

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 None.

3 POLICY

- 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 “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 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 “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).”

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.
- 5.2 Screen for Conflicting Interests of panel members and do not use panel members with a Conflicting Interest.
- 5.3 Inform potential experts that they will be asked to provide individual written recommendations and that their reports, as well as their identities, will be publicly available during the public review and comment period.
- 5.4 Publish in a form accessible to the public:
 - 5.4.1 A request for written comments, including an Internet link to the protocol, relevant sections of grant applications, parental permission and assent documents, and relevant excerpts from the IRB minutes and correspondence.
 - 5.4.2 The date and location of the expert panel meeting (to be held a minimum of 30 days after the notice is posted.)

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- 5.4.3 Indicate that the panel meeting will be open to the public and that the public will be given an opportunity to comment at the panel meeting.
- 5.4.4 Note that written comments on posted materials must be submitted at least 7 days before the day of the panel meeting to be considered by the panelists (which will allow the public 21 days to comment on posted materials);
- 5.4.5 Indication that the panelists' reports/recommendations (see below) will be posted 14 days after the panel meets.
- 5.4.6 Invite comments for up to 30 days after the meeting of the convened panel for review and consideration by the panel.
- 5.5 Open the meeting to the public.
- 5.6 After the convened panel discussion occurs and public comments are received, have each panel member write an independent recommendation as to whether the protocol should proceed, proceed with modifications, or not proceed.
- 5.7 Post panel reports on the organization's website for informational purposes for 30 days after the panel meeting.
- 5.8 Review the panel deliberations, reports, public comments, and make one of the following recommendations within 90 days of the convened panel meeting:
 - 5.8.1 The organization approves support of the research as submitted;
 - 5.8.2 The organization approves support of the research, but with required and/or recommended modifications; or
 - 5.8.3 The organization disapproves support of the research.
- 5.9 Inform the IRB and the investigator.
- 5.10 Post the decision on the organization's Website.

6 MATERIALS

- 6.1 CHECKLIST: Pregnant Women (HRP-412)
- 6.2 CHECKLIST: Non-Viable Neonates (HRP-413)
- 6.3 CHECKLIST: Neonates of Uncertain Viability (HRP-414)
- 6.4 CHECKLIST: Children (HRP-416)
- 6.5 WORKSHEET: Criteria for Approval and Other Considerations (HRP-314)

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