



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 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:

That the research in fact satisfies the conditions of IRB approvable research in 7.202 (HRP-413) - WORKSHEET - Non-Viable Neonates, 7.203 (HRP-414) - WORKSHEET - Neonates of Uncertain Viability, or 7.205 (HRP-416) - WORKSHEET - Children, or 7.201 (HRP-412) - WORKSHEET - Pregnant Women.

- 3.2.1 All of the following criteria are met:

- 3.2.1.1 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.

- 3.2.1.2 The research will be conducted in accordance with sound ethical principles;

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 4.202 (HRP-314) - WORKSHEET - Criteria for Approval, 7.203 (HRP-413) - WORKSHEET - Non-Viable Neonates, 7.203 (HRP-414) - WORKSHEET - Neonates of Uncertain Viability, or 7.205 (HRP-416) - WORKSHEET - Children.

4 RESPONSIBILITIES

- 4.1 The IO or designee carries out these procedures.

5 PROCEDURE

- 5.1 Research in this category that is not federally funded and does not involve FDA-regulated products will be reviewed by a special panel convened by the Institutional Official or designee to make the determinations that would be otherwise be made by HHS or FDA when evaluating research in this category.
- 5.2 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.
- 5.3 Screen for Conflicting Interests of panel members and do not use panel members with a Conflicting Interest.
- 5.4 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. A panel report that provides an introduction, a list of the panel members and their expertise, the summary of the panel's meeting deliberations, their conclusions and recommendations will be generated.



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- 5.5 Have a separate three-member approval panel, composed of at least one scientist with appropriate expertise and one ethicist review the panel deliberations, reports and make one of the following recommendations within 60 days of the convened panel meeting:
 - 5.5.1 The organization approves support of the research as submitted;
 - 5.5.2 The organization approves support of the research, but with required and/or recommended modifications; or
 - 5.5.3 The organization disapproves support of the research.
- 5.6 Inform the IRB and the investigator.
- 5.7 The Institutional Official/Senior Leadership (President and/or those he delegates (e.g. Chancellor, Provost) may disapprove the study, but may not approve a study that was disapproved by the three-member approval panel.
- 5.8 Retain the panel report and the decision of the three-member approval panel retained in the IRB records.

6 MATERIALS

- 6.1 4.202 (HRP-314) - WORKSHEET - Criteria for Approval.
- 6.2 7.201 (HRP-412) - WORKSHEET - Pregnant Women.
- 6.3 7.202 (HRP-413) - WORKSHEET - Non-Viable Neonates.
- 6.4 7.203 (HRP-414) - WORKSHEET - Neonates of Uncertain Viability.
- 6.5 7.205 (HRP-416) - WORKSHEET – 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.