Review of Not Otherwise Approvable Research

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1. PURPOSE

1.1. When research is not subject to the federal regulations for the protections of ***human subjects research*** because it is not ***supported or funded by a federal department or agency***, the US Department of Health and Human Services (DHHS) and Food & Drug Administration (FDA) will not conduct a review of the research to determine whether it can be approved. This ***policy*** establishes the process for the University of Georgia to review research involving ***children***, ***pregnant women, neonates, or fetuses*** that is not otherwise approvable by the University of Georgia Institutional Review Board (UGA IRB) but presents a reasonable opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of these subjects.

2. POLICY

2.1. When research is not otherwise approvable, but because the research is not subject to regulatory approval and no government agency will conduct a review of this research to determine whether it can be approved, the Institution will conduct its own review that closely parallels the regulatory review process.

2.2. The IRB must first determine that the protocol does not meet the conditions for approval of research involving children, pregnant women, neonates or fetuses using the *Worksheet: Criteria for Approval.*

2.3. UGA will convene an independent Review Panel of Experts in pertinent disciplines.

2.4. UGA must provide an opportunity for review and comments by the local community where the research is to be conducted before deciding whether to proceed with the research.

2.5. All of the following criteria must be met in order for the study to proceed:

2.5.1. The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children, pregnant women, neonates or fetuses.

2.5.2. The research will be conducted in accordance with sound ethical principles; and,

2.5.3. Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, or the ***consent*** of subjects.

2.6. Individuals with ***conflicting interests*** will not be allowed to review the protocol.

2.7. The ***Institutional Official (IO)*** or Designee makes the final determination regarding whether the research may be supported by the Institution based on all available materials and recommendation of the Expert Review Panel.

3. PROCEDURES: Institutional Review Board and Institutional Official

3.1. The IRB determines that research involving children, pregnant women, neonates or fetuses as subjects does not meet the criteria for approval, but presents a reasonable opportunity to understand, prevent, or alleviate a serious problem affecting those subjects' health or welfare.

3.2. The IRB also determines that the proposed research and the consent forms and/or parental permission/assent forms comply with all regulatory and institutional requirements and are otherwise approvable.

3.3. After the IRB has determined that research is not otherwise approvable, the IO or Designee identifies a Review 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.

3.4. In selecting the members of the Expert Review Panel, the IO or Designee screens for Conflicting Interests. Only individuals without any Conflicting Interests will be able to serve as Panel Members. The criteria described in Section 3.1 of the *Policy and Procedures: Conflicting Interests of IRB Members and Consultants* will be used as a guide in this determination.

3.5. The IO or Designee must inform the potential Panel Members that their review responsibility includes an individual written report of their recommendations and that their reports, as well as their identities, will be made publicly available during the public review and comment period.

3.6. The following will be published in a form that is readily accessible to the public (e.g., on the UGA IRB website):

3.6.1. The complete protocol, relevant sections of any grant applications or contracts, parental permission and assent documents or consent forms, and any relevant excerpts from the IRB minutes and correspondence.

3.6.2. A request for written comments from the public.

3.6.3. The date and location of the Expert Review Panel meeting; this meeting must be held at least 30 days after the public posting of notice.

3.6.4. Information that the Expert Review Panel meeting will be open to the public and that the public will be given an opportunity to comment at the Panel's meeting.

3.6.5. Information that in order to be considered by the Panelists, the written comments on posted materials must be submitted at least 7 days before the day of the meeting (which will allow the public 21 days to comment on the posted materials).

3.6.6. Information that the Panel's reports/recommendations will be posted 14 days after the Panel's meeting.

3.6.7. An invitation to provide comments for up to 30 days after the meeting of the convened Panel for review and consideration by the IO or Designee.

3.7. The meeting will be made open to the public.

3.8. After the convened meeting of the Expert Panel and receipt of the public comments, each Panel Member must prepare an independent written recommendation as to whether the protocol should proceed, proceed with modifications, or not proceed.

3.9. These individual reports of the Panel Members must be posted on the UGA's IRB website for 30 days after the panel meeting for informational purposes.

3.10. Within 90 days of the convened meeting of the Expert Panel, the IO or Designee reviews the panel deliberations, reports, public comments, and make one of the following recommendations:

3.10.1. UGA approves support of the research as submitted;

3.10.2. UGA approves support of the research, but with required and/or recommended modifications; or

3.10.3. UGA disapproves support of the research.

3.11. Once this determination has been made, the IRB Chair, the ***Principal Investigator***, the ***Senior University Officials***, and the sponsor (if any) will be immediately informed of the decision.

3.12. The decision will be posted on UGA's IRB website.

4. **MATERIALS**

4.1. Worksheet: Criteria for Approval

5. REFERENCES

5.1. 45 CFR §46.207, 45 CFR §46.407

5.2. 21 CFR §50.24(e), 21 CFR §50.54(b), 21 CFR §812.66

5.3. Policy and Procedures: Conflicting Interests of IRB Members and Consultants

5.4. OHRP Guidance: Children as Research Subjects and the HHS "407" Process, http://www.hhs.gov/ohrp/policy/populations/guidance_407process.html