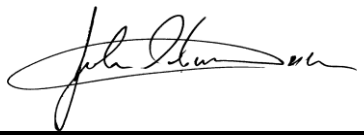
KESSLER FOUNDATION

Policies and Procedures Manual
IRB

SUBJECT: Research Involving Minors as Participants	**POLICY # 5011**
APPROVED: **Richard J. Greene, M.D., Ph.D.** **IRB Chair**  **John DeLuca, Ph.D.** **Vice President for Research** 	**EFFECTIVE DATE:** **January 1, 1998** **REVISED DATE:** **May 29, 2014**

PURPOSE

The purpose of this Policy is to provide the IRB with guidelines for consideration of research studies involving children as participants.

The special vulnerability of children makes consideration of involving them as research subjects particularly important. To safeguard their interests and to protect them from harm, special ethical and regulatory considerations are in place from reviewing research involving children. Title 45 CFR Part 46, Subpart D provides “Additional Protections for Children Involved as Subjects of Research” (From IRB Guidebook: Chapter VI Special Classes of Subjects – OHRP – DHHS).

POLICY

Kessler Foundation is committed to protection of the rights of children involved as subjects of research.

Regulations regarding informed consent given in Subpart A, section 46.116 (General Requirements for Informed Consent) have special meaning in research involving children. A principal requirement of informed consent is that "information be given to the subject in language understandable to the subject," a condition that would be difficult to achieve for children using standard consent forms prepared for adults.

PROCEDURE

I. Requirements for Permission by Parents or Guardians and for Assent by Children

A. The IRB will determine that adequate provisions are made for soliciting the assent of the children when, in the judgment of the IRB, the children are capable of providing assent. In

determining whether children are capable of assenting, the IRB will take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB 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, the assent of the children is not a necessary condition for proceeding with the research (45 CFR 46.408(a). Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accordance with general informed consent provisions.

B. The IRB will determine that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that permission of one parent is sufficient for research involving minimal risk or for research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects. For research involving greater risk and no prospect of direct benefit to subjects, permission is to be obtained from 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.

C. 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), it may waive the consent requirements, provide an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and confirm the waiver is not inconsistent with Federal, State, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

D. Permission by parents or guardians will be documented using a written Informed Consent Document.

E. When the IRB determines that assent is required, it will also determine whether and how assent must be documented.

F. Any female under 18 years of age, who has given birth to a child and is mentally and physically able to act on her own behalf, is considered by New Jersey law to be an emancipated minor and is rightfully allowed to provide sole consent for treatments and procedures to be conducted upon herself or her child.

II. Wards

A. Children who are wards of the State or any other agency, institution, or entity can be included in research only if such 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.

B. If the research is approved, the IRB will require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or

in lieu of the parents. One individual may serve as advocate for more than one child. The advocate will be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

III. New Jersey Law

A. Majority is attained at age 18.
B. Married minors may consent to medical or surgical care or to participation in research study for themselves and their children. An unmarried female minor may consent to care related to her pregnancy or treatment for her child.
C. A minor who is or professes to be afflicted with venereal disease or suffering from drug use or dependency may consent to related medical or surgical treatment or to a research study pertaining to such conditions.
D. The treating physician or research investigator may decide whether or not to inform a minor's spouse, parents, or guardian concerning care needed by or given to a minor.