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POLICY

Assent

Assent: agreement by an individual not competent to give legally valid informed consent (e.g., a child or cognitively impaired person) to participate in research. An assent is typically paired with parental permission from a parent or guardian, and together they comprise the informed consent to participate.

Children (minors) are a vulnerable research population and, as such, require additional protections when they are potential research subjects. Subpart D of both 45 CFR 46 (DHHS), and 21 CFR 50 (FDA) require certain additional protections for children involved as subjects in research. The requirements of Subpart D apply to all non-exempt research involving children conducted under the auspices of Northeastern Illinois University. The regulations require that adequate provisions be made for soliciting the assent of all children involved in research, when the children are capable of providing assent. In determining whether children are capable of assenting, the ages, maturity and psychological state of the children should be taken into account.

In general, children should be given developmentally appropriate information about a research study in a language and manner that is understandable to them, given their age, maturity, and cognitive abilities.

For children under the age of 7: Typically, minors under 7 years old should provide oral assent. The oral assent script should be conversational and stated in such a way that is understandable and age-appropriate. **The script or study records must document that assent was obtained.** Assent should be obtained along with the consent of a parent or guardian.

For children aged 7-11 years: This age group should be fully informed about the research, using language appropriate to their age and maturity, and either written or oral assent should be obtained from those deemed capable of making a meaningful decision. Assent should be obtained along with the consent of a parent or guardian.

For children aged 12-17 years: Children in this age group should be fully informed about the research and written assent should be obtained. /P <

Waiver of Documented (Signed) Parental Permission

The IRB may waive the requirements to obtain documented (signed)

the subject to adequately consider whether or not to participate;