IRB SOP 703
Informed Consent: Research Involving Children

Purpose

This Standard Operating Procedure (SOP) documents the ethical and regulatory considerations involving children involving in human subject's research. This SOP complements SOP 702: Informed Consent Documentation

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 to21ha (s)-5.1

criterion, but intellectual and emotional development also need be considered. The child must be able to identify the benefits and risks of the research, and to be able to reason about the consequences of participation as well as a typical 7 year old. A valuable function of seeking assent from the minor is to provide information that the minor and his/her parents may use in their decisions concerning the research.

In seeking assent, undue advantage should not be taken of the child's developmental limitations related to his/her voluntariness (acquiescence to authority figures and any lack of ability to express his/her rights).

4.0 Dissent of Children

Dissent from participation or withdrawal from research is always to be honored unless the protocol affords access to a therapeutic intervention that is not otherwise available. In that case, parental consent for therapeutic intervention may override a child's dissent. However, that information must be provided to the child prior to the intervention procedure.

5.0 Waiver of Assent

Parents or guardians may, with IRB approval, override a young child's objections to interventions that hold the prospect of direct benefit to the child in accordance with 45 CFR §46.408(a). Assent may also be waived by the IRB under 45 CFR §46.116(d).

6.0 Wards

Health and Human Services regulations at 45 CFR §46.408 set specific requirements for children who have been declared wards of the state or any other agency, institution, or entity.

1. Wards can participate in research approved under §46.406 or §46.407 if:
    a) The research is related to their status as a ward.
    b) The research is conducted in schools, camps, hospitals, institutions, or similar settings where the majority of children involved in research are not wards.

2. The IRB will require appointment of an advocate for each child who is a ward.
    a) The advocate serves in addition to any other individual acting on behalf of the child as a guardian or in the absence of the parent(s).
    b) The advocate may represent more than one child.
    c) The advocate must have the background and experience to act in the best interest of the child for the duration of the child's participation in research.
    d) The advocate must not be associated in any way with the research, the

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

7.0 Re-consent of participants reaching the age of majority

All minor participants actively participating in an IRB-approved study must be consented using the adult IRB-approved informed consent document at the first visit after reaching the legal age of majority. If the minor participated in a study that is completed, except for data analysis, re-consent is not required.

The now adult participant has the right to refuse to continue participation in the study. This is to be respected and undue pressure or coercion to continue may not be applied. While new data may not be collected on participants refusing participation, existing prior data collected under the assent/proxy consent process can be used.

If, upon reaching the age of majority, the now adult participant is found decisionally impaired or is of diminished capacity, the participant remains vulnerable and the proxy/parental consent remains in effect. This must be documented in the study records and the IRB must be notified.

8.0 Consent and Assent Documents

8.1 Parental/Guardian Consent Form

If the participant is under the age of 7 years, only a Parental/Guardian Consent Form is required. The Parental/Guardian Consent Form should include all relevant elements of informed consent as outlined previously and be wf -0.003 TnTT1 4

When your study is...	Then this is required...
Minimal Risk	One parent/legal guardian may be sufficient
Greater than Minimal Risk, Direct Benefit to participant	One parent/legal guardian may be sufficient but the IRB must determine whether one or two is required
Greater than Minimal Risk, No Direct Benefit to participate, but likely to yield generalizable 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

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1.5 Assent expires when a child becomes an adult. At that time, the subject must sign the IRB approved adult consent for the research study.

2.0 IRB Responsibilities

The IRB shall take care in approving research where the child is suffering from a life threatening illness with little real chance of therapeutic benefit from the research. The IRB shall be cautious in allowing the parents to overrule the child's dissent where experimental therapy has little or no reasonable expectation of benefit.

2.1 The IRB reviews the degree of risk and discomfort involved in the research in relation to the direct benefits it offers to the child before it can determine whether or not the IRB will approve the study.

2.2 When determining whether children are capable of assenting, the IRB shall take into account the age, maturity, and psychological state of the children targeted for the study population. This determination may apply to all children involved in the study, or on a case-by-case basis, as deemed necessary by the IRB.

2.3 The IRB determines the appropriate ages for assent and the method of documentation of assent.

2.4 The IRB must assure that special protections afforded to children found in 45 CFR 46, Subpart D have been met for this subject population. The IRB documents this review on the IRB Reviewer Form completed by the designated IRB member.

2.4.1 Although the IRB may determine that subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with 45 CFR 46.116

2.5 The IRB membership includes experts in pediatrics or field of profession involving work with children. When the IRB renders its determination, it will include:

2.5.1 The children's category and corresponding rationale under which the

History:

Effective Date: January 2019
Revisions: November 2021

Responsible Office:

Office of Research Compliance and Assurance