IRB SOP 901
Research Involving Children

Purpose

The purpose of this policy and procedure is to outlines the requirements for research involving children. It is the policy of the Institutional Review Board to review all research proposals involving participation of children in accordance with Health and Human Services regulations at 45 CFR 46 Subpart D, 21 CFR 50 Subpart D and applicable state law.

Scope

This SOP applies to all research involving children, regardless of funding source.

Applicability

This policy applies to all human subjects' research conducted under the auspices of University of South Alabama involving children as subjects.

Definitions

Assent: A child's affirmative agreement to participant in research. Mere failure to object should not, absent affirmative agreement, be construed as assent. Assent is typically paired with permission from a parent or guardian, and together they comprise the informed consent to participate.

Children: Persons who have not attained the legal age for consent to treatments or procedures inv

Riskier procedures might include the biopsy of internal organs, spinal taps or the use of drugs whose risks to children have not yet been established. Behavioral interventions likely to cause psychological stress or directed at groups at risk of violent or self-destructive behaviors may also exceed minimal risk levels.

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1.2 Determination of Possible Benefits

- When assessing potential benefits of research intervention, the IRB considers the

2.0 Classification of Risk

As per U.S. Federal regulations (45 CFR 46 and 21 CFR 50, Subpart D), permissible research involving children are limited to those activities that meet one of four categories, based on the level of risk and potential for benefit to the individual participant.

2.1 Research not involving greater than minimal risk (§46.404 and §50.51);
2.2 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual participants (§46.405 and §50.52);
2.3 Research that involves more than minimal risk and presents the prospect of no direct benefit to individual participants, but generalizable knowledge (societal benefit) (§46.406 and §50.53); or
2.4 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (§46.407 and §50.54)

Risk Determination	Benefit Assessment	IRB Action
Minimal risk	With/without direct benefit	Approvable
Greater than minimal risk	Potential benefit to child	Approvable
Greater than minimal risk	No direct benefit to individual, but offers general knowledge about child's condition or disorder	Approvable case-by-case
Greater than minimal risk	No direct benefit to child, but other potential to, "understand,"	

The IRB will also consider the extent to which research procedures would be a burden to any child, regardless of whether the child is accustomed to the proposed procedures.

3.0 Parental Permission

Parental, guardian, or Legally Authorized Representative signature is required for any study in which a minor is the subject population unless otherwise stated by the IRB. The requirement for one versus two parental signatures is determined by the IRB. The federal regulations state that permission from both parents is required but empowers IRBs to consider investigator requests to obtain consent from only one parent. The IRB determines whether the permission of both parents is necessary, and the conditions under which one parent may be considered not reasonably available

Per 45 CFR 46.408(c), in addition to the normal waiver requirements, the IRB may waive the parental permission requirement if it determines that a research protocol designed for conditions or a subj6 (e)5 (o)-1.0a-4 (d)uidtions0 (re)-1 (q)-4(r c)4 (o)8.1 (e)trtal pe(a s)2 (u)