

Children's

Hospital & Regional Medical Center
Office of the Vice President for Research

OPERATING PROCEDURES/POLICIES

Committee: Institutional Review Board
Policy Number: IRB-39
Effective Date: June 20, 2005

POLICY TITLE:

RESEARCH INVOLVING CHILDREN WHO ARE WARDS OF THE STATE

POLICY:

Children who are wards of the state require additional protections to ensure their safety and welfare are protected when they are involved in research. Permission for children who are wards to take part in research must meet all federal regulations and state law pertaining to protections for children who are wards. Permission for the child to take part in research must be obtained from the child's legally authorized representative as defined by state law. The assent of the child shall be obtained when in the judgment of the IRB the children are capable of providing assent. Wards may only be involved in research that involves greater than minimal risk and no prospect of direct benefit to the child if federal criteria for such research are met. (45 CFR 46.409 and 21 CFR 50.56)

DEFINITIONS:

"Children" are persons who have not attained the legal age for consent to treatment or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted [45 CFR 46.402 (a)].

"Assent" means a child's affirmative agreement to take part in research. Mere failure to object, absent affirmative agreement, is not to be construed as assent [45 CFR 46.402 (b)].

"Permission" means the agreement of parent(s) or guardian of the child or ward to take part in the research [45 CFR 46.402 (c)].

"Parent" means a child's biological or adoptive parent [45 CFR 46.402 (d) and 21 CFR 50.53(p)].

"Guardian" means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care [45 CFR 46.402 (e)].

"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. [21 CFR 50.3(q)]

PROCEDURE:

- 39.1 Permission for children to take part in research who are wards must be obtained from the person legally authorized to grant such permission by the State.
- 39.2 In cases where parental rights have not been terminated by the State, the IRB shall determine if the child's natural parent(s), in addition to the legally authorized person, shall also provide permission for their child to take part.
- 39.3 When research is approved by the IRB under category 45 CFR 46.406 or 21 CFR 50.53 or category 45 CFR 46.407 or 21 CFR 50.54, children who are wards may be enrolled in the research only if:
- A. The research is related to the child's status as wards; or
 - B. The research is conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved in the research are **not** wards. [45 CFR 46. 409(a) and 21 CFR 50.56(a)]
- 39.4 If the IRB approves enrollment of children who are wards in research that is approved under 45 CFR 46.406 or 21 CFR 50.53 or 45 CFR 46.407 or 21 CFR 50.54, the IRB shall require appointment of an advocate for each child who is a ward. This advocate is in addition to the legally authorized representative appointed to act on behalf of the child as guardian or in loco parentis. The advocate must have the background and experience to act in the best interest of the child. The advocate must be available to act in the child's best interest for the duration of the child's participation in the study. The advocate may not be associated in any way with the research, the investigator(s), or the guardian organization. The advocate may serve in this role for more than one child (ward). [45 CFR 46.409 (b) and 21 CFR 50.56(b)]
- 39.5 When the situation as described above in 39.4 applies, the principal investigator of the research study must provide the IRB documentation of the qualifications of the persons who will act as advocates for the children who are wards. The PI must provide documentation of the training the advocate will receive in human subjects protections training prior to that person serving as a child advocate for wards in the research.

Submitting Committee: Institutional Review Board

Approved by: Douglas S. Dehema 6/20/05
Chair Date

Elizabeth Trias 6/20/05
Manager Date