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| SOP: Not Otherwise Approvable Research, Federally Funded or Regulated | | | |
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1 PURPOSE

- 1.1 This procedure establishes the process for research that is not otherwise approvable by a convened IRB panel but is federally funded or regulated, so a government agency conducts a review of this research to determine whether it can be approved.
- 1.2 This process begins when the convened IRB determines that research involving children, pregnant women, fetuses or neonates as participants is not otherwise approvable, but presents a reasonable opportunity to understand, prevent, or alleviate a serious problem affecting those participants' health or welfare.
- 1.3 The process ends when the government agency or designee communicates a decision to the IRB.

2 PREVIOUS VERSION

- 2.1 Revised from previous version dated 11/01/2023.

3 POLICY

- 3.1 Northwestern University will notify the applicable federal agency such as the Office of Human Research Protections (OHRP), the Food and Drug Administration (FDA), or other federal agency of any IRB determinations of research involving children, pregnant women, fetuses or neonates as participants that is not otherwise approvable, but may be reviewed by a government agency to determine whether it can be approved.
- 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; and
 - 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 participants 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)."
- 3.3 The research may proceed only if the applicable government agency or designee makes a determination as indicated in the applicable regulation.

4 RESPONSIBILITIES

- 4.1 The IRB Office staff carry out this procedure.

5 PROCEDURE

- 5.1 Following the meeting, an IRB Compliance Analyst (or IRB Analyst) reviews the determination to verify whether the convened IRB determined that the research presents a reasonable opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children, pregnant women, fetuses or neonates, and also whether the research is federally funded or regulated.

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- 5.1.1 If the convened IRB determined that the research involves the health or welfare of children as participants when using CHECKLIST: Children (HRP-416), confirm that the meeting minutes document required findings under 21 CFR §50.54 or 45 CFR §46.407.
- 5.1.2 If the convened IRB determined that the research involves the health or welfare of pregnant women, fetuses or neonates as participants when using CHECKLIST: Pregnant Women (HRP-412), CHECKLIST: Non-Viable Neonates (HRP-413), or CHECKLIST: Neonates of Uncertain Viability (HRP-414), confirm that the meeting minutes document required findings under 45 CFR §46.207.
- 5.1.3 If the research is not federally funded nor regulated, refer to SOP: Not Otherwise Approvable Research, Not Federally Funded nor Regulated (HRP-044).
- 5.2 Prepare the submission with the applicable participant type to the appropriate government agency using the letter template (HRP-723).
 - 5.2.1 If the research is federally funded and thus subject to oversight by DHHS, the submission is sent to OHRP's Division of Policy and Assurances.
 - 5.2.2 If the research is regulated by the FDA, the submission is sent to the FDA's Office of Pediatric Therapeutics.
 - 5.2.3 If the research is both federally funded and regulated by the FDA, the submission is sent to OHRP's Division of Policy and Assurances.
 - 5.2.4 If the research is conducted, funded, or supported by the US Department of Defense (DoD), the submission is sent to the Institution's assigned point of contact for the project (e.g., Human Protection Administrator [HPA]) for the specific branch that is supporting the research.
 - 5.2.5 If the research is supported by another government agency that is not listed above, report to the appropriate agency and corresponding address.
- 5.3 Compile attachments to include with the submission as listed in the letter template (HRP-723), including redacted IRB meeting minutes, IRB application, protocol, informed consent/assent form(s), grant application, relevant IRB correspondence (such as determination letter(s) and study team responses), and any other relevant information or documents reviewed by the IRB for the study.
 - 5.3.1 IRB meeting minutes will only include minutes for the study being submitted and are redacted to obscure the names of IRB reviewers. If the study was deliberated at multiple convened IRB meetings, include each set of minutes.
- 5.4 Send draft letters and attachments to the IRB Director and/or designee for review.
- 5.5 Send the final version to the applicable federal agency within approximately 10 business days of finalizing the IRB meeting minutes.
- 5.6 Provide follow-up information to the applicable external agency (e.g., FDA, OHRP, DoD) as needed.
- 5.7 Save the submission with attachments and correspondence in the appropriate folder.
- 5.8 Communicate the government agency's determination to the IRB, preferably the same convened IRB that made the initial determination.

6 MATERIALS

- 6.1 WORKSHEET: Criteria for Approval (HRP-314)
- 6.2 CHECKLIST: Pregnant Women (HRP-412)
- 6.3 CHECKLIST: Non-Viable Neonates (HRP-413)
- 6.4 CHECKLIST: Neonates of Uncertain Viability (HRP-414)
- 6.5 CHECKLIST: Children (HRP-416)
- 6.6 TEMPLATE: Not Otherwise Approvable Research, Federally Funded or Regulated (HRP-723)



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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