

**DECATUR MEMORIAL HOSPITAL
INSTITUTIONAL REVIEW BOARD**

SUBJECT: SPECIAL POPULATIONS - CHILDREN

STANDARD: PATIENTS RIGHTS AND ORGANIZATION ETHICS EFFECTIVE: 06/99

PURPOSE: Institutional Review Board (IRB) review and approval of research activities involving children shall be in compliance with the regulations regarding human subject research and the additional safeguards set forth in 45 CFR Part 46, Subpart D and 21 CFR Part 50.20.

DEFINITIONS:

“Children” are persons who are under the age of 21, or have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction where it will be conducted. *

“Assent” means a child’s affirmative agreement to participate in research. Mere failure to object should not, absent, absent affirmative agreement, be construed as assent.

“Permission” means the agreement or parent(s) or guardian to the participation of their child or ward in research.

“Parent” means a child’s biological or adoptive parent.

“Guardian” means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

“Mature Minor” in the state of Illinois refers to a person 16 years of age or over and under the age of 18 years who has demonstrated the ability and capacity to manage his own affairs and to live wholly or partially independent of this parents or guardian. A minor who claims mature minor status must petition the court for a determination of maturity regarding a medical decision.

“Emancipated Minor” in the State of Illinois refers to a mature minor who has petitioned the court and been ordered emancipated. An emancipated minor may enter into valid legal contracts and “shall have such other rights and responsibilities as the court may order that are not inconsistent with the specific age requirements of the State or Federal constitution or any State or Federal law.”

*Per Illinois State Law: Consent to performance of a medical or surgical procedure may be given by: 1) a married person who is a minor, 2) a parent who is a minor, 3) a pregnant woman who is a minor or 4) by any person 18 years of age or older. For treatments of drug or alcohol abuse or sexually transmitted disease, a minor of 12 years or older may give consent to care related to diagnosis or treatment of the disease.

EXCEPTION: The exemption for research involving survey or interview procedures or observations of public behavior found at CFR 46.101 (b) (2) does **not** apply to research involving children. Except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

PROCEDURE:

Upon presentation of research involving children, the IRB will classify the research into one of the four following categories:

1. **Research not involving greater than minimal risk.** Criteria for approval includes: a) adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians.
2. **Research involving greater than minimal risk, but presenting the prospect of direct benefit to the individual subjects.** Criteria for approval includes:
 - a. the risk is justified by the anticipated benefit to the subject.
 - b. The relationship of risk to benefit is at least as favorable as any available alternative approach; and
 - c. Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.
3. **Research involving greater than minimal risk, but presenting the prospect of no direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.** Criteria for approval includes:
 - a. the risk represents a minor increase over minimal risk;
 - b. the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social or educational settings; and
 - c. the intervention or procedure is likely to yield generalizable knowledge about the subject's disorder or condition that is of vital importance for the understanding or amelioration of the subject's disorder or condition; and
 - d. adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.
4. **Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem, affecting the health or welfare of children.** Criteria for approval includes:
 - a. the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and
 - b. the Secretary, after consultation with a panel of experts in pertinent disciplines (for example; science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either: 1) that the research in fact satisfies the conditions of CFR 46.404, 46.405, or 46.406, as applicable or 2) the following:
 - i) the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children:
 - ii) the research will be conducted in accordance with sound ethical principles;
 - iii) adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians.

CONSENT/ASSENT PROCEDURES:

1. Following classification of the research involving children, the IRB shall determine that adequate provisions exist for soliciting the assent of children and the permission of their parents or guardians.

GUIDELINES:

TYPE OF RESEARCH

REQUIREMENTS

1) No greater than minimal risk	Assent of child and permission of at least one parent*
2) Greater than minimal risk and prospect of direct benefit	Assent of child and permission of at least one parent*
3) Greater than minimal risk and no prospect of direct benefit	Assent of child and permission of both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent* has legal responsibility for the care and custody of the child
4) Any other research	Assent of child and permission of both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent* has legal responsibility for the care and custody of the child
	IRB finds that the research presents a reasonable opportunity to further the Understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children, AND

*Note: In a case of divorce, consent ordinarily rests with the custodial parent. However, when the custodial parent is not available, the parent who is available has actual custody and may provide consent if the treatment is medically necessary. A non-custodial parent may not give consent for a non-essential treatment or procedure.

2. To determine whether children are capable of assenting, the IRB shall take into account:
 - a) the ages
 - b) maturity and
 - c) psychological state of the children involved
3. The child must be given an explanation of the proposed research procedures in a language that is appropriate to the child's age, experience, maturity and medical condition. This should include a discussion of any discomforts and inconveniences the child may experience. The explanation may be written, drawn, or verbal.
4. If appropriate, the IRB may require that either an IRB member or an advocate for the child be present during the assent and permission procedures to verify the child's understanding and support the child's preferences.

ACTION:

The IRB shall determine if all children to be involved in the protocol must give assent, or if the IRB must determine that for each individual child.

The IRB may determine that the assent of children is not necessary if:

- 1) the capability of some or all of the children is so limited that they cannot reasonably be consulted or that 2) 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.

The IRB may waive parental/guardian consent requirements, within the limits of the law, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children).

Wards of the State:

In order for children who are wards of the State or any other agency, institution, or entity to be included in research, the IRB must first determine that the research is:

- 1) related to their status as wards; or 2) conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards. The IRB shall require consent from the appropriate person appointed by the court.

DOCUMENTATION:

1. Permission by parents and/or guardians shall be documented in accordance with and to the extent required in CFR 46.117 (see policy re: Informed Consent for Clinical Trials).
2. Assent, when required, must be documented by the person providing the explanation or the person assigned as an advocate for the child.
3. The IRB minutes must include:
 - a. Discussion of risk and benefits of the research study;
 - b. Determination of classification of the study;
 - c. Determination of assent/permission requirements.
4. The investigator shall be notified in writing of the assent/permission requirements and determination of classification of the study in addition to the requirements found in the policy for Informed Consent for Clinical Trials.

APPLICABLE TO: Investigators, IRB members

APPROVED BY:

President and CEO

REVISED: 01/01