

## Human Research Protection Program Policies & Procedures



### Obtaining Assent from Children for Research Participation

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#### Background:

Over the past couple of decades, medical and legal experts have given much thought to the special issues surrounding children's participation in clinical trials. For minors, legal permission for their participation in research must be given by parents or guardians after going through the informed consent process on their behalf. However, many people involved in treating young people believe that the child or adolescent should play a role in the decision to enter a research study. The American Academy of Pediatrics calls this "empower[ing] children to the extent of their capacity" and talks about this shift in thinking in "Informed Consent, Parental Permission, and Assent in Pediatric Practice." The National Commission for Protection of Human Subjects of Biomedical and Behavioral Research established age 7 as a reasonable minimum age for involving children in some kind of assent process. It is felt that most children this age can understand information tailored for their knowledge and developmental level.

Health care providers want young people to know that they have a say in what happens to them and that their questions and input are valued. Encouraging their involvement in decision-making is done out of respect for their rights as individuals and the desire to give them a sense of ownership in what happens during the trial. Even though children cannot "consent," because true consent implies full understanding, they are now routinely asked whether they agree (assent) or do not agree (dissent) to participate. The National Cancer Institute advises that child subjects' parents or guardians are no longer asked to give "proxy consent" but instead give "informed permission."

#### I. Scope:

This policy covers the requirements for assent to research from children who are unable to provide legally effective informed consent.

#### II. Policy:

1. Prior to the conduct of any research involving a human subject, the PI (or designee) must obtain legally effective informed consent from the human subject or the human subject's legally authorized representative (LAR). This includes permission from a parent or other legal guardian in the case of a research participant who has not reached the age of consent.
2. While children may be legally incapable of giving informed consent, they nevertheless may possess the ability to assent to or dissent from participation. Out of respect for children as developing persons, children should be asked whether or not they wish to participate in the research, particularly if the research: (1) does not involve interventions

likely to be of benefit to the subjects; and (2) the children can comprehend and appreciate what it means to be a volunteer for the benefit of others.

- a. For minors who are unable to provide legally effective informed consent, assent should be sought for those capable of providing assent. That age is generally 7 years old, but it is up to the discretion of the IRB and the researcher to determine the capacity for the child participant to assent.
  - b. The IRB must determine for each protocol - depending on such factors as the nature of the research and the age, status, and condition of the proposed subjects - whether all or some of the children are capable of assenting to participation.
  - c. When the research offers the child the possibility of a 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 may determine that the assent of the child is not necessary [45 CFR 46.408(a)]. Additionally, in such circumstances a child's dissent, which should normally be respected, may be overruled by the child's parents, at the IRB's discretion.
3. The complexity of the assent process should be determined by the capacity of the study population and individual child subjects.

### **III. Procedure:**

#### **1. Assent Requirements**

- a. Assent is in addition to permission from the parent or guardian.
- b. Assent from children must be obtained and documented when they are capable of providing it.
- c. In determining whether children are capable of providing assent, consider ages, maturity and psychological state of the children involved. This determination can be made by the IRB for all children to be involved in the research under a particular protocol, or by the investigators for each child, as appropriate.
- d. Although there are very formal requirements for the elements that must be present in a consent form, no such requirements exist for assents.
  - i. This means that the investigator can propose assent content that he/she believes will best inform the children about the study.
  - ii. The length of the assent form should be proportional to the complexity of the study and the age of the participants.
  - iii. When soliciting assent, the child should be given an explanation of the proposed research procedures in a language that is appropriate to the child's age, experience, maturity, and condition. This explanation should include a discussion of any discomforts and inconveniences the child may experience if he or she agrees to participate.
- e. Use the OHSU template or a comparable format to create an assent form if applicable. For a population that will not use an assent form, such as children who can speak but not write, describe the assent process in the research documentation.

#### **2. The Assent Process**

1. When appropriate, the child should be present when the research procedures are explained to the parent(s)/guardian(s). The concepts should then be simplified for

the child and explained orally and with an assent form when appropriate. See OHSU Policy on Children as Research Subjects for more information.

2. If the child does not assent, then the child's wishes should be respected except in cases where the research offers the child the possibility of a direct benefit that is important to the health or well-being of the child and is available only in the context of the research. If the child is not able to read the assent form, and verbal assent is obtained using the content in the assent form, the person obtaining assent should place in the chart or research record a statement with the following content:

*I have discussed this clinical research study with \_\_\_ using language which is understandable and appropriate for the participant. I believe that I have fully informed him/her of the nature of the study and its possible risks and benefits. I believe the participant understood this explanation and assents to participate in this study.*

#### IV. Authority

##### Federal Regulations:

**45 CFR §46, Subpart D** requires obtaining assent from child subjects when appropriate.

**21 CFR §50:** FDA Safeguards for Children in Clinical Investigations – identical to 45 CFR §46 Subpart D – except “clinical investigations” replaces the term “research.”

##### Guidance:

National Cancer Institute – [Children's Assent to Clinical Trial Participation](#) (January 11, 2011)

#### V. Definitions

**Children** are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under state law. (45 CFR §46.402(a))

**Assent** means a child's affirmative agreement to participate in research. (45 CFR §46.402(b))

**Ward** means a child who is placed in the legal custody of the State or other agency, institution, or entity, consistent with applicable Federal, State, or local law. (45 CFR 46.409)

#### VI. Additional Resources

##### OHSU HRPP Policies and Procedures:

- Research with Children as Subjects
- Obtaining Consent
- Assurance of the Elements of Informed Consent

##### OHSU IRB Forms:

- Assent Form - Standard