Obtaining Assent and Parental Permission

Tricia Eifler, CIP
Assistant Director
Office of Research Integrity and Compliance
Ann & Robert H. Lurie Children’s Hospital of Chicago
Subpart D – Children as a Vulnerable Population

- **Children** - persons who have not reached the legal age for consent to treatments or procedures involved in the research
- **Assent** - a child's affirmative agreement to participate in research
- **Permission** - the agreement of parent(s) or guardian for the participation of their child or ward 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
Subpart D – Risk Categories

- **46.404** Research involving no greater than minimal risk to subjects

- **46.405** Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

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

- **46.407** Research that the IRB believes does not meet the conditions of 404, 405, or 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.
When is Parental Permission Required?

- Parents or guardians must provide permission for a child under the age of 18 to participate in research
  - Unless parental permission is waived by the IRB
- One parent may sign the parental permission for research with risk determination of 404 or 405
- Two parents must sign the parental permission for research with risk determination of 406 or 407
Considerations in Obtaining Parental Permission

- Recommended that parental permission be sought prior to assent
  - For some studies (e.g., studies in a classroom setting), it may be appropriate for the assent to be obtained first
- Same regulations apply as obtaining informed consent
  - Required elements of informed consent
  - Must be obtained prior to beginning any study procedures
When One Parent is Unavailable

- Research with risk category 406 or 407 requires both parents to provide permission
- Only one parent may sign if the other parent is not reasonably available
  - E.g., one parent is deceased, unknown, incompetent, or when only one parent has legal responsibility for the care and custody of the child
- When only one parent accompanies the child to a visit, the research team should contact the other parent to discuss the study and to arrange to obtain parental permission
  - The phone consent process may be followed, and the signed parental permission be scanned, mailed, or faxed.
  - The signature pages must be combined in regulatory files
When can Parental Permission be Waived?

- The protocol design includes conditions or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects
  - E.g., study includes neglected or abused children
  - The study must include an appropriate mechanism to protect the children
- The IRB grants a waiver of Parental Permission when the research meets the same conditions as those for waiver of informed consent in research involving adults
- Waivers of parental permission are not allowed for FDA regulated research
When is Assent Required?

- The regulations do not specify a required age for obtaining assent
- Lurie Children’s IRB requires written assent for subjects ages 12-17
- All children should be engaged in the assent process, regardless of age
  - Research personnel obtaining assent must make the assent process appropriate based on the subjects age, maturity, and psychological state
Considerations in Obtaining Assent

- Assent must be obtained prior to any study procedures beginning
- Dissent of the child must be respected, even if the parent(s) have granted permission
  - Failure to object should not be construed as assent
  - Conversely, if the child assents but the parent(s) do not grant permission, the child cannot be enrolled
- The study must be explained in a language understandable to the child
  - This must include a discussion of any discomforts and inconveniences the child may experience
Children Who Turn 12 or 18 During the Study

Per Lurie Children’s IRB Policy:

- Children who turn 12 years of age during the course of the study must provide written assent before their participation continues.
- Children who turn 18 years of age during the course of the study must provide written consent before their participation continues.
When Can Assent Be Waived?

- The IRB may determine that assent is not required for some or all children if:
  - The capability of the children is so limited that they cannot reasonably be consulted.
  - 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 IRB grants a waiver of assent when the research meets the same conditions as those for waiver of informed consent in research involving adults.

- For studies occurring at Lurie Children’s, if unexpectedly enrolling a child who cannot provide assent, a single waiver of assent can be requested and approved by the Lurie Children’s IRB Chair.
Tips for Writing Assent Forms

- Keep it simple!
  - Language should be appropriate to subjects ages (12-17)
  - Medical terminology, abbreviations, and acronyms being used should be explained upon their first use or replaced with a simpler word/phrase
Special Populations

• A minor who is also a parent may consent to research participation of his/her own child

• Children who are wards of the state
  - Prior approval from the Department of Children and Family Services (DCFS) required regardless of risk category
  - Research categorized as 406 or 407 must utilize a Research Subject Advocate for each ward enrolled, must be related to their status as wards, and be conducted in a setting where the majority of children are not wards
For More Information

- Lurie Children’s IRB Policy and Procedure Manual:
  - Section 11: Informed Consent
  - Section 12: Vulnerable Populations

- Parental Permission and Assent Form Templates:
  - Parental Permission
  - Adolescent Assent

- Tips for writing consent and assent forms

- Contact Information:
  - Tricia Eifler 773-755-7482 teifler@luriechildrens.org