Little Voices, Big Choices

Best Practices in Pediatric Research Consent and Child Assent and Other Considerations

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September 25, 2025

Objectives

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- Insight on how the IRB reviews/approves research involving children
- Learn best practices for obtaining parental consent
- Improve approaches to child assent
- Consider additional ethical and practical factors in pediatric research

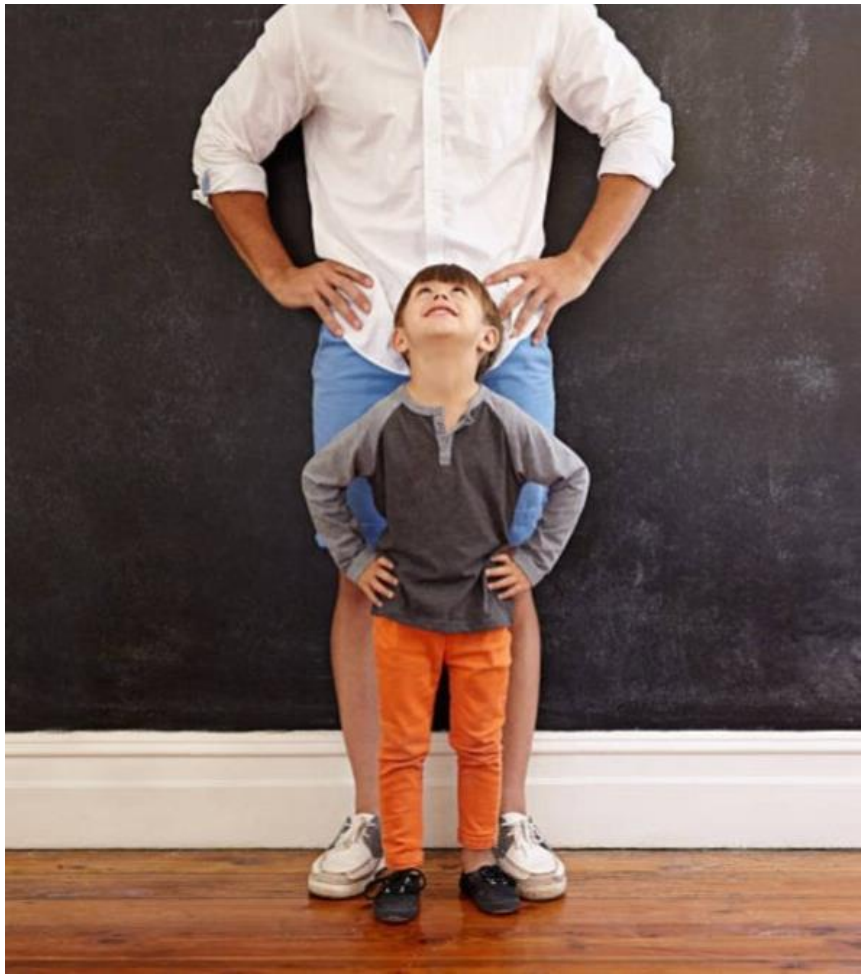
Obtaining Parental Permission and Child Assent

Informed consent is **required** for research involving human subjects, including children.

Since children cannot legally provide informed consent, additional protections are necessary.

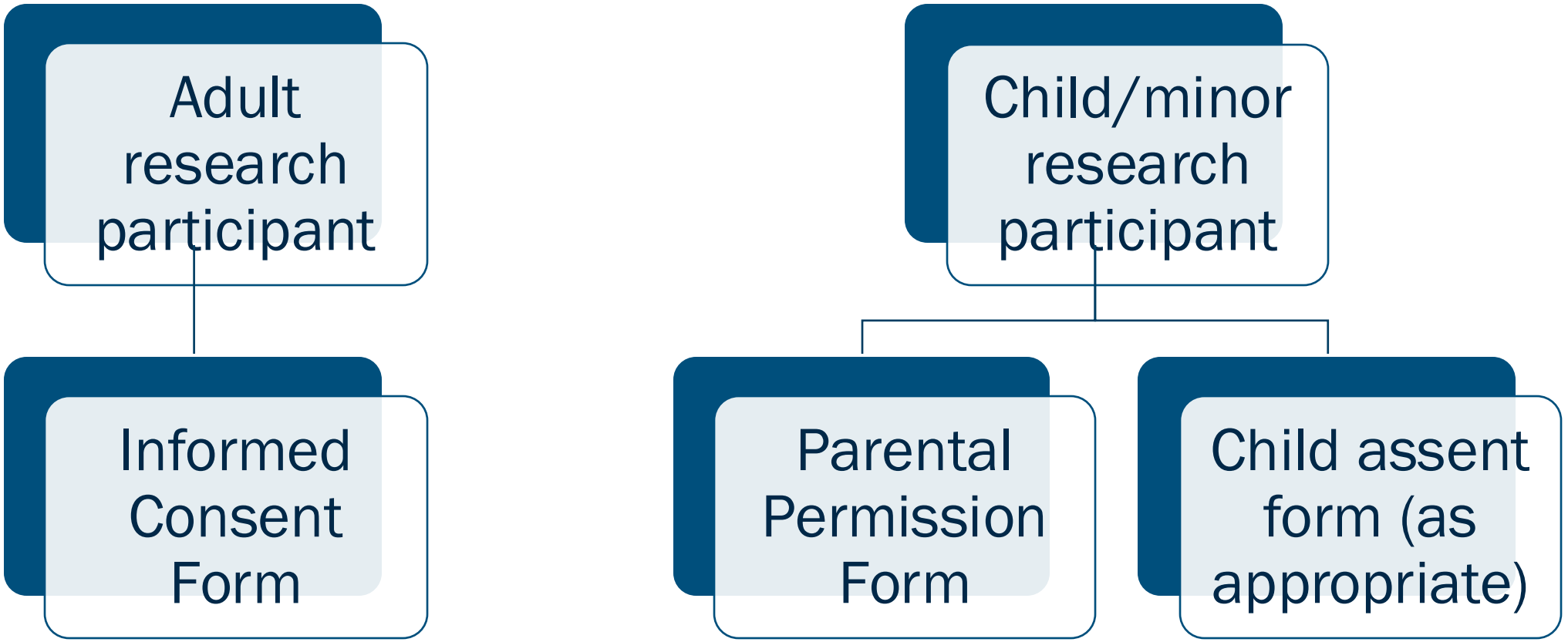
Parental permission and child assent must be obtained before a child can participate in research.

Different considerations for parental permission and child assent.



What does this mean?

Special requirement for research involving children in research

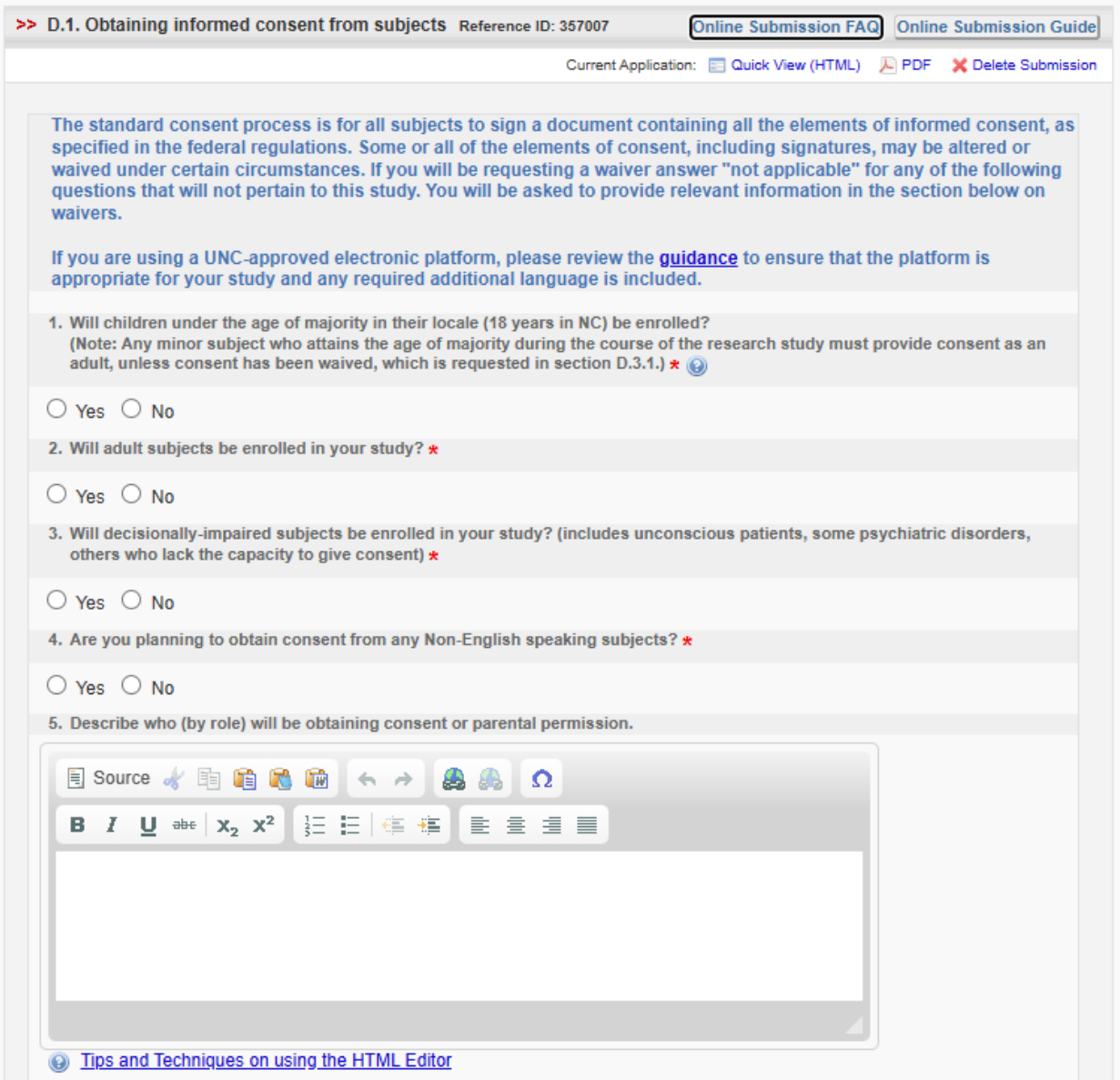


What information needed for IRB Approval?

- Make children's involvement clear from the start.
- Even chart reviews should mention if they intend to get medical records from child subjects
- The reason we need to know is that we need to be sure that risk mitigation strategies are appropriate for the inclusion of children in the study activities
- We also need to be sure that you have put good practices into place for the consent and assent process for the child subjects (unless you are applying for a waiver).

IRB Submission (Local IRB)

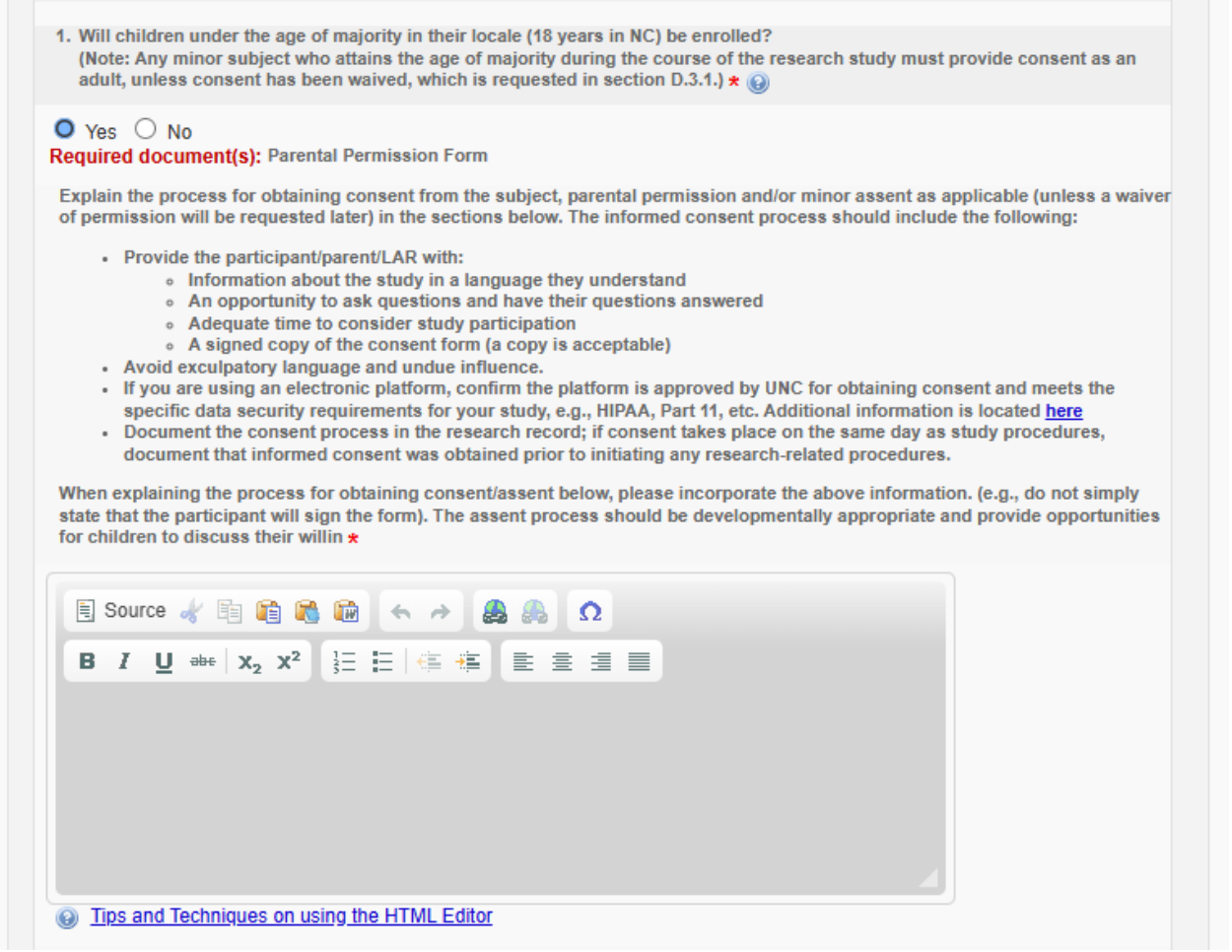
UNC IRB application



IRB Submission (Local IRB) - continued

UNC IRB application

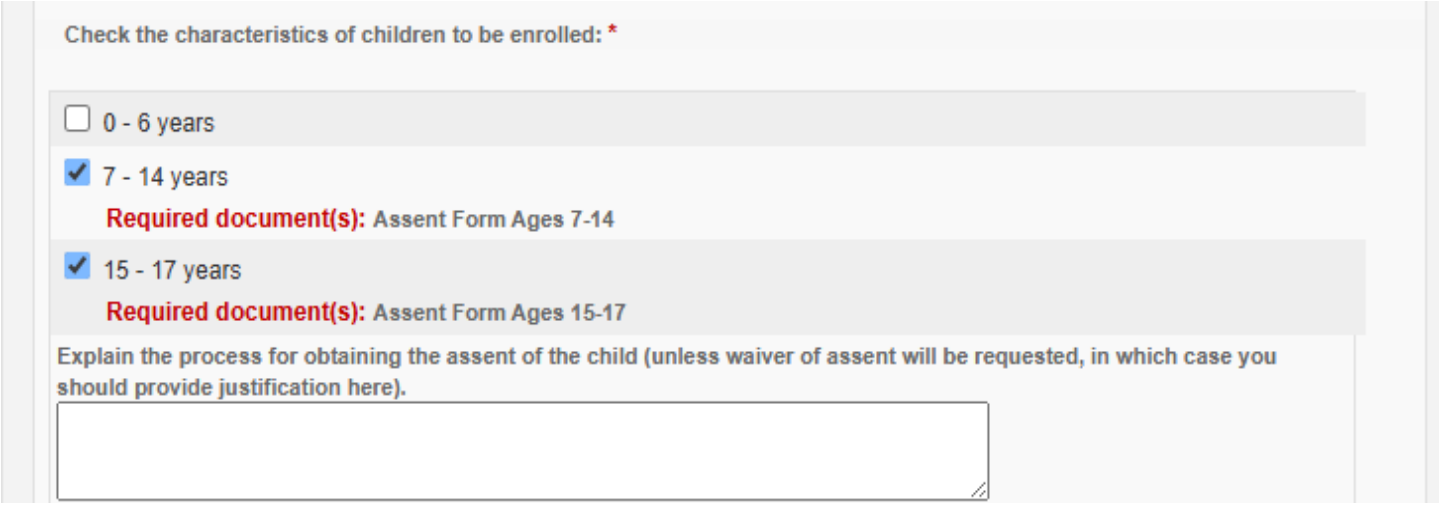
- Guidance for language to include for parental permission.



IRB Submission (Local IRB) - continued

UNC IRB application

- Assent forms to be appropriate for specific age



IRB Submission (Commerical IRB)

- Commercial IRB submissions will also want to know if study teams intend to include children in research
- Sponsor may have already submitted the study wide application, and the commercial IRB may have already determined assent and at what age.
- Study teams should still think critically and be thoughtful of the study and target population
- Study team should evaluate the consent templates to make sure the risk level is in alignment

Parental Permission

- Permission = agreement of parent(s) or guardian to the participation of their child or ward in research.
- Parent = 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.
- Parental permission is essentially a similar manner to obtaining informed consent for adults.
- One or both parents/guardian must be provided with key study information in order to decide whether to allow the child to participate.

Level of Risk

- 4 main categories of risk
  - Each category are based on level of risk involved, prospect of direct benefit to the research subject, and the anticipated research findings.
- All four categories must satisfy the requirements for parental or guardian permission and child assent.
- Required signatures of parent(s) or guardian are determined by the IRB and the overall determination of level of risk.

Level of Risk (Continued)

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Category 1 45 CFR 46.404	Category 2 45 CFR 46.405	Category 3 45 CFR 46.406	Category 4 45 CFR 46.407
Research not involving greater than minimal risk to the children.	Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual child subjects involved in the research.	Research involving greater than minimal risk and no prospect of direct benefit to the individual child subjects involved in the research, but likely to yield generalizable knowledge about the subject's disorder or condition.	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.

Level of Risk (Continued)

Three of the four categories of human research involving children may be approved by an Institutional Review Board (IRB).

Category 1
45 CFR 46.404

Research not involving greater than minimal risk to the children.

Category 2
45 CFR 46.405

Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual child subjects involved in the research.

Category 3
45 CFR 46.406

Research involving greater than minimal risk and no prospect of direct benefit to the individual child subjects involved in the research, but likely to yield generalizable knowledge about the subject's disorder or condition.

Level of Risk (Continued)

Category 1: 45 CFR 46.404 – Research not involving greater than minimal risk to the children.

Category 2: 45 CFR 46.405 - Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual child subjects involved in the research.*
(in some circumstances, 46.405 may require two parent signatures)

One parent/guardian signature required

Level of Risk (Continued)

Category 3: 45 CFR 46.406 - Research involving greater than minimal risk and no prospect of direct benefit to the individual child subjects involved in the research, but likely to yield generalizable knowledge about the subject's disorder or condition.

Category 4: 45 CFR 46.407 - 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

Two parent/guardian signatures required

Level of Risk (Continued)

- One study can have more than one child finding if there are different subject groups being subjected to different risks.
- For example, studies with a purely observational control arm and interventional arm where the intervention presents greater than minimal risk. This may mean that the study receives both a 404 and a 406 findings, and that two parent consent only needs to be obtained for kids in the interventional arm.

Two Parent Signature Considerations

Consider when/how to review the study permission form to the parents.

- Will both parents be present at the first visit?
- Review the consent with both parents by phone if one parent will not be at the first visit
- If review prior to visit, have one parent sign the form prior to the visit and have other parent bring original to the first study visit to sign with the study team.
- Study team will need to document process on Documentation of Informed Consent form and/or with NTF

Two Parent Signature Considerations

- Like the first signature, the second signature has to be from someone that has legal decision making authority over the child
- This could be a second parent or a legally appointed guardian
  - If there is a court appointed guardian for the child, they will have paperwork proving their authority
  - In cases where the child's parents are divorced, it is generally the case that the non-custodial parent still retains a legal say in decisions for the child, so you would need both of those parents to sign the consent form unless there is proof (like court paperwork) that the other parent does not have a right to make these decisions for the child

Two Parent Signature Considerations

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What if the second parent not available?

- Specific considerations only:

Consent must be provided by two parents. If consent cannot be provided by the second parent, provide the reason(s) below.

The second parent:

- ☐ Is deceased
- ☐ Is unknown
- ☐ Is not legally competent
- ☐ Does not have legal custody
- ☐ Is "not reasonably available"
- ☐ Other reason: _____

- Reason should be documented on Consent form (if req by IRB) and also documented on DOIC.

Child Assent

- Assent = a child's affirmative agreement to participate in research.
- Child must actively show his or her willingness to participate in the research, rather than just complying with directions to participate and not resisting in any way.
- Silence is not assent. The child must actively agree.

Child Assent

- IRB will consider different factors to determine if child is capable of assent
  - Such as age, maturity, developmental level, and psychological state of the children involved.
- Important for study teams to be able to explain at the level of the child, so that they will be able to understand what is being asked of them
- Level of detail will vary based on maturity levels.
  - Adolescent will understand more than school age and this should be reflected in the assent documents.

Considerations for Obtaining Assent

Consider the research activity and the age, maturity, and psychological state of the children involved.

Develop assent procedures that enable the child's understanding of their participation.

IRB may determine to use written assent forms for children aged seven and older, adapted for their reading level.

Study assent forms are often developed with a specific age range.

- Examples would be separate forms for ages 7-10, 11-14, 15-17

Considerations for Obtaining Assent (Continued)

Study teams must get consent from parents AND assent from the child before the child can be enrolled in the study

- If the parent(s) consent but the child does not provide assent or expresses dissent, then the child should not be enrolled.
- If the child provides assent, but the parent(s) do not provide consent, then the child should not be enrolled.

Which comes first?

Regulations do not indicate the order in which to get parental permission and child assent.

Most often, study teams will get parental permission first.

After obtaining parental permission, then the study team can focus on reviewing the assent with the child.

Set up for success

- When approaching the child for assent, it is helpful to be very clear that it is their choice to participate.
- It can be very empowering for the child to know that they have a voice.
- For younger ages, celebrate the opportunity for the child to decide and then be able to sign* the assent form.

*Young children may not be able to provide a true signature. Instruct them to write their first and last name the best they can. Document any notes on the DOIC regarding their signature. Ex. Subject only able to write nickname, etc.

Aging up during the research study

- Informed consent process should be an ongoing process throughout the study.
- Reconsent and reassent should be completed if there is new information that impacts safety, benefits, or willingness to participate
- Consider re-assent as the child enters a new age cohort for which there is a different assent process/form.

  *This is not mandated by regulations and may differ among study teams.
- Study team will need to consent the child when they reach age of majority (18 years old).

  *This is mandated and required by regulations.

HIPAA Considerations

- HIPAA form is still used for research with children but with additional considerations.
- The HIPAA form is a legal document that should only be signed by adults (18 and older).
  - Signed by participant if research subject is an adult
  - Signed by parent if child is research subject
    - Personal Representative: Include signature, printed name and description of authority, ex parent, mother, father
- If study will not ever include those over 18, consider removing the participant signature line to avoid confusion.

HIPAA Considerations

- Example signature block for minor only study:

Print Name of Participant

Personal Representative of the Participant (for participants <18 years old or as otherwise applicable):

Signature of Personal Representative

Printed Name of Personal Representative

Description of Authority to Act for the Participant

Date

When do we need a HIPAA?

- If study teams do not need any information from EMR, ex. all info is provided verbally from patient/parent/guardian, then HIPAA may not be required.
- IRBIS B.2.2. Will you need ongoing access to PHI (e.g., medical records) to conduct the study beyond identification of potential subjects as addressed above OR will you need to retain PHI obtained for screening? In this case, you will need to obtain a signed HIPAA Authorization from each subject.
- If there is any potential that study teams will need to access EMR for any reason, HIPAA is required
  - Ideal to get signed HIPAA at the time of getting signed parental permission/consent

Questions

References

- Content
  - https://clinicalresearch.unc.edu/playbooks/my-study-lifecycle/study-conduct/obtaining-parental-permission-and-child-assent/
  - https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/children-research/index.html
- Images
  - https://www.istockphoto.com/photo/little-boy-copying-his-fathers-pose-gm476733674-66195207?searchscope=image%2Cfilm
  - https://www.shutterstock.com/image-photo/photo-cheerful-confident-kid-dressed-white-2444457125
  - https://www.mindchamps.org/blog/teach-kids-decision-making-skills/
  - https://insight.ieeeusa.org/articles/effective-questioning-techniques/

Evaluation

Please complete the post-session evaluation. https://go.unc.edu/NRPSurveyPedsICF in the chat or scan the QR code.

Email: NRP@unc.edu if further questions or suggestions for future education.