Informed Consent (IC) Module: Pediatric Assent

Erin Ferraro, BSN, RN, OCN©, Nurse Educator
Credit to: Elizabeth Ness MS, BSN, RN, CRN-BC™, Director, Office of Education and Compliance
Credit to: Trish Whitcomb, RN
Center for Cancer Research, NCI
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Children, Research and Assent

- Parent or legal guardian must give legal permission
- Parents and guardians must participate in an informed consent process just as they would if they themselves were considering enrolling in a clinical trial
- Investigator responsible for:
  - Informing parent/guardian about the research study
  - Assessing understanding and voluntariness
  - Obtaining permission for child to enroll

Assent

- Assent is the child's affirmative agreement to participate in research
- Failure to object to participation should not be construed as assent
- IRB's may waive the requirement for assent (capacity-based waiver)

Documentation of Assent

- Discretion of the IRB
- Age appropriateness needs to be considered
- Assent template

Types of Permissions

- Minimal risk (Category 404)
- Research involving greater than minimal risk with prospect of direct benefit (Category 405)
- Research involving greater than minimal risk with no prospect of direct benefit but likely to yield generalizable knowledge (Category 406)
- Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (Category 407)

Re-consenting Study Subject: Signing a New IC Document

- Investigator is required to inform subject of new findings (e.g., toxicities) and to ensure that they are still willing to participate on clinical trial
- IRB or sponsor may require that the subject sign the IRB approved updated IC document
- Consent child when they turn 18 if they were assented