



SOP: Not Otherwise Approvable Research

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1. PURPOSE

- 1.1. This procedure establishes the process to review research that is not subject to federal regulation and is also not otherwise approvable under 21 CFR §50.54, 45 CFR §46.207, or 45 CFR §46.407, but which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children, pregnant women, fetuses, or neonates.
- 1.2. This procedure begins when the convened IRB determines that research falls into a not otherwise approvable category.
- 1.3. This procedure ends when the IRB is informed of the <Organizational Official's> decision.

2. POLICY

- 2.1. None

3. RESPONSIBILITY

- 3.1. The [Organizational Official] carries out these procedures.

4. PROCEDURE

- 4.1. Determine whether to review the research.
 - 4.1.1. If a determination is made not to review the research, inform the IRB and take no further action under this SOP.
- 4.2. Identify a panel of five or more experts in pertinent disciplines (e.g., science, medicine, education, ethics, and law) and relevant subject advocates willing to serve on a public panel.
 - 4.2.1. Determine whether any panel member has a <Conflicting Interests>.
 - 4.2.2. Do not use panel members with a <Conflicting Interest>.
- 4.3. Provide panel members with all information reviewed by the convened IRB.
- 4.4. Ask panel members to provide individual written recommendations.
- 4.5. Set a date for a meeting.
- 4.6. Conduct the meeting:
- 4.7. After the meeting have each panel member write an independent recommendation for one of the following:
 - 4.7.1. The research should proceed because it falls into an approvable research on "CHECKLIST: Nonviable Neonates (HRP-307)," "CHECKLIST: Neonates of Uncertain Viability (HRP-306)," or "CHECKLIST: Children (HRP-310)" or
 - 4.7.2. The research does not meet the above criterion but should proceed because the following criteria are met:
 - 4.7.2.1. 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.
 - 4.7.2.2. The research will be conducted in accordance with sound ethical principles.
 - 4.7.2.3. 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 (HRP-400)," "CHECKLIST: Non-Viable Neonates (HRP-307)," "CHECKLIST: Neonates of Uncertain Viability (HRP-306)," or "CHECKLIST: Children (HRP-310)."
 - 4.7.3. The research with modifications should proceed under one of the above criteria.



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- 4.7.4. The research should not proceed.
- 4.8. Review the panel report and make one of these recommendations:
 - 4.8.1. Approve the research as submitted
 - 4.8.2. Approve the research with modifications or
 - 4.8.3. Disapprove the research
- 4.9. Inform the IRB and the investigator.
- 4.10. Place the study on the agenda of a convened IRB.

5. REFERENCES

- 5.1. 21 CFR §50.54
- 5.2. 45 CFR §46.207 and §46.407