Standard Operating Procedure (SOP)

SOP #: 401.104	HRP-104 Non-Committee Review Conduct	
Executive Owner: Vice President Research Operations		Effective Date: 6/11/2018 Review Date: 09/18/2019

Scope	This standard operating procedure (SOP) applies to the <Research Personnel> and Institutional Review Board (IRB) staff members, chair and committee members at AdventHealth Orlando.
Purpose	This procedure establishes the process to conduct <Non-Committee Review>. This procedure begins when a <Designated Reviewer> has been notified to conduct a <Non-Committee Review> and ends when a <Designated Reviewer> has notified the HRPP staff member handling the submission of the completion of the review.
Qualified Personnel	<Designated Reviewers>; IRB Staff Members
Training	Not applicable.
Supplies & Equipment	Not applicable.
Procedure	<Designated Reviewers> are to review the materials described in "POLICY: IRB Member Review Expectations (HRP-020)." <Designated Reviewers> may not disapprove research a. Consider whether you have a <Conflicting Interest>. 1. If so, assign the review task to another <Designated Reviewer>. b. If the request is for study closure that does not meet "WORKSHEET: Closure Criteria (HRP-413)", communicate with the investigator. 1. If the investigator withdraws the submission, stop processing. 2. If the investigator will not withdraw the submission, return to the HRPP staff member handling the submission for <Committee Review>. c. 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: 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 d. If there is missing information, follow the procedures in "SOP: Regulatory Review (HRP-101)."

e. 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 (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. "Approve": The initial, continuing, or modification submission meets either:
    1. The criteria in "WORKSHEET: Exemption (HRP-423)", or.
    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>.
    3. For continuing review or review of modifications to previously approved HUD uses, the criteria in "WORKSHEET: Expedited (HRP-424)," "WORKSHEET: Criteria for Approval HUD (HRP-450)."

    4. Document that the IRB determined that the proposed research met the criteria for approval.
        1. In the case of a financial interest that is <Related to the Research> document instead that the IRB determined that proposed research with the management plan for the financial interest met the criteria for approval.
4. "Conditionally Determine Not Human Research": The submission with changes can be determined "Not Human Research."
5. "Conditionally Determine Human Research Not Engaged" The submission with changes can be determined "Human Research Not Engaged."
6. "Conditionally Approve": The submission with changes can be granted the action of "Approve."
    1. Document that the IRB determined that the proposed research with the requested modifications met the criteria for approval.
        1. In the case of a financial interest that is <Related to the Research> document instead that the IRB determined that proposed research with the requested modifications and with the management plan for the financial interest met the criteria for approval.
7. "Close": The submission meets "WORKSHEET: Closure Criteria (HRP-413)".

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

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

1. The action
2. If the action is "Approve" or "Conditionally Approve," document whether the approval level was "Exempt" or "Expedited."
    1. For "Exempt," document the category or categories allowing the exemption in "WORKSHEET: Exemption (HRP-423)."
    2. For "Expedited," document the category or categories allowing review using the expedited procedure in "WORKSHEET: Expedited (HRP-424)"
    3. For "Expedited," document either that continuing review is not required or document the period of approval (not to exceed one year) and the reason for continuing review.
        1. If continuing review is determined to be required, but is not required by "WORKSHEET: Criteria for Approval (HRP-400)", document the rationale for the determination.
3. If the research falls into a category in "WORKSHEET: Expedited Review (HRP-424)" allowing initial review by the expedited procedure that is greater than <Minimal Risk>, document that rationale for the greater than <Minimal Risk> determination.

g. Update <Regulatory Review> findings as needed.
h. Notify the HRPP staff member handling the submission when done.
i. Return any materials that are part of the permanent record.
j. Destroy or return any temporary copies of materials.

Definition(s)

IRB: Institutional Review Board

Reference(s)

Not applicable.

Related Documents

Not applicable.

Keywords

IRB, institutional review board, IRB member