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).

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.

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
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.