

9 Requirement for Informed Consent:
9.4 Children as Research Participants

Effective Date: 9/11/2009
Revised: 5/24/2012,
3/8/2013

As a vulnerable population, children require additional protections when participating in research. Additional protections include the requirement for permission of a parent or guardian for research participation, unless this requirement has been waived by the IRB.

1.0 Parent or guardian permission.

Investigators must make adequate provisions for soliciting the written permission of each child's parent or guardian for their participation in research, unless the IRB has waived the requirement.

1.1 Research involving no more than minimal risk.

The permission of only one parent or guardian is required for research that involves no more than minimal risk.

1.2 Research involving more than minimal risk, and no direct benefit to subjects.

The permission of both parents (or guardians) is required for research that involves more than minimal risk, and no potential for direct benefit to subjects. Exceptions include situations where one parent or guardian is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

1.3 Permission process and documentation.

Obtaining permission of a parent or guardian is equivalent to the process of informed consent, as described in SOPs *9.1 Consent Process*, and *9.2 Documentation of Informed Consent*. The language used in Parent/Guardian permission forms should reflect that permission is being sought for their child to participate in research. Suggested templates are available on the IRB website.

2.0 Child assent.

Investigators must make adequate provisions for soliciting assent (agreement) of children to participate in research, where the children have sufficient capacity to make this decision. Under certain circumstances, this requirement may be waived by the IRB (see 3.0 below).

2.1 Children 7 – 12 years of age.

An investigator must obtain assent from participants from 7 through 12 years of age, unless the child displays intellectual/emotional development below that of the average 7 year old child. A *Child Assent Form*, containing very simplistic terms and language, is used for this age group. Suggested templates and examples are available on the IRB website.

2.2 Children 13 – 17 years of age.

An investigator must obtain assent from participants from 13 through 17 years of age, unless the youth displays intellectual/emotional development below that of the average 7 year old child. A *Youth Assent Form*, containing simplistic terms and language, is used for this age group. Suggested templates and examples are available on the IRB website.

2.3 Assent process and documentation.

Obtaining assent from children for research participation is essentially equivalent to the process of informed consent, and documentation of informed consent, as described in SOPs 9.1 *Consent Process*, and 9.2 *Documentation of Informed Consent*. In determining capacity to provide assent, a child's age, maturity, and psychological status should be considered. This judgment may be made for all children in a study, or for each child, as the IRB deems appropriate. Suggested templates for assent forms are available on the IRB website.

2.4 Children attaining age of majority while enrolled in research.

When a child who was enrolled in a research study with parent or guardian permission reaches the age of majority, the investigator must obtain their legally effective informed consent to continue ongoing research interactions, interventions, or data collection.

3.0 Waiver or alteration of child/youth assent.

The IRB may waive the requirement to obtain child assent, under any one of the following conditions.

3.1 Capability of children is limited that they cannot reasonably be consulted.

Institutional policy has considered children under 7 years of age, in general, to have limited capacity for understanding. Therefore, it is generally not necessary to seek their assent for research participation; only parent or guardian permission is required.

3.2 Research with potential for direct benefits (45 CFR 46.408(a), 21 CFR 50.55(c)(2)).

In most circumstances, a minor's deliberate objection should be regarded as a veto of his/her involvement in a research project. Parents or guardians may, however, with IRB approval, override a young child's objections to an intervention or procedure that holds the prospect of direct benefit to the participant that is important to their health or well-being and are available only in the context of the research.

3.3 Minimal risk research (45 CFR 46.116(d), 21 CFR 50.55(d)).

The IRB may approve a consent (assent) procedure that does not include, or which alters, some or all the elements of informed consent, or waive the requirement to obtain assent, provided that the IRB finds and documents that:

- the research involves no more than minimal risk to the subjects;
- the waiver or alteration will not adversely affect the rights and welfare of the subjects;
- the research or clinical investigation could not practicably be carried out without the waiver or alteration;

and

- whenever appropriate, the subjects will be provided with additional pertinent information after participation (i.e., de-briefed).

4.0 Waiver or alteration of parent/guardian permission.

The IRB may waive the requirement to obtain written parent or guardian permission for a child's research participation under one of the following provisions below. In some situations, the IRB may require that parents be provided with written information about the research, but not asked to sign a form, or otherwise provide active indication of their permission. This process is sometimes termed 'passive consent', where information is sent to parents, but a response is only required from those wishing to 'opt-out' of research participation for their child. Such a process does not constitute legally effective informed consent, and may be used only when the IRB has waived the requirement.

4.1 Neglected or abused children.

The requirement for parental permission may be waived by the IRB if such permission is not a reasonable requirement to protect the subjects (e.g., neglected or abused children), and the waiver is not inconsistent with Federal, state or local law. An appropriate mechanism for protecting the children who will participate as subjects is required. The choice of an appropriate mechanism would depend on the nature and purpose of the research activities, the risk and anticipated benefit to subjects, and their age, maturity, status and condition.

4.2 Public benefit or service programs (45 CFR 46.116(c)).

The IRB may waive the requirement to obtain written permission of a parent or guardian for studies of public benefit or service programs, provided that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:

- (i) public benefit or service programs;
- (ii) procedures for obtaining benefits or services under those programs;
- (iii) possible changes in or alternatives to those programs or procedures; or
- (iv) possible changes in methods or levels of payment for benefits or services under those programs;

AND

(2) The research could not practicably be carried out without the waiver or alteration.

4.3 Minimal risk research (45 CFR 46.116(d)).

The IRB may waive the requirement to obtain written permission of a parent or guardian for minimal risk research, provided that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration;

and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation (e.g., debriefed).

4.4 State law permits minors to consent.

North Dakota state law permits minors 14 years or older to consent for treatment for sexually transmitted disease, alcoholism, or drug abuse without permission of a parent or guardian.

In addition, a minor may receive emergency treatment, pregnancy testing and prenatal care without permission of a parent or guardian. If the research involves these types of procedures, the IRB may waive the requirement to obtain written permission of a parent or guardian.

4.5 Limitations on IRB approval of waivers.

Other laws or school policies may prohibit the IRB's approval of a waiver of the requirement for informed consent, parent permission, or child assent.

4.5.1 Family Educational Rights and Privacy Act (FERPA).

Research conducted in a public or private school may be subject to the Family Educational Rights and Privacy Act (FERPA), governing the use of academic records. Where applicable, use of academic records for research generally require the signed permission of a parent or guardian (if the student is a minor) or signed consent of the student. Refer to SOP 11.1 *Use of Confidential Records* for more information.

4.5.2 Protection of Pupil Rights Amendment (PPRA).

Research conducted in a public or private school may be subject to the Protection of Pupil Rights Amendment (PPRA), governing the content of third party surveys of students. Where applicable, PPRA requires written permission from a parent or guardian for third-party surveys or evaluations that collect information on sensitive topics, such as:

- political affiliations or beliefs of the student or their parent(s)
- mental or psychological problems of the student or their family
- sex behavior or attitudes
- illegal, anti-social, self-incriminating, or demeaning behavior
- critical appraisals of other individuals with whom respondents have close family relationships
- legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers
- religious practices, affiliations, or beliefs of the student or their parent, or
- income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program)

5.0 Additional IRB determinations for approval of research involving children.

In order to approve research involving children, the IRB must make additional determinations regarding the level of risks and benefits, and applicable category of approval. Refer to SOP 10.1 *Vulnerable groups: Children* for more information.

6.0 Mandated reporting of child abuse or neglect.

Depending on the nature of the research project, an investigator may anticipate the possibility of obtaining information regarding child abuse or neglect. Researchers may be subject to mandatory reporting of suspected cases, and should disclose (in the permission form) to parents or guardians the possibility of reporting such information to the authorities. Mandated reporters include: physician, nurse, dentist, optometrist, medical examiner or coroner, or any other medical or mental health professional, religious practitioner of the healing arts, schoolteacher or administrator, school counselor, addiction counselor, social worker,

child care worker, foster parent, police or law enforcement officer, juvenile court personnel, probation officer, division of juvenile services employee, or member of the clergy. In addition to those individuals required to report, any other person may also report suspected child abuse or neglect, in accordance with ND State law.

DEFINITIONS:

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

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 where the research will be conducted. In North Dakota, a minor is someone under 18 years of age; this may vary from state to state.

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

Informed consent: the voluntary agreement of a participant, or their legally authorized representative, to take part in research, after being provided with sufficient information about the study, in a language and terminology understandable to them, and sufficient opportunity to consider their decision.

Legally authorized representative: an individual authorized by a judicial body or other appropriate body to give consent on behalf of a prospective subject to the subject's participation in research. May include: a health care agent (named as a durable power for health care decision maker while the subject had competency), or a court-appointed guardian.

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.

Parent: a child's biological or adoptive parent.

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

REFERENCES:

[45 CFR 46, Subpart D](#) Additional Protections for Children Involved as Subjects in Research

[21 CFR 50, Subpart D](#) Additional Safeguards for Children in Clinical Investigations

OHRP FAQ, [Research Involving Children](#)

US Dept. of Education Family Educational Rights and Privacy Act ([FERPA](#))

US Dept. of Education Protection of Pupil Rights Amendment ([PPRA](#))

ND Century Code Chapter 50-25.1 [Child Abuse and Neglect](#)

ND Century Code Chapter 14-10 [Minors](#)

RELATED FORMS:

IRB Protocol Form

Children in Research Attachment form

Informed Consent Waiver or Alteration Request
Child/Youth assent templates
Parent/Guardian permission templates

RELATED STANDARD OPERATING PROCEDURES:

9.1 Consent Process
9.2 Documentation of Informed Consent
9.3 Waiver or Alteration of Informed Consent Requirements
10.1 Vulnerable Groups – Children
11.1 Use of Confidential Records