IRB SOP 703
Informed Consent: Research Involving Children

Purpose

This Standard Operating Procedure (SOP) document outlines ethical and regulatory considerations involving children involving in human subjects research. This SOP complements SOP 702: Informed Consent Documentation and SOP 901: Research Involving Children, which should be used in conjunction with this SOP.

Scope

This SOP applies to all research involving children, regardless of funding source under the auspices of the University of South Alabama.

Applicability

Under Alabama law (Ala. Code 26-1-1), a minor is a person younger than 19 years old, unless such a person has been emancipated. A person who is 18 years old and is either married or widowed is automatically emancipated. Further, Alabama law permits a person who is 18 years of age or older to consent to participate in research conducted by a college or university that is accredited by a federally recognized accrediting agency if the research has been approved by

with permission from a parent or guardian, and together they comprise the informed consent to participate.

Child: Persons who have not attained the legal age for consent to treatments or procedures involved in research and clinical investigations under the applicable law of the jurisdiction in which the research will be conducted. Children are a vulnerable population [45 CFR §46.602 (a)] [21 CFR§50.3]

participate in any non-exempt (and some exempt) research projects unless waived by the IRB under the provisions of Health and Human Services regulations at 45 CFR §46.116(d).

1.1 The IRB will make a determination whether permission of one or both parents is required for research approvable under 45 CFR §46.404 or §46.405.

1.1.1 If the research involves activities that are no more than minimal risk, consent of only one parent must be obtained.

1.1.2 If the research involves greater than minimal risk but presents the prospect of direct benefit to the individual participants, consent of only one parent may be obtained.

1.1.3 If the research involves greater than minimal risk and no prospect of direct benefit to individual participants, consent of both parents must be obtained unless one parent is deceased, unknown, incompetent, or not reasonably available. Consent of both parents is not required, however, when only one parent has the legal responsibility for the care and custody of the child.

2.0 Assent of Children

In addition to obtaining of parental/legal guardian consent (permission), the investigator must also solicit assent of minor participant age 7 years or older, unless the participant displays intellectual or emotional development below that of the average 7-year-old child.

Obtainment of assent shows respect for a child's developing autonomy. In most circumstances (non-therapeutic research), a child's deliberate objection should be regarded as a veto to his/her involvement in the research.

For research conducted in educational settings the IRB may approve a waiver of consent for children as old as 12 years old.

Assent may be waived if its pursuit may require comprehension of fine distinctions between the required behaviors. For example, data is collected in the classroom. The behavior/work/participation is required and assent is being sought to use the data above and beyond its original purpose (for research not just for as an educational practice). The waiver is associated with a protocol that involves no more than minimal risk

specifically exclude IRB members from serving as a child advocate if the other conditions are met.

6.0 Re-consent of participants reaching the age of majority

All minor p

When your study is...	Then this is required...
Minimal Risk	One parent/legal guardian may be sufficient
Greater than Minimal Risk, Direct Benefit t participant	One parent/legal guardian may be sufficient but the I must determine whether one or two is required
Greater than Minimal Risk, No Direct Bene to participate, but likely to yield generalizab knowledge about the participant's condition	Both parents/legal guardians, unless one parent is deceased, unknown, incompetent, not reasonably available, or does not have legal responsibility for the custody of the child
Greater than Minimal Risk, No Direct Bene to participant, but results may alleviate serious problems of children's health or welfare	Both parents/legal guardians, unless one parent is deceased, unknown, incompetent, not reasonably available, or does not have legal responsibility for the custody of the child

1.2 Plans should be described regarding if and how assent will be obtained and documented for IRB review and approval.

1.3 An Investigator must take into account the ages, maturity, and psychological state of the children involved when planning methods to obtain and document assent. The USA IRB recommends the following:

1.3.1 Parental permission utilizing an informed consent document;

1.3.2 Ages less than 7 years: An oral script in very simple language appropriate for children less than 7 years of age. The oral assent script should be conversational and stated in such a way that is understandable and age-appropriate;

1.3.3 Ages 7 to 11 years: This age group should be fully informed about the research, using language appropriate to their age and maturity, and assent should be obtained from those deemed capable of making a meaningful decision; and

1.3.4 Ages 12 to 18 years: Children in this age group should be fully informed about the research and documented assent should be obtained. The child may either sign his/her own Assent Form or may verbally assent to participate in the study, but in either case, the information provided to the subj š •Z}µo ‰‰Œ}‰Œ] š š} šZ]v]À] µ o[•
developmental abilities An assent form which may be in the same language as the adult consent document. In the instance, both the adolescent and the parents(s)/guardian(s) sign the form, with a signature line for the adolescent first. The signature line for parental consent/permission should follow.

1.3.4.1 Assent form should include:

- why the research is being conducted;
- what will happen and for how long or how often;
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  no;
- explanation if it will hurt and if so for how long and how often;
- what the child's other choices are;
- description of any good things that might happen;
- whether there is any compensation for participating; and
- ask for questions.

1.4 v /vÀ •š]P š}Œ •Z}µo v}š •}o]]š Z]o [• •• vš Á]šZ}
her wishes seriously. In situations where the potential benefits of the study are •µ Z šZ š šZ ‰ZÇ•]] v• v ‰ Œ vš• Á]oo voŒ}oo šZ
wishes, the child should simply be told what is planned and should not be deceived. In such cases, the Investigator should request a waiver for assent from the IRB before enrolling the child.

1.5

determination by the Secretary of the Department of Health and Human Services (DHHS) is received. The Office of Research Compliance will be notified when the IRB determines a study is determined to meet 45 CFR 46.407. Documentation sent to the Secretary include:

IRB minutes from the convened meeting documenting the IRB findings;
The complete IRB application and informed consent documents;
The relevant protocol and/or grant application; and
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applicable.

2.5.4 If DHHS Office of Research Protections (OHRP) grants approval under Category 46.407, then the IRB may grant final approval.

2.5.5 If OHRP requires changes in the process of approval, or any other Z v P • Œ u (š Œ š Z / Z ^ ‰ ‰ Œ } À ‰ v] v P _ amendment must be submitted for review and approved by the IRB Chair or his or her designee, unless the IRB Chair determines the changes submitted are major, which require IRB at a convened meeting.

2.6 When children as wards of the State are involved in research under 45 CFR 46.407, the required additional individual acting on behalf of the child as guardian or *in loco parentis* may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, v P Œ • š } š] v U š Z • š] v š Œ • š } (š Z Z] o (} Œ participation in the research and who is not associated in any way with the Investigators, or the guardian organization.

Regulated Documents:

45 CFR 46.116
45 CFR 46 Subpart D
45 CFR 46.404-46.407
21 CRF 50 Subpart D

University Related Documents:

SOP 701: Informed Consent
SOP 702: Consent Documentation
SOP 901: Research Involving Children

History:

Effective Date: January 2019
Revisions: November 2021

Responsible Office:

Office of Research Compliance and Assurance