UNIVERSITY OF MIAMI

SOP: Not Otherwise Approvable Research

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1 PURPOSE

1.1 This procedure establishes the process for the organization 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 IRB determines that research involving children, pregnant women, or fetuses as subjects is not otherwise approvable, but presents a reasonable opportunity to understand, prevent, or alleviate a serious problem affecting those subjects' health or welfare.

1.3 The process ends when the Institutional Official/ Organizational Official (IO/OO) or designee communicates a decision to the IRB.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Reconciliation to Huron HRPP Toolkit 4.5, dated 12/10/2021

3 GUIDING PRINCIPLES

3.1 When research 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, this organization will conduct its own review that parallels the regulatory process.

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 HRP-413 - CHECKLIST - Non-Viable Neonates, HRP-414 - CHECKLIST - Neonates of Uncertain Viability, or HRP-416 - CHECKLIST - Children, or HRP-412 - CHECKLIST - Pregnant Women; and

3.2.2 All of 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;

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 HRP-314 - WORKSHEET - Criteria for Approval, HRP-413 - CHECKLIST - Non-Viable Neonates, HRP-414 - CHECKLIST - Neonates of Uncertain Viability, or HRP-416 - CHECKLIST – Children.

4 RESPONSIBILITIES

4.1 The IO/OO or designee carries out these procedures.

5 PROCEDURE

5.1 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.

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

5.1.2 Provide the experts with access to all of the study documents, including the IRB minutes, via eProst

5.1.3 Request the experts to discuss at a meeting the advantages, disadvantages and the ethical concerns associated with enrolling children, non-viable fetuses, fetuses of uncertain viability and pregnant women and determine whether the proposed research should move forward as written.

5.1.4 Create and maintain a written record of the meeting and the discussions.

5.1.4.1 Upload a copy of the written record as comment in eProst.

5.2 After the convened panel discussion occurs, have each panel member write an independent recommendation as to whether the protocol should proceed, proceed with modifications, or not proceed.

5.2.1 Upload a copy of each panel member's written recommendation in eProst.

5.3 The OVPRS and Executive Vice President for Research will review the research, the panel deliberations, and written recommendations and make one of the following recommendations within 90 days of the convened panel meeting:

5.3.1 The organization approves support of the research as submitted;

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

5.3.3 The organization disapproves support of the research.

5.4 If the OVPRS and Executive Vice President for Research recommends support of the research, they will provide the IRB with their decision and the IRB will consider the recommendation, any modifications required or recommended, the record of the panel's deliberations and the written recommendations made by the panel of experts when it reconsiders the proposed research.

5.5 The IRB will make the final decision as to whether to approve or disapprove the inclusion of the vulnerable class in the proposed research.

5.6 If the IRB approves the research, it will require the PI to incorporate the required revisions made by the OVPRS and Executive Vice President for Research into the protocol, consent, or other research documents.

5.7 HSRO staff will notify the Investigator of the OVPRS and Executive Vice President for Research decision to disapprove support of the research.

5.8 HSRO staff will notify the PI and the institution of the IRB's determination in compliance with WORKSHEET Communication of Review Results (HRP-303).

6 MATERIALS

6.1 HRP-303 - WORKSHEET - Communication of Review Results

6.2 HRP-314 - WORKSHEET - Criteria for Approval

6.3 HRP-412 - CHECKLIST - Pregnant Women

6.4 HRP-413 - CHECKLIST - Non-Viable Neonates

6.5 HRP-414 - CHECKLIST - Neonates of Uncertain Viability

6.6 HRP-416 - CHECKLIST - Children

7 REFERENCES

7.1 45 CFR §46.207, 45 CFR §46.407

7.2 21 CFR §50.24(e), 21 CFR §50.54(b), 21 CFR §812.66

7.3 AHRPP elements I.1.D, II.1.D, II.2.E-II.2.E.2, II.4.A