PARENTAL PERMISSION AND CHILD ASSENT

Description

Parental permission and child assent is used prior to involving children in research. Investigators are responsible for ensuring that the permission of each child's parents or guardian is sought unless consent is not required by the IRB (i.e., waiver of consent is granted). This guidance outlines the requirements of parental permission and child assent in research.

Definitions

A. ***Assent*** means a participant's affirmative agreement to participate in research. In this guidance, *assent* refers to the child's affirmative agreement to participate in research. The absence of an objection, without affirmative agreement, should not be interpreted as assent.

B. The Department of Health and Human Servies (DHHS) and the Food and Drug Administration (FDA) definition of ***children*** are people who have not reached the legal age for consent to treatments or procedures involved in the research, under applicable law of the jurisdiction in which the research will be conducted. See IGS: Research Involving Children to read the applicability of this definition under Utah law.

C. The DHHS and FDA definition of a ***guardian*** is an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

D. ***Parent*** means a child's biological or adoptive parent. Utah state law specifies that any parent, whether an adult or a minor, may provide consent to health care for his/her child.

E. ***Permission*** is the agreement of parent(s) or guardian to the participation of their child or ward in research.

Category of Risk in Children's Research and Parental Permission

Parental permission is required for children involved in research as outlined in Subpart D (Additional Safeguards for Children Involved in Research). First, the University of Utah Institutional Review Board (IRB) must determine which approvable category the research falls under. The requirement of obtaining permission from one parent/guardian or both parents/guardians varies depending on the category under which the research falls, as explained in detail below.

Regulatory Category of Permitted Research with Children	Is permission required from one parent or both parents?
(1) The research is **minimal risk**. [45 CFR 46.404; 21 CFR 50.51]	The IRB determines whether the permission of **one parent or both parents** is required.
(2) Greater than minimal risk with the prospect of direct benefit or may contribute to the well-being of the child. [45 CFR 46.405; 21 CFR 50.52]	The IRB determines whether the permission of **one parent or both parents** is required.
(3) Greater than minimal risk and no prospect of direct benefit, but likely to yield generalizable knowledge about the child's disorder or condition. [45 CFR 46.406; 21 CFR 50.53]	**Both parents** must give their permission.
(4) Research not otherwise approvable, but which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. Research in this category must be reviewed and approved by the Secretary of DHHS or the Commissioner of the FDA. [45 CFR 46.407; 21 CFR 50.54]	**Both parents** must give their permission.

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.

When Both Parents Must Give Permission
When permission is required of **both parents**, both 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.

- ☑ "Not reasonably available" does not apply to situations when a parent is at work, traveling, not immediately available by electronic means, or living in another state or country, without more to justify the investigator's inability to reach the parent and seek permission. For more, see *Parental Permission in Research Involving Children, Focusing on "Not Reasonably Available"* (link at end of document).

Parental Permission

Children may be included in research only if parental permission is obtained in writing from the parents or legal guardian as outlined in the chart above, except where the IRB has explicitly waived such permission or in cases where the person is no longer considered to be a child (refer to the Investigator Guidance Series: Research Involving Children).

Guardians
In Utah, a guardian is a person who has qualified as a guardian pursuant to testamentary or court appointment, or by written instrument. Utah state law allows for a guardian to "consent to any health care not prohibited by law" for the guardian's ward and therefore meets the DHHS and FDA definition of guardian. The University of Utah IRB will accept permission from a guardian for a child to participate in research provided that the researcher has established that the guardian has legal authority to do so.

- ☑ The researcher should retain a copy of the documentation that validates an individual's status as a guardian.

For research involving children that takes place outside of Utah, the investigator is responsible for identifying individuals who meet the DHHS and FDA definition of "guardian" and making a clear outline of how the study team will validate an individual's status as a guardian.

Under what circumstances may parental permission be waived by the IRB?
The required elements of informed consent also apply to parental permission. The elements of parental permission may be altered or waived entirely consistent with the provisions for waiver contained in 45 CFR 46.116. Parental permission may not be altered or waived for FDA-regulated research.

In addition to the provisions for waiver contained in 45 CFR 46.116, a waiver may be granted if the IRB determines that a non-FDA regulated research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the children (e.g., neglected, or abused children) under 45 CFR 46.408(c). This waiver may be granted only when an appropriate mechanism for protecting the children who will participate is substituted and provided the waiver is not inconsistent with federal, state, or local law.

Documentation of Parental Permission
The requirements for documentation of parental permission are the same as for documentation of informed consent. A waiver of documentation may be granted according to the same conditions as with documentation of informed consent .

Investigators may combine a consent document with parental permission if it is clear throughout the document that both consent and parental permission are being sought. The language throughout the document should refer to both the parent and child.

- ☑ The signature block for the 2nd parent should only be included on a parental permission document when requested by the IRB.

Assent

Investigators must provide the IRB with information regarding the plan to obtain assent from children involved in the research. Because the IRB must evaluate the age, maturity, and psychological state of the children, it is important for the investigator to provide as much information about the children who will be recruited. **Generally, the IRB requires assent from children 7 or older but this may vary depending on other factors.** Once the IRB has enough information about the assent process, the IRB determines whether assent is a requirement of all children, some of the children or none of the children.

Under what circumstances is assent not required by the IRB?
If assent is NOT a requirement for some or all children, the IRB must make one (or more) of the following findings:

- The children are not capable of providing assent based on the age, maturity, or psychological state.
- The capability of the children is so limited that they cannot be reasonably consulted.
- The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the child and is available only in the context of the research.
- The assent process is entirely waived consistent with the provisions for waiver of consent contained in 45 CFR 46.116 (consistent with the provisions for waiver of consent/parental permission). Note: The University of Utah IRB does not require investigators to complete waiver of consent form in ERICA

Examples:

1. A study involves teenagers from ages 12-16 years old. The researcher plans to recruit teenagers who appear to be of appropriate age and maturity and appear to be in an appropriate psychological state to assent to be in research. The IRB would likely determine assent is a requirement of all the children.
2. A study involves infants from ages 3 months to 9 months old. The IRB determines assent is not required or any of the children. The IRB would likely determine the children are not capable of providing assent based on the age of the children.
3. A study involves children from ages 1-10 years old. A toddler would be unable to assent to the procedures involved. The IRB determines that the assent is required of only some of the children. For those under the age of 7, the IRB would likely determine the children are not capable of providing assent based on age of the children. For those 7 or older, the IRB would generally require assent be obtained.
4. A study involves children from ages 9-17 years old. The researcher plans to recruit children that are cognitively impaired due to traumatic brain injury. The IRB may determine assent is not required of any of the children because the capability of the children is so limited that they cannot be reasonably consulted.

Documentation of Assent
Once the assent process has been completed, an assent document will typically be used to document assent. If the investigator plans to document assent using another method or does not plan to document the assent process, the IRB must approve of such a plan.

The assent document should be written in a way that is suitable for the child's age. Typically, the University of Utah IRB recommends one assent document to be written for younger children (7-11) and one assent document for older children (ages 12-17). In some cases, one assent document would be acceptable (e.g., the study is enrolling children ages 10-15 and uses one assent document).

Children Who Reach the Legal Age of Consent

What is required when a child reaches the legal age of consent?
Informed consent is an on-going process throughout the duration of a research project. When a child who was enrolled in research with parental/guardian permission subsequently reaches the legal age of consent to the procedures involved in ongoing research, the investigator should seek and obtain legally effective informed consent for the now-adult participant for any ongoing interactions or interventions with the participants unless the IRB determines that the requirements for obtaining informed consent can be waived. Prior parental permission and child assent are not equivalent to legally effective informed consent for the now-adult participant.

If the study does not have an IRB-approved consent document for adult participants, an amendment is required to obtain approval of the consent document prior to use.

Points to Address

New Study Application:	1. **Consent Process page:** Both the parental permission and assent process should be described. • When describing the plan to obtain assent, include any details regarding the age, maturity, psychological state of the children, or cognitive impairments that will help the IRB assess whether assent will be a requirement of some, all, or none of the children. • The plan for documentation of parental permission and assent must be described in detail. • If a child may reach the age for legal consent during their participation in the study, outline the procedure for obtaining consent.

References & Links

Additional Protections for the Inclusion of Children in Research (OHRP): 45 CFR 46, Subpart D	*http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartd*
Additional Protections for the Inclusion of Children in Research (FDA): 21 CFR 50	*https://www.ecfr.gov/cgi-bin/text-idx?SID=c1bb67c3931c37346737f72ba213bd81&mc=true&node=pt21.1.50&rgn=div5*
Consent Document Models – Assent Models and Parental Permission Models	*https://irb.utah.edu/informed-consent/consent-document-models.php*
Investigator Guidance Series: Research Involving Children	*https://irb.utah.edu/guidelines/investigator.php*
Parental Permission in Research involving Children, Focusing on "Not Reasonably Available", SACHRP Recommendation, October 17, 2018	*https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-d-november-13-2018/indes.html*