



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, and since 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 greater than minimal risk also involves children or prisoners as subjects and is not otherwise approvable, but presents a reasonable opportunity to understand, prevent, or alleviate a serious problem affecting those subject's health or welfare.
- 1.3 The process ends when the Institutional Official or designee communicates a decision to the IRB.

**2 REVISIONS FROM PREVIOUS VERSION**

- 2.1 None.

**3 GUIDING PRINCIPLES**

- 3.1 When research is not otherwise approvable, and 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 The research satisfies the conditions of IRB approvable research in "CHECKLIST: Prisoners (HRP-415)," or "CHECKLIST: Children (HRP-416);"
  - 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 prisoners or children.
    - 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: Prisoners (HRP 415), or "CHECKLIST: Children (HRP-416)."

**4 RESPONSIBILITIES**

- 4.1 The Institutional Official 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 Provide to the panel of experts the protocol, consent document and other materials submitted for review and ask them to provide individual written recommendations as to whether it is appropriate to include prisoners and/or children in the research.
- 5.4 A Committee that includes a majority of the IRB members from the Committee originally reviewing the research and the Chairs from each of the other IRB Committees will review



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the recommendations, deliberate and make one of the following motions within 30 days of receiving all of the written recommendations:

- 5.4.1 The organization approves support of the research as submitted;
  - 5.4.2 The organization approves support of the research, but with required and/or recommended modifications; or
  - 5.4.3 The organization disapproves support of the research.
- 5.5 A majority of the members present (IRB Committee members and Chairs) must vote in favor of the motion.
- 5.6 HSRO staff will notify the Investigator and Institution in compliance with WORKSHEET Communication of Review Results (HRP-303).

**6 MATERIALS**

- 6.1 CHECKLIST: Non-Viable Neonates (HRP-413)
- 6.2 CHECKLIST: Neonates of Uncertain Viability (HRP-414)
- 6.3 CHECKLIST: Children (HRP-416)
- 6.4 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