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IRB Connection

HUMAN SUBJECTS OFFICE

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Research with Children Edition

Federal regulations for the protection of human subjects (45 CFR 46) include a specific section (Subpart D) on the involvement of children in research. Children are a vulnerable subject population and their participation requires additional consideration by the IRB. Investigators conducting research with children should be familiar with the applicable regulatory requirements.

Risk and IRB Review

Federal regulations allow for approval of research involving children only if the IRB determines one of the following as provided in

1) The research does not involve greater than minimal risk to subjects (§46.404)
2) The research involves greater than minimal risk to subjects but presents the prospect of direct benefit to the individual subjects (§46.405)
3) The research involves greater than minimal risk and no prospect of direct benefit to individual subjects, but is likely to yield generalizable knowledge about the subject's disorder or condition (§46.406)
4) The research is not otherwise approvable but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (§46.407)

Under §46.407, an opportunity for public review and comment must be allowed. After public comment and consultation with a panel of experts, the Secretary of Health and Human Services makes a decision regarding approval of the research. Under all four possible determinations above, the investigator must propose adequate plans to solicit the assent of the children and permission of the parents or guardians.

Assent

The assent of children must be obtained when the IRB determines the children are capable of providing knowledgeable agreement. In making this decision, whether children are capable, the IRB takes into account the ages, maturity, and psychological state of the proposed participants. This judgment may be made for all children in a particular study, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the research procedure will directly benefit the health or well-being of the children and is available only in the context of the research, assent is not required. Even when the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under the same regulatory criteria in which waivers of consent are allowed.

Parental Permission

When parental permission is required, the IRB may determine that the permission of one parent is sufficient for research that does not involve greater than minimal risk (§46.404) or is more than minimal risk, but likely to benefit the child (§46.405). When research falls under §46.406 or §46.40, and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

The IRB may waive the requirement for parental permission for studies in which it is necessary to protect the subjects (e.g., neglected or abused children). A waiver of parental permission under these circumstances may be allowed provided there is an appropriate mechanism for protecting the children who will participate and that the waiver is not inconsistent with federal, state, or local law. The choice of an appropriate mechanism (e.g., appointing a child advocate or an assent monitor) depends upon the nature and purpose of the study, as well as the age, maturity, status, and condition of the subjects.

Applicable Regulatory Definitions

Children/Minors

Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted (45 CFR 46.402(a)). In the State of Iowa, the legal age of consent is 18.

Assent

A child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent (45 CFR 46.402(b)).

Permission

The agreement of parent(s) or guardian to the participation of their child or ward in research (45 CFR 46.402(c)). Note that permission is not consent.

Guardian

An individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care (45 CFR 46.402(e)).

Minimal Risk

The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 CFR 46.102(i)).

HawkIRB: Procedures for Obtaining Parent Permission and Assent

Describing Parental Permission

Investigators must provide a description of how permission from the parents/legal guardians of minor subjects will be obtained, as well as plans for the assent process in Section VII.D of the HawkIRB application. Similar to the manner in which consent for adult subjects must be described, the permission of parents/legal guardians for the participation of their children in research must include the following details:

1) How are parents/legal guardians informed about the study?
2) What are the procedures for obtaining permission from the parent/legal guardian?
3) How and when does the parent/legal guardian receive a copy of the Consent Document?
4) Are they given time to read the document?
5) Does someone on the research team review the document with the parent/legal guardian?
6) What does this review entail?
7) If permission will be obtained by mail, the details of this process and any follow-up must also be described.

Selecting and Describing the Assent Process for Minors

The HawkIRB application provides six options regarding the assent process for minors that may be selected for IRB approval. Investigators should select an appropriate assent process based on the subject population's age, maturity, and ability to read and comprehend a written document. The options provided in HawkIRB range from asking the minor to sign an assent or consent document (with their parent(s)), to obtaining verbal assent only, to no assent procedure because the investigator is requesting a waiver of assent. Investigators will also need to provide a detailed description and the rationale for each assent option selected. For example, if the option "minors will be given an assent or consent document to read, but will provide only verbal assent" is selected, a reasonable response is that because the subject population consists of children who are 7-10 years old, the children are able to read an assent document and provide verbal assent.

The federal regulations do not require a signed Assent Document for minors participating research. However, in most cases, some indication of agreement to participate must be received from the minor subject before beginning research procedures.

Additional Considerations: When Minors "Age Up"

Section VII.D of the HawkIRB application is also the appropriate place for investigators conducting longitudinal studies to describe plans for obtaining consent from minors once they "age up." Readers may recall the August 2013 newsletter which discussed UI IRB policy requiring investigators who have ongoing contact with subjects (continued interaction, ongoing data collection, etc.) to propose plans to obtain consent from subjects once they turn 18 for their continued participation in the research study.

Research with Children in Foster Care

There are specific recruitment and consent considerations for the enrollment of children who are wards of the court or in foster care. Investigators who intend to conduct research involving these populations will need to plan for identifying the legal guardian and obtaining permission from that person. Unless parental rights have been terminated, permission must be obtained from the parent. Investigators should keep in mind that the legal guardian may not be the person who has physical custody of the child. In some cases, the person who has physical custody may be able to consent for medical procedures but cannot provide permission for the child to be in a research study. For studies determined by the IRB to involve greater than minimal risk without a prospect of benefit to the child, an advocate will need to be appointed for each child who is a ward of the court.

Pregnancy in a Minor Subject Population

When a child undergoes a pregnancy test for research purposes, additional information must be provided in the Informed Consent Document (ICD). Minors in research must be afforded the same rights they would normally have in a clinical setting with regard to their privacy of test results. Minors 12 years of age and older should be offered the choice as to whether or not their pregnancy results will be shared with their parents/legal guardians. For children younger than 12 who have a positive pregnancy test, or if abuse is suspected at any age, the proper authorities must be informed and parents or guardians must be informed of the pregnancy. Specific language regarding pregnancy testing in children should be included in the ICD and is provided in the Appendix section of the template ICD form in HawkIRB. Additionally, investigators conducting research with minors should keep in mind that in the State of Iowa, anyone under the age of 18 is legally a minor unless emancipated sooner by marriage; childbirth does not emancipate minors. Investigators conducting research involving minors who have children of their own will need to obtain permission from the minor's parent/legal guardian for their participation in the study unless the minor is legally emancipated or a waiver of consent has been obtained.

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