1 PURPOSE

1.1 This procedure establishes the process for the institution to review research that is not otherwise approvable, but because the research is not subject to regulatory approval, no government agency will conduct a review of this research to determine whether it can be approved.

1.2 This process begins when the convened IRB determines that research involving children, pregnant women, fetuses, or neonates as participants is not otherwise approvable, but presents a reasonable opportunity to understand, prevent, or alleviate a serious problem affecting those participants' health or welfare.

1.3 The process ends when the Institutional Official or designee communicates a decision to the IRB.

2 PREVIOUS VERSION

2.1 Revised from previous version dated 08/01/2024.

3 POLICY

3.1 When the IRB determines that research involving children, pregnant women, fetuses, or neonates as participants is not otherwise approvable, and the research is not federally funded nor regulated, so no government agency will conduct a review of this research to determine whether it can be approved, this Institution may conduct its own review that parallels the regulatory process to determine whether it can be approved.

3.2 The criteria used to make a determination are:

3.2.1 That the research in fact satisfies the conditions of IRB approvable research in "CHECKLIST: Non-Viable Neonates (HRP-413)," "CHECKLIST: Neonates of Uncertain Viability (HRP-414)," or "CHECKLIST: Children (HRP-416)," or "CHECKLIST: Pregnant Women (HRP-412)."

3.2.2 All the following criteria are met:

3.2.2.1 The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children or pregnant women, fetuses, or neonates.

3.2.2.2 The research will be conducted in accordance with sound ethical principles; and

3.2.2.3 Adequate provisions are made for soliciting the assent of children, the permission of their parents or guardians, and the consent of subjects as required by "WORKSHEET: Criteria for Approval and Other Considerations (HRP-314)," "CHECKLIST: Non-Viable Neonates (HRP-413)," "CHECKLIST: Neonates of Uncertain Viability (HRP-414)," or "CHECKLIST: Children (HRP-416)."

3.3 The research may proceed only if the Institutional Official or designee approves support of the research.

4 RESPONSIBILITIES

4.1 The Institutional Official or designee carries out these procedures.

5 PROCEDURE

5.1 Confirm that the convened IRB documented in their meeting minutes the required findings under 45 CFR §46.407 or 45 CFR §46.207.

5.2 Determine whether to review the research.

5.2.1 If a determination is made not to review the research, inform the IRB and take no further action under this SOP.

5.3 Identify a panel of five or more experts in pertinent disciplines (e.g., science, medicine, education, ethics, and law) and relevant subject advocates to review the protocol.

5.4 Screen for Conflicting Interests of panel members and do not use panel members with a Conflicting Interest.

5.5 Provide the expert panel members with all information reviewed by the earlier convened IRB.

5.6 Set a date for a convened panel discussion.

5.7 After the convened panel discussion occurs.

5.7.1 Generate a panel report that provides an introduction, a list of the panel members and their expertise, the summary of the panel's meeting deliberations, and their conclusions and recommendations.

5.7.2 Have each panel member write an independent recommendation as to whether the protocol should proceed, proceed with modifications, or not proceed.

5.8 Review the panel deliberations and recommendations and make one of the following determinations within 90 days of the convened panel meeting:

5.8.1 The institution approves support of the research as submitted;

5.8.2 The institution approves support of the research, but with required and/or recommended modifications; or

5.8.3 The institution disapproves support of the research.

5.9 Inform the IRB and the investigator.

Have the IRB retain the panel report and Institutional Official or designee's determination in the IRB's records.

6 MATERIALS

6.1 WORKSHEET: Criteria for Approval (HRP-314)

6.2 CHECKLIST: Pregnant Women (HRP-412)

6.3 CHECKLIST: Non-Viable Neonates (HRP-413)

6.4 CHECKLIST: Neonates of Uncertain Viability (HRP-414)

6.5 CHECKLIST: Children (HRP-416)

7 REFERENCES

7.1 45 CFR §46.207, 45 CFR §46.407