

CUNY HRPP Policy: Children as Research Subjects

1. Applicability

This policy applies to all non-exempt human subject research involving children in which CUNY becomes engaged.

2. Definitions

2.1. Children

Persons who have 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.

2.1.1. New York State Jurisdiction

According to New York State law, a **minor** is any person who is not an adult. Relatedly, an **adult** is any person who is eighteen years of age or older or has married.

2.1.1.1. Any person who is eighteen years of age or older, or is the parent of a child or has married, may give effective consent for medical, dental, health and hospital services for himself or herself, and the consent of no other person shall be necessary.

2.1.1.2. Any person who has been married or who has borne a child may give effective consent for medical, dental, health and hospital services for his or her child.

2.1.1.3. Any person who is pregnant may give effective consent for medical, dental, health and hospital services relating to prenatal care.

2.1.2. Other Jurisdictions

When recruiting children as research subjects from a jurisdiction outside of New York State, the Principal Investigator (PI) is responsible for ensuring compliance with the legal age of consent requirements of that jurisdiction. The PI must provide this information to the IRB as part of his/her IRB application.

2.2. Assent

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

2.3. Permission

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

2.4. Parent

A child's biological or adoptive parent.

2.5. Guardian

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

3. Criteria for Inclusion of Children in Research

CUNY UI-IRBs may approve research involving children as subjects only when the research meets one of the following criteria:

3.1. Research not involving greater than minimal risk

The IRB finds that no greater than minimal risk to children is presented, and adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians.

3.2. Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects

The IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being only if the IRB finds that:

- a. The risk is justified by the anticipated benefit to the subjects;
- b. The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; AND
- c. Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.

3.3. 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

The IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that:

- 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 situations;

- c. The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; AND
- d. Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians.

3.4. Research not otherwise approvable under criteria 3.1-3.3 above, which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children

Research that the IRB does not believe meets the requirements of 3.1-3.3 above only if:

- 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 one of the following consultations have taken place:
 - i. For federally funded or supported research, the Secretary of the funding agency, 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 3.1-3.3 above, as applicable; OR
 - (2) All of the following:
 - a) 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;
 - b) The research will be conducted in accordance with sound ethical principles; AND
 - c) Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians.
 - ii. For non-federally funded or supported research, the Vice Chancellor for Research, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law), the sponsor of the research, if any, and relevant community representative(s), has determined that:
 - (1) 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;
 - (2) The research will be conducted in accordance with sound ethical principles; AND

- (3) Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians.

4. Child Assent

The IRB shall 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 shall 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.

4.1. Child Assent Process

When the IRB determines that assent is required, it shall also determine the adequacy of the child assent process. For longitudinal studies, the IRB may require re-assenting procedures at certain age appropriate intervals; and consent process when the child reaches adulthood.

4.2. Documentation of Child Assent

When the IRB determines that assent is required, it shall also determine whether and how assent must be documented. In general, when the literacy and maturity of the subject population allows, CUNY UI-IRBs require:

- a. Oral assent from children under the age of 7.
- b. Simple one-page assent document for children between the ages of 7 and 12.
- c. Assent document similar to the consent document used for adults for children between the ages of 13 and 17.

4.3. Waiver of Child Assent

The IRB may waive the requirement for obtaining child assent if the IRB determines that:

- a. The capability of some or all of the children is so limited that they cannot reasonably be consulted; OR
- b. 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; OR
- c. The IRB finds that ALL of the following conditions are met:
 - i. The research involves no more than minimal risk to the subjects;
 - ii. The waiver will not adversely affect the rights and welfare of the subjects;
 - iii. The research could not practicably be carried out without the waiver; AND
 - iv. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

5. Parent or Guardian Permission

The IRB shall determine that adequate provisions are made for soliciting the permission of each child's parents or guardian, as follows:

- a. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research that meets the criteria in 3.1 and 3.2 above.
- b. For research that meets the criteria in 3.3 or 3.4 above and permission is to be obtained from parents, both parents must give their permission, 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.

5.1. Parent or Guardian Permission Process

All requirements for the informed consent process as outlined in [CUNY HRPP Policy: Informed Consent Process and Documentation](#) apply to the parent or guardian permission process.

5.2. Documentation of Parent or Guardian Permission

All requirements for the documentation of informed consent as outlined in [CUNY HRPP Policy: Informed Consent Process and Documentation](#) apply to the documentation of parent or guardian permission.

5.3. Waiver of Parent or Guardian Permission

The IRB may waive the requirement for obtaining parent or guardian permission if the IRB determines that ONE of the following sets of conditions apply:

- a. ALL of the following conditions are met:
 - i. 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); AND
 - ii. An appropriate mechanism for protecting the children who will participate as subjects in the research is substituted; AND
 - iii. The waiver is consistent with federal, state or local law.
- b. ALL of the following conditions are met:
 - i. The research involves no more than minimal risk to the subjects;
 - ii. The waiver will not adversely affect the rights and welfare of the subjects;
 - iii. The research could not practicably be carried out without the waiver; AND
 - iv. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

6. Wards

- 6.1. Children who are wards of the state or any other agency, institution, or entity can be included in research that meets the criteria in sections 3.1 or 3.2 above.
- 6.2. Children who are wards of the state or any other agency, institution, or entity can be included in research that meets the criteria in sections 3.3 or 3.4 above only when:
 - a. One of the following criteria is met:
 - i. The research is related to their status as wards; OR
 - ii. The research is conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.
 - b. The IRB shall 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 loco parentis*. One individual may serve as advocate for more than one child. The advocate shall 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 other way with the research, the investigator(s), or the guardian organization.

7. IRB Responsibilities

The reviewing IRB is required to make each of the determinations outlined in this policy, as applicable. Each of these determinations, and the basis for each determination, must be documented in the reviewer's comments for reviews conducted by an expedited review process, and in the meeting minutes for reviews conducted by the convened IRB.

References

1. [Code of Federal Regulations, Title 45 – Public Welfare DHHS, Part 46 – Protection of Human Subjects](#)
2. New York State Public Health Law, Article 25, Title 1, Section 2504: *Enabling certain persons to consent for certain medical, dental, health and hospital services.*
3. New York State Public Health Law, Article 29-CC: *Family Health Care Decisions Act.*