

University of Rochester	Office for Human Subject Protection		
	Research Subject Review Board	Effective Date: 011/5/2020	
	Research Involving Children	Policy 601	Version: 1.4

POLICY

1. Purpose

- 1.1. Define the special ethical and regulatory considerations that apply to research involving children as research subjects.
- 1.2. To indicate when research involving children: 1) requires assent of the child as well as permission of the parent(s) or legal guardian(s), 2) does not require child assent, 3) may waive parental permission, or 4) requires only consent by the child.

2. Scope

This policy applies to all research conducted with children.

3. Definitions

- 3.1. 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 [45 CFR 46.402(a)]. In New York, the legal age for consent to treatments or procedures is 18. Accordingly, for purposes of this policy, a child (sometimes referred to in this policy as a “minor”) is defined as a person under the age of 18. (Note: New York law also allows persons under the age of 18 years to consent to certain types of medical testing and treatment and health care services. [See, Section 6.2.1 below]).
- 3.2. Parent – A child’s biological or adoptive parent.
- 3.3. Guardian – An individual who is appointed by a court as the legal guardian of a child.
- 3.4. Assent – A child’s affirmative agreement to participate in research.
- 3.5. Minimal Risk – The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [45 CFR 46.102(i)].

4. References

- 4.1. DHHS 45 CFR 46 Subpart D: 45 CFR 46.404, 45 CFR 46.405, 45 CFR 46.406, 45 CFR 46.407, 45 CFR 46.408, 45 CFR 46.409; EPA 40 CFR 26 Subpart D
- 4.2. FDA 21 CFR 50 Subpart D: 21CFR 50.51, 21 CFR 50.52, 21 CFR 50.53, 21 CFR 50.54
- 4.3. Public Health Law Section 2504, Public Health Law Section 2305, Mental Hygiene Law 33.21
- 4.4. SMH Policy 9.05; Policy 602 Research Involving Pregnant Women;

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Policy 604 Research Involving Decisionally Impaired Persons

- 4.5. Guideline on Assessing Consent Capacity in Children;
Guideline for SADCR Review of Research Involving Children

5. Responsibilities

- 5.1. The Reviewing IRB is responsible for determining whether research involving children is acceptable under one of the following four categories, and for documenting the determined category along with the discussion of the risks and benefits of the study:

Note: The Reviewing IRB is responsible for applying the additional protections under 40 CFR 26 Subpart D when reviewing research that involves the Environmental Protection Agency.

- 5.1.1. Research involving **no more than minimal risk** (45 CFR 46.404 and 21 CFR 50.51), if:

- Adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians. *The Reviewing IRB may find that the permission of one parent/guardian is sufficient.*

- 5.1.2. Research involving **greater than minimal risk but presenting the prospect of direct benefit** to the individual subjects (45 CFR 46.405 and 21 CFR 50.52), if:

- The risk is justified by the anticipated benefit to the participants.
- The relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternatives, and
- Adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians. *The Reviewing IRB may find that the permission of one parent/guardian is sufficient.*

- 5.1.3. 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 (45 CFR 46.406 and 21 CFR 50.53), if:

- The risk represents a minor increase over minimal risk;
- The intervention or procedure presents experiences to the children that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social or educational situations;
- 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
- Adequate provisions are made for soliciting the assent of the children and the permission of both parents (or guardians).

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5.1.4. Research not otherwise approvable which **presents an opportunity to understand, prevent or alleviate a serious problem affecting the health or welfare of children** (and 45 CFR 46.407 and 21 CFR 50.54), if:

- The Reviewing IRB finds and documents 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
- The Secretary of DHHS or the Commissioner of Food and Drugs, as applicable, (or the RSRB for non-federally funded studies), after consultation with experts in pertinent disciplines (e.g., science, medicine, education, ethics and law), and following opportunity for public review and comment, finds that either:
 - the research in fact satisfies one of the categories set forth above or
 - confirmation 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; the research will be conducted according to sound ethical principles; and adequate provisions are made for soliciting the assent of children and the permission of both parents (or guardians).

5.2. The Reviewing IRB is responsible for determining whether parental/guardian permission is required (see section 6.1.2 regarding waiver of parental permission) and, when required, how many parents/guardians must provide permission.

5.2.1. When the Reviewing IRB determines that permission is required from both parents/guardians, the study team must obtain permission from both parents/guardians for the child to participate, unless one parent/guardian is deceased, unknown, incompetent, or not reasonably available, or unless only one parent has legal authority to make health care decisions for the child. Note that the University of Rochester does not consider parents who are unavailable due to scheduling conflicts to be “not reasonably available”.

5.3. The Reviewing IRB is responsible for determining whether assent is required (see section 6.1.3 regarding requirement for assent).

5.3.1. The Reviewing IRB will determine whether children are capable of providing assent by taking into account the ages, maturity and psychological state of the children involved. The judgment may be made for all children involved in the research under a particular protocol, or for each child, as deemed appropriate. [45 CFR 46.408(a), 21 CFR 50.55(b)]

5.3.2. If the Reviewing IRB determines that assent is required, the process for documentation of assent must also be determined (see section 6.1.1 regarding assent documents).

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5.4. Parents and legal guardians have the authority to provide permission for a child to participate in research. Permission of caregivers and/or service providers is not permitted.

5.4.1. For children who are wards of the state or any other agency, institution, or entity, permission must be obtained from an individual who is authorized under state/local law to consent on the child's behalf. With these cases, it is important to ensure that permission is being sought from the appropriate individual(s) and that documentation of this authority be maintained with the signed permission form.

5.4.2. In cases where an Investigator wants to get permission from someone other than a child's parents, the Investigator should ask that individual for court papers authorizing the individual to consent on behalf of the child to general medical care. If this documentation does not exist, and the Investigator still wants to obtain permission from that individual, the Investigator should consult with the University Office of Counsel or RSRB to assist in determining who has the legal authority to consent to the child's participation in research.

5.4.3. School principals, teachers, clinic personnel, etc. do not have the authority to give "blanket" permission for their students/patients/clients to participate in research. In classroom research, it must be made clear that the research is not part of the regular educational program and that the student's grades or standing will not be affected by not participating.

5.4.4. In certain situations, a child may consent in lieu of parent or guardian permission (see Section 6.2.1).

5.5. Investigators and research personnel are responsible for ensuring that the Reviewing IRB requirements for obtaining and documenting parental permission and assent are executed.

5.6. Investigators are responsible for ensuring that research is not proposed that involves the intentional exposure of children to any substance according to 40 CFR 26 Subpart D.

6. Requirements

6.1. When the RSRB is the Reviewing IRB, research involving children must include a Permission Form, and an Assent Form (or Assent Script) as applicable to the nature of the study (see section 6.1.2 for waiver of parental permission and section 6.1.3 when assent may not be required).

6.1.1. Development of Permission and Assent Forms

Permission by parent(s) or guardian(s) will be documented in a manner similar to that used to document informed consent for adults (see [RSRB Consent Document Templates](#)). Information about the research must be presented in a language and format that is understandable to the parent and child. The parent and child should have an understanding of the research procedures and it should be clear that their

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participation is voluntary. The RSRB uses the guidance set forth in Appendix 1 to determine age-appropriate consent format.

6.1.2. Waiver of Parent/Guardian Permission

6.1.2.1. The requirement for parental permission may be altered or waived under at least one of the following exceptions, as long as the research is not regulated by the FDA:

- i. Research meets regulatory criteria set forth at 45 CFR 46.116(d) for alteration or waiver of consent, for example:
 1. No-risk or minimal-risk research with older adolescents (e.g., anonymous surveys in high school students).
 2. Observational studies (no intervention) of public behavior (e.g., classroom activities).
 3. Studies of existing data.
- ii. The Reviewing IRB determines that the protocol is designed for a condition 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), provided that another appropriate mechanism for protecting the children is substituted (e.g., subject advocate), and the determination is not inconsistent with federal, state or local law [45 CFR 46.408(c)].
- iii. The Reviewing IRB determines that the protocol contains treatments or procedures for which parental permission is not required under New York State Law (see Section 6.2.1).

6.1.2.2. If the Reviewing IRB grants a waiver of parental permission, additional approval by the Senior Associate Dean for Clinical Research (SADCR), or designee, is required (with the exception of studies that only include activities accessing and using biospecimens or data with no subject interaction or intervention). See *Guideline for SADCR Review of Research Involving Children*.

- When the RSRB is the Reviewing IRB and grants a waiver of parental permission, the RSRB must document its findings justifying the waiver.

6.1.3. Decisions Not to Require Assent

6.1.3.1. The Reviewing IRB may determine, under the following condition(s), that assent of the child is not necessary for the research to proceed [45 CFR 46.408(a), 21 CFR 50.55(c)]:

- i. A child or all children involved in the study are incapable of assenting based on age, maturity or psychological state; or,

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- ii. 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 (e.g., children with life-threatening illnesses who are entered into open-label treatment protocols).

6.1.3.2. The Reviewing IRB may not require assent, although subjects may be capable of providing assent, under circumstances in which consent may be waived in accordance with 45 CFR 46.116(d) and 21 CFR 50.55(d). For example, assent is not sought from the child because a non-agreement of the child, especially in older children (e.g., 17), may be ethically troublesome. The University medical center offers a Clinical Ethics Consultation Service as a resource to subjects, families and staff.

6.2. Children in New York State Giving Informed Consent

6.2.1. Children (minors) may give consent to participate in research without parent or guardian permission if they have attained the legal age to consent for treatments or procedures involved in the research under the law of the state in which the research will be conducted [45 CFR 46.402(a)]. Accordingly, for the purposes of research activities and under the following conditions, the Reviewing IRB may permit minors to provide their own informed consent to participate in research within the State of New York without the requirement for permission of a parent or guardian; provided that the minor is determined to be capable of understanding the nature, risks, benefits, and alternatives to participating in the research (see Section 6.2.2).

- i. The subject has married or is the parent of a child (occurs with the birth of a child). [NYS Public Health Law Section 2504, SMH Policy 9.05].
- ii. The subject is a minor participating in research for reproductive health services, such as birth control, emergency contraception, care for sexually transmitted diseases and HIV/AIDS.
- iii. The subject is a pregnant minor participating in research relating to pre-natal care (see also *Policy 602 Research Involving Pregnant Women*).
- iv. Parents who are minors may give permission for their own children to participate in research; as long as they are capable of providing consent (see Section 6.2.2).
- v. Minors over the age of 16 may, in some situations, consent to psychiatric treatment. If research is proposed that involves administration of psychotropic medication to minors over 16, or other psychiatric care without parent or guardian permission, the RSRB will consult the Office of Counsel.

6.2.2. The Investigator will ensure the protocol indicates inclusion of minors and will describe appropriate measures to ensure that minors being considered for

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participation as subjects have the capacity to comprehend the nature of the research and their research rights (see *Guidance on Assessing Capacity in Children*).

- 6.2.3. The Reviewing IRB will determine and document whether participation of minors described in 6.1.2.1 above without permission of a parent or guardian, or permission by a minor for his or her own child is appropriate based on the risk level of the proposed research and that adequate protections for this population have been implemented.
- 6.3. A child cannot be enrolled if either the parent(s) refuses permission or the child subject refuses assent, unless parental permission has been waived or child assent is not required.
- 6.4. Research involving wards of the state or any other agency, institution, or entity may be included in research approved under 45 CFR 46.406 or 45 CFR 46.407, only if an advocate is appointed to 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*, and, the research meets the following criteria (45 CFR 46.409):
 - 6.4.1. Related to their status as wards, or
 - 6.4.2. Conducted in schools, camps, hospitals, institutions, or similar setting in which the majority of children involved as participants are not wards.
- 6.5. If a child turns 18 while actively participating in the study, he/she must give consent as an adult to continue participation in the study (e.g., long-term studies where subjects are enrolled as children, but who will turn 18 while they are actively undergoing research procedures/follow-up). If the subject is unable to give consent as an adult due to decisional impairment, see *Policy 604 Research Involving Decisionally Impaired*.
- 6.6. When the RSRB is the Reviewing IRB, the RSRB may require that the study team identify a research subject advocate who is independent from the study and available for consultation with research subjects as needed throughout the course of the study.
- 6.7. When the RSRB is the Reviewing IRB and the research involves children outside New York State (or outside of the country), the RSRB will determine who meets the DHHS definition of "children" through available resources, obtaining legal opinion from a qualified person in the other jurisdiction (e.g., IRB administrator or IRB chair in the local jurisdiction), or contact/consultation with University Office of Counsel.

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Appendices:

Appendix 1: Summary of RSRB Permission/Assent Guidance


Revision History:

3/2014: Section references corrected; Section 6.1.2.1 minor changes for clarification
1/2015: Sect 4.1 and 5.1 'note' EPA regulatory references and Sect 5.6 added per AAHRPP
1/2018: Sect 4.4 add hyperlinks to documents; updating RSRB to Reviewing IRB throughout where applicable; Sect 6.1.2.2 added an exception; Sect 6.2.4 moved under Sect 6.1.2.2; editorial changes
11/2020: Sect 6.4 clarified wards of the state language; update signatories, administrative changes


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APPENDIX 1

Summary of RSRB Permission/Assent Guidance

Subject Age Range**	Document Type(s)	Notes
7 and under	Parent Permission	No assent script or form required
8-12 years	Parent Permission + Assent Script	<ul style="list-style-type: none"> • Age-appropriate • Oral • Permits subject to opt out if parent(s) opt in • Signature of subject not required (but should document subject's name) • Documentation of person obtaining assent
13-17 years	Parent Permission + Assent Form	<ul style="list-style-type: none"> • Age-appropriate • Written • Permits subject to opt out if parent(s) opt in • Signature of subject and person obtaining assent required
18 years and older	Consent Form	When a subject reaches 18 years of age while participating in a study, the appropriate consent process should be conducted for the now adult subject to consent to participate in the research for him/herself.
Under 18: Minor May Otherwise Consent	Consent Form	<ul style="list-style-type: none"> • No parent permission form required • Documentation of comprehension required (see Guidance on Assessing Capacity in Children) • Appointment of advocate may be required
Under 18: Child Assent Not Required	Parent Permission	<ul style="list-style-type: none"> • No assent script or form required • Understanding of the child subject is still desirable and should be documented as applicable
Under 18: Waiver of Parental Permission	Assent Form	<ul style="list-style-type: none"> • No parent permission form required • Appointment of advocate may be required

** Age ranges provided above for obtaining assent from a child are only guidelines. The ages, maturity and psychological state of the children involved should be taken into consideration when determining whether and how to obtain assent.