Albert Einstein College of Medicine

Enrollment of Children in Research

I. Purpose

This Procedure describes the protections that apply when children are enrolled as subjects in human research conducted under the auspices of the Einstein Institutional Review Board ("IRB").

II. Scope

This Procedure applies to all human research involving children conducted under the auspices of the Einstein IRB.

III. Definitions

Child: a person who has not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

Assent: A child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

Guardian: An individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

NOTE: The investigator should check appropriate state and local laws and regulations before conducting research to determine the definition of a guardian, as research must comply with the laws regarding guardianship in all relevant jurisdictions. The Office of General Counsel may provide assistance.

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

Parent: a child's biological or adoptive parent who has legal custodial rights to make healthcare decisions on behalf of a child.

IV. Procedure

If research involves children as subjects, the Einstein IRB follows Subpart D of the DHHS regulations or equivalent protections as allowed by law. Additional protections are required when children are research subjects, depending on the degree of risk involved in the research. Informing, empowering, and showing respect for children can be served by obtaining their *assent* to participate in research when appropriate.

Assent

The Office of Human Research Affairs ("OHRA") offers the following general guidelines for obtaining assent, with the understanding that capacity to give assent and understand the research varies depending on a child's individual cognitive development. For each study, the requirements for assent are determined by the IRB on a case-by-case basis.

1. **Children under 7**
   1.1. The Einstein IRB presumes that children under 7 do not to have the capacity to give assent.
2. **Children 7-12**
   2.1. The Einstein IRB presumes that children ages 7 or older have the capacity to give assent. Research protocols should describe the provisions that will be made for soliciting assent from children.
   2.2. For children ages 7 to 12, a separate assent form should be used in addition to the informed consent document that the parent or legal guardian is required to sign. The IRB will consider whether documentation of assent must include the minor's signature, be described in a progress note, or witnessed.
3. **Adolescents over 12**
   3.1. Adolescent children may sign the same consent document as the parent or legal guardian, since many adolescents of this age have the cognitive ability to understand the purpose, procedures, risks, benefits, and alternatives to participation in a research protocol. For studies in which parental consent will be obtained, the consent form should have separate signature lines for the adolescent and the parent.

The IRB may waive the assent requirement under the same circumstances in which consent may be waived in research involving adults, as specified in 45 CFR 46.116.

Additionally, the IRB may determine that the requirement for minor assent may not apply in the following situations:

1. If the child is not capable of assenting based on the IRB's assessment of age, maturity, and psychological state. This judgment may be made by the IRB in regard to any specific protocol or for each individual child.
2. When the research holds out a prospect of direct benefit that is important to the health or well-being of the child and is generally available only in the context of the research.

Parental Permission

Parental/guardian permission may be waived by the IRB under the same circumstances in which consent may be waived in research involving adults, as specified in 45 CFR 46.116.

NOTE: *In contrast to HHS policy, FDA regulations require parental permission for all drug trials.*

In certain cases, parental or guardian permission is not a reasonable requirement to protect the subject. In such cases, parental permission may not be required, if for treatment or services for which the adolescent is afforded the right to privacy and consent. See the below section on "New York State Law and Adolescent Consent" for more information. Such determinations are made on a case-by-case basis at the discretion of the Einstein IRB.

Inconsistencies Between Parental Permission and Child Assent

At times, there may be inconsistency between parent permission and child assent. Usually a "no" from the child overrides a "yes" from a parent, but a child typically cannot decide to be in research over the objections of a parent. There are individual exceptions to these guidelines (such as when the use of an experimental treatment for a life-threatening disease is being considered).

In cases when the adolescent wishes to participate yet his or her parents refuse to consent and there is a prospect of direct benefit to the adolescent, the investigator may contact the OHRA for guidance.

Pediatric Risk Categories

When reviewing research involving children, the IRB will determine which of the four risk-benefit categories described in 45 CFR 46 Subpart D and 21 CFR 56 Subpart D the research fits into. Each category has its own requirements for obtaining parental permission and assent by the children themselves.

1. Research not involving greater than minimal risk
    1.1. Requires assent of child and permission of at least one parent
2. Research involving greater than minimal risk, but presenting the prospect of direct benefit to the individual subjects
    2.1. Requires assent of child and permission of at least one parent
    2.2. The anticipated benefit justifies the risk
    2.3. The anticipated benefit is at least as favorable as that of alternative approaches
3. Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition
    3.1. Requires assent of child and permission of both parents
    3.2. The level of risk may be only a minor increase over minimal risk
    3.3. The research must be likely to yield generalizable knowledge about the child's disorder or condition that is of vital importance for the understanding or amelioration of the disorder or condition
    3.4. The intervention or procedure presents experiences to the child that are reasonably commensurate with those in the child's actual or expected medical, dental, or expected medical, dental, psychological, social, or educational situations
4. Research not otherwise approvable, which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children
    4.1. Requires assent of child and permission of both parents
    4.2. The IRB must find 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
    4.3. The HHS Secretary or the FDA Commissioner must approve the research, after consultation with a panel of experts in pertinent disciplines (e.g., science, medicine, education, ethics, law) and following publication in the *Federal Register* and public comment

Children Who Are Wards

Children who are wards of the state or any other agency, institution, or entity can be included in the above pediatric risk Categories 3 and 4 (research involving greater than minimal risk and no prospect of direct benefit to the individual subject) only if the IRB determines and documents that the research is:

- Related to their status as wards; or
- Conducted in schools, camps, hospital, institutions, or similar settings in which the majority of children as participants are not wards.

If the research meets the condition(s) above, an advocate must be appointed for each child who is a ward, in addition to any other individual acting on behalf of the child as a guardian or in loco parentis.

The advocate must 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. The advocate must not be associated in any way (except in the role as advocate or member of the IRB) with the research, the researchers, or the guardian.

If an investigator wishes to enroll a child who is a ward in research involving greater than minimal risk with no prospect of direct benefit to the child that has not already been approved to enroll wards, an amendment must be submitted in order for the IRB to make the appropriate determination.

New York State Law and Adolescent Consent

When research is conducted in New York, there are some instances when individuals under the age of 18 may consent to research involving specific confidential medical care. These are determined on a case-by-case basis, at the discretion of the Einstein IRB. If there are questions about specific cases, the investigator should contact the OHRA. For research conducted at Montefiore, the PI must follow Administrative Policy & Procedure JC08.1, "Adolescent Consent, Privacy and Confidentiality."

The following categories of individuals under 18 may consent to participate in research and to disclosure of protected health information, if the research involves the provision of medical care:

- An adolescent who is a parent of a child may give consent for him/her self and for the child.
- An adolescent who is married may give consent for him/herself.
- An adolescent who is pregnant may give consent for her prenatal care.
- In New York State, "emancipated minors" are not given statutory authority to consent to medical treatment and disclosure of protected health information, except by court order or as otherwise covered in this Procedure.

Additionally, the right to privacy is afforded to adolescents who have the right to consent to the given treatment or services. Adolescents my consent to, and retain the right to privacy for, the following:

- Medical care related to prevention or treatment of pregnancy, including emergency contraception and birth control (except sterilization).
- Abortion.
- Medical care related to the diagnosis, treatment, and collection of medical evidence related to a sexual assault or rape.
- Diagnostic services, such as a skeletal X-ray, to diagnose child abuse or neglect.

- Medical care related to the prevention, diagnosis, or treatment of a sexually transmitted disease, including HPV vaccine.
- HIV testing, and/or diagnosis, prevention, and treatment of HIV/AIDS.
- Medical care related to LGBTQ-related issues. In addition, the fact of a subject's LGBTQ status is confidential and should not be disclosed except with consent of the subject. Note that gender transitioning treatment, including pubertal suppression and hormonal treatment, requires parental/guardian involvement and consent.
- Prevention and treatment of substance use, including tobacco, drugs, and alcohol.

When an adolescent has consented to research involving any of the items to which they retain the right to privacy, the investigator is not permitted to inform a parent or legal guardian without the adolescent's authorization.

Research conducted outside of New York must comply with the laws regarding the legal age of consent for research and/or treatment in all relevant jurisdictions. The Office of Legal Counsel may provide assistance with regard to the laws in other jurisdiction.

V. Effective Date

Effective as of: July 1, 2020

Revised as of: September 6, 2023

VI. Procedure Management and Responsibilities

Einstein's Office of Human Research Affairs is the Responsible Office under this Procedure. The Executive Dean is the Responsible Executive for this Procedure. The OHRA Director is the Responsible Officer for the management of this Procedure.