

**Children's Hospital and Health System, Inc.
Administrative Policy and Procedure
Children's Research Institute**

SUBJECT: Human Research Review Board - HRRB - Assent

POLICY

I. Purpose:

- A. To ensure that there are adequate provisions for soliciting and documenting the assent of prospective subjects capable of some degree of understanding prior to participation in a research study at Children's Hospital of Wisconsin (CHW).
- B. Additionally, to describe when informed consent must be obtained as subjects reach the legal age of consent while enrolled in a study.

II. Policy:

A. Definitions

- 1. Assent: Assent is a child's affirmative agreement to participate in research. Failure to object, by itself, does not constitute assent.
- 2. Children: Persons who have not attained the legal age for consent to treatments or procedures involved in research, under the applicable law of the jurisdiction in which the research will be conducted. In Wisconsin, the legal age of consent is 18 years of age.
- 3. Guardian: An individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.
- 4. Legally Authorized Representative: An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in a research study. Under Wisconsin law, a Legally Authorized Representative may be the parent, guardian or legal custodian of a minor, the person vested with supervision of a child under state law, the guardian of a person adjudged incompetent, as defined under state law, the personal representative or spouse of a deceased subject, or any person authorized in writing by the subject or a health care agent designated by the subject as a principal under state law if the subject has been found to be incapacitated under state law except as limited by the power of attorney for health care instrument.
- 5. Parent: A child's biological or adoptive parent.

B. Procedures for Obtaining Assent

1. The Human Research Review Board (HRRB) shall determine that adequate provisions are made for soliciting the assent of children, when in the judgment of the HRRB the children are capable of providing assent. When judging whether children are capable of assent, the HRRB is charged with taking into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all subjects to be involved in research under a particular protocol, or for each subject, as the HRRB deems appropriate.
2. The assent procedure should reflect a reasonable effort to enable the child to understand, to the degree they are capable, what their participation in research would involve.
 - a. For children whose age and maturity level limits their ability to fully comprehend the nature of the research activity but who are still capable of being consulted about participation in research, it may be appropriate to focus on conveying an accurate picture of what the actual experience of participation in the study is likely to be (e.g., what the experience will be, how long it will take, whether it might involve any pain or discomfort).
 - b. For research activities involving adolescents whose capacity to understand resembles that of adults, the assent procedure should likewise include information similar to what would be provided for informed consent by adults or for parental permission.

C. Waiver of Assent

1. If the HRRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, assent is not a necessary condition for proceeding with the research.
2. Even where the HRRB determines that the subjects are capable of assenting, the HRRB may still waive the assent requirement under circumstances in which consent can be waived as stated in the HRRB Informed Consent policy.

- #### D. Consent After 18 Years of Age: When a subject who was enrolled in research with parental permission subsequently reaches the legal age of consent (18 years of age in Wisconsin), the investigator must seek and obtain the legally effective informed consent for the now adult subject for any ongoing interactions or interventions with the subjects.

PROCEDURE

- A. Investigator must submit a completed assent form(s) along with the initial study application if he/she feels obtaining assent is appropriate. If the investigator does not feel obtaining assent is appropriate, he/she should state this on the application along with the reason(s) on which the determination is based.
- B. The HRRB shall make the final determination on whether assent will be required and document its findings in the meeting minutes. The HRRB shall not approve a research study that requires assent for which an assent form has not been submitted. Investigators will receive prompt written notification of the HRRB's decision to require assent.
- C. The investigator is responsible for determining if/when a subject reaches the legal age of consent. If the investigator needs to make any changes to the currently HRRB-approved informed consent document, the modified form must be submitted to the HRRB for review and approval as an amendment before it is used. (See "HRRB Research Revisions and Amendments" policy)

Approved by the Medical Executive Committee 10/02/2006

Jon E. Vice, President CHHS, Inc.

References:

- A. 45 CFR 46.408

Documentation (Documents & Forms):

- A. HRRB Registration Form
- B. Request for Waiver of Informed Consent