET: Expedited Review (HRP-424)" allowing review using the expedited procedure

4.6.2.2.2. Document the period of approval (not to exceed one year) or that continuing review is not required.

4.6.2.2.3. 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.

4.6.3. If the research is subject to <Revised Requirements> and the research falls into a category in "WORKSHEET: Expedited Review (HRP-424)" allowing initial review by the expedited procedure, but you determine that the research involves greater than <Minimal Risk> to subjects, document that rationale for the determination that the research involves greater than <Minimal Risk> to subjects.

4.7. If you cannot apply any of the above actions, inform the HRPP staff that convened IRB review is required.

4.7.1. If the reason that you cannot apply any of the above actions is because the research is subject to <Revised Rule> and falls into a category in "WORKSHEET: Expedited Review (HRP-424)" allowing initial review by the expedited procedure, but involves greater than <Minimal Risk>, document the rationale that the research involves greater than <Minimal Risk>.

SOP: Non-Committee Review Conduct

Document No.:	Edition No.:	Effective Date:	Page:
HRP-104	**001**	**17 DEC 2018**	**Page 3 of 3**

CENTER FOR
HEALTH SCIENCES

4.8.   Notify the HRPP staff member handling the submission when done.

5.   REFERENCES

5.1.   None