Obtaining Assent from Minors

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Objectives

- Definitions
- Requirements
- Obtaining Assent
- Documenting assent
- Assent waivers
- Special circumstances & considerations

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Definitions

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Minors (Children)	Minors are who have not attained the legal age for consent in research under the jurisdiction of law. In Texas, a minor is <18.
Emancipated Minor	A minor who wishes to have the legal capacity of an adult can ask a Texas court for the *removal of disabilities of minority*.
Assent	A child's affirmative agreement to participate in research.
Permission	The agreement of parent(s) or guardian to the participation of their child in research.
Parent	A child's biological or adoptive parent.
Guardian	An individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care.

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Is child assent always required when research involves children?

No

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Requirements

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Considerations of Assent

Required when… children can provide assent. (45 CFR 46.408(a))

May not require if research provides prospect of direct benefits to health or well-being of child & only available in the research context. (45 CFR 46.408(b))

May be waived in accordance with (45 CFR 46.116)

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Age Range	Assent Required?	Parental/Guardian Permission Required?	Comments
Birth – Age 6	No	Yes	Capability is so limited that they cannot reasonably be consulted.
Ages 7 – 10	Yes	Yes	Children may be capable depending on the maturity and psychological state. Verbal or written assent may be required but must not be waived by the IRB if the child is unable to provide assent.
Ages 11 – 17	Yes	Yes	Children are expected to be capable of providing assent. Written assent is usually required unless waived by the IRB.

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Subpart-D Parental/Guardian Signature Requirements

Determination	Provisions	Signature Requirements
Minimal Risk (45 CFR 46. 404/21 CFR 50.54)	Adequate provisions are made for soliciting the Assent of children and Parental\LAR consent (46.408, 21 CFR 50.55).	One parent is sufficient
Greater than Minimal risk with the prospect of direct benefit to the participant (45 CFR 46. 405/21 CFR 50.55)	The risk\benefit is justified. Adequate provisions are made for obtaining the Assent of the children and Parental\LAR consent (45 CFR 46.408).	One Parent is sufficient

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Subpart-D Parental/Guardian Signature Requirements

Determination	Provisions	Signature Requirements
Greater than Minimal risk with no prospect of direct benefit but likely to yield generalizable knowledge (45 CFR 46. 406/21 CFR 50.56)	The risk is an increase over only minimal risk. The risk of the intervention or procedure is reasonably commensurate with those inherent in actual, or expected medical, dental, psychological, social, or educational situations. Generalizable knowledge is likely from the research which is of vital importance for the understanding or amelioration of the disorder or condition. Adequate provisions are made for obtaining the Assent of the children and Parental\LAR consent (45 CFR 46.408).	Both parents unless one is deceased, unknown, incompetent, or not reasonably available, only one parent has legal responsibility for the care\custody of the minor.

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Subpart-D Parental/Guardian Signature Requirements

Determination	Provisions	Signature Requirements
Research that the IRB believes does not meet the conditions of 45 CFR 46.404, 46.405, or 46.406, but finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children. (45 CFR 46. 407 B)	The research may proceed only if the Secretary, HHS, after panel experts' consultation and following an opportunity for public review and comment, determines either: (1) that the research in fact satisfies the conditions of 45 CFR 46.404, 46.405, or 46.406, or (2) the following: • to understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; • the research will be conducted in accordance with sound ethical principles; **and** • adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in regulations at 45 CFR 46.408. If the research involves a product that is FDA-regulated, FDA's regulatory requirements at 21 CFR 50.54 must also be met.	Signature requirements based on the regulations at 45 CFR 46.408

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IRB Considerations for Assent

- IRB considers the ages, maturity, and psychological state of the children and information conveyed in assent.
- The nature of the proposed research activity.
- Child capacity to provide assent in a research project.
- Adolescent consent forms may be similar to adult consent forms.
- The assent procedure should reflect a reasonable effort to enable the child to understand, to the degree they are capable, what their participation in research would involve.

Obtaining Assent

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Process of obtaining consent from parents

- When only one parent accompanies the child to a visit, they should be asked to provide the contact information of the other parent. The investigator/study team should contact the other parent to discuss the study and to arrange to obtain consent.
- The child may not be enrolled until the study team has obtained consent from both parents and assent (as applicable). It is important for the investigator to document all attempts to contact the absent parent, along with the basis for any determination that they are “reasonably unavailable.”

Assent

- If assent is determined appropriate the investigator must obtain assent from minors deems capable of understanding the nature and consequences of participation in the study regardless of the age.
- The child should be given an explanation, at a level appropriate to the child's age, maturity and condition, of the procedures to be used, their meaning to the child in terms of discomfort and inconvenience, and the general purpose of the research.

Documenting Assent

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Documentation

- Permission by parents or guardians shall be documented in accordance with and to the extent required by 46.117 of subpart A of 45 CFR part 46.
- Essentially, parental permission should be documented in a manner like that used to document informed consent.
- IRB may find that waiver of documentation of informed consent is appropriate under the regulations at 46.117.
- Assent can be documented in a manner like that used to document adult consent (e.g., medical records, EPIC, REDcap, etc.,)

How should child assent for research participation be documented?

- If assent is determined appropriate, documentation of assent is required. Generally, assent of the child is documented by having the child sign the consent form in the designated signature section.
- If a child is enrolled onto a study and turns 10 while actively participating on a study, written assent must not be documented. However, the study team should continue the consent conversation with the child and parent/guardian throughout the study.
- Documenting the assent that you obtained from child in the medical records.

Minimal Risk Studies – Signature Section

- One Parent or Guardian signature is required unless the IRB waived.

Surrogate Signature Section			
Printed Name of Participant	Signature of Participant Giving Assent (*If incapable of signing, person obtaining consent should initial here*)	Date	AM PM Time
Printed Name of Person Giving Consent for Participant (If applicable)	Signature of Person Giving Consent ☐Parent/☐Guardian/☐Legally Authorized Representative	Date	AM PM Time
Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date	AM PM Time

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More than Minimal Risk Studies – Signature Section

- Two Parent or Guardian signature is required unless the IRB waived.

Signature Section (two parent signatures)

Printed Name of Participant	Signature of Participant giving Assent (*If incapable of signing, person obtaining consent should initial here*)	Date	Time AM PM
Printed Name of Parent 1 Giving Consent for Child	Signature of Parent 1 Giving Consent	Date	Time AM PM
Printed Name of Parent 2 Giving Consent for Child	Signature of Parent 2 Giving Consent (***Required unless:*** *deceased, unknown, incompetent, not readily available, or no longer has legal parental rights)*	Date	Time AM PM
Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date	Time

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Assent Waivers

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When does child assent for research be waived?

- The IRB may waive its requirements for obtaining or documenting assent if the IRB determines:
- Capability of some or all of the children are limited such that they cannot be reasonably consulted, or
- The research intervention or procedure(s) involved hold out a prospect of direct benefit that is important to the health or well-being of the children, and is available only in the context of the investigation, or
- The research meets the following requirements:
  - the research involves no more than minimal risk to the participants; and
  - the waiver will not adversely affect the rights and welfare of the participants; and
  - the research could not practicably be carried out if assent was required; and
  - If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format; and
  - When appropriate, pertinent information is provided after participation.

Special Circumstances & Considerations

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Do parental permission and child assent for research involving children have to occur at the same time or in any order?

HHS regulations do not specify the order.

IRB have the discretion to determine the appropriate order.

At UTSW, the appropriate order is determined based on the type of research and the context in which research will be conducted.

More than minimal risk research – parental or guardian permission before seeking child's assent unless IRB waives parental or guardian permission.

Minimal risk research – if applicable child assent prior to seek parental or guardian permission (based on IRB's discretion).

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What happens when there is disagreement between a child and parents about research participation?

- For a research study, IRB determined that Child's assent needs to be sought and documented.
- For example, Child does not want to participate in that research, but parents or guardians provided granted permission for child's participation then What do we need to do?

THE CHILD'S DECISION PREVAILS

- However, if the procedures involved in the research holds out the prospect of direct benefit to child's health and wellbeing, and is only available in the context of the research, then research team can request IRB may waive the assent requirements for consideration as per the regulations under 45 CFR 46.408(a)

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If by law a child can consent to treatment without parental permission, can they also consent to participate in research related to that treatment?

If research on a specific treatment involves solely treatments or procedures for which minors can give consent outside the research context (under applicable state and local laws, for example, research on sexually transmitted diseases or pregnancy), such individuals would not meet the definition of children as defined at 45 CFR 46.402(a).

Thus, additional protection for children (subpart D) would not apply to the research and parental permission (or waiver thereof) is not a consideration for these minors. Under these circumstances, minors may provide their own informed consent.

What happens if a child reached the legal age of consent while enrolled in a study?

- As per the regulations, informed consent is an ongoing process throughout the duration of a research participant.
- When a child was enrolled in research with parental or guardian permission and subsequently child reached the legal age of 18 (as per Texas state law) in an ongoing interactions or interventions in the research, then under the requirements of 45 CFR part 46.408 regulation child's participation is no longer regulated regarding parental or guardian permission and subject assent.
- Similarly, if research does not involve any ongoing interaction or interventions with the subjects but where research involves continuously to collect the identifiable data or specimens, then it would be important to obtain the legally effective informed consent of the now-adult subjects.
- However, under both circumstances, IRB may consider, if appropriate, a waiver under 45 CFR 46.116(d) of the requirements for obtaining informed consent for the subjects to continue their participation in the research.

What happens when a parent says no to discussing assent with child?

- Under 45 CFR §46.405 regulations where one of the criteria is adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in §45 CFR 46.408.
- §45 CFR 46.408 further states that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that 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 children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research.

Special Circumstances

1) If parents are separated and only one parent retains custody of the child, does the research team still needs the permission of the other parent?

- You may proceed with single parent who has legal custody for the child and can be documented during consent/assent process under subpart D regulations.

Special Circumstances

2) If the parent asks not to contact the other parent for some reasons as an example of other parent is not involved in the child's life. How to proceed?

- Document the reason during consent/assent process due to not reasonably available, so obtained only single parent signature. Be very cautious with this approach to ensure that you do not violate any court orders.

Special Circumstances

3) How to document if one of parent is unknown that no idea or no way to contact the other parent for child's research?

- Research note or note to file to explain about the 'unknown' situation for the other parent unable to get the signature for child's research.

Special Circumstances

4) How many attempts can be made to reach the other parent to obtain the signatures?

- There are no guidance or regulations around this, but the best practice is to try 3 times and document every time about trying to reach the secondary parent.

Special Circumstances

5) When both parents are not present at the initial contact with the research team, can the research team consent one parent and child (who can participate at that time) and later contact other parent?

- This is appropriate, if the research procedures are not performed before obtaining both parents signatures and documented properly about the consent process.
- The participant may not be considered as “enrolled” to research until two parent signatures are obtained in this scenario.

Special Considerations

- In Texas, a minor may consent to medical, dental, psychological, and surgical treatment for him or herself, and hence may also consent to research for the same circumstances/treatment, if the minor is:
  - is on active duty with the armed services of the United States of America;
  - is:
    - 16 years of age or older, and
    - residing separate and apart from the his/her parents, managing conservator, or guardian (with or without consent and regardless of duration), and
    - managing his/her own financial affairs (regardless of the source of the income);

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Special Considerations

- is seeking the diagnosis and treatment of an infectious, contagious, or communicable disease that is required by law or a rule to be reported by the licensed physician or dentist to a local health officer or the Texas Department of Health, including all diseases within the scope of Section 81.041, Health and Safety Code;
- is unmarried, pregnant and consents to hospital, medical, or surgical treatment, other than abortion, related to the pregnancy;
- is seeking an examination and treatment for drug or chemical addiction, drug or chemical dependency, or any other condition directly related to drug or chemical use; or
- is serving a term of confinement in a facility of the Texas Department of Criminal Justice.

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Take home message

- Assent may be required and should be an ongoing process.
- The process for obtaining oral and/or written consent for children and minors is similar to that of obtaining consent for adults.
- Assent and/or Parental Permission should be documented, although the IRB may modify the standards based on age, maturity, developmental status or other considerations that may determine the appropriateness of a given approach.
- The IRB may waive assent for children in cases where the IRB determines that the child or children are incapable of providing assent.
- Certain special provisions and circumstances needs to be considered for assent process.

Questions?

Thank you for attending.

We'd love to hear your feedback. We invite you to provide your evaluation of Research Matters and of the Human Research Protection Program.

https://ais.swmed.edu/redcap/surveys/?s=3PRJFCFJJW

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