

10 Vulnerable Groups:

10.1 Children

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Children are considered a vulnerable research population because their intellectual and emotional capacities are limited. Federal regulations require additional protections when children will be involved in research. These protections include limited categories of research that may involve children, as well as a requirement for parent or guardian permission.

1.0 Categories of research that may involve children.

There are four categories of research that the IRB may utilize to approve non-exempt research involving children.

1.1 Research or clinical investigations not involving greater than minimal risk (45 CFR 46.404, 21 CFR 50.51)

The IRB may approve research involving no greater than minimal risk, provided that adequate provisions are made for soliciting the assent of the children and the permission of at least one of their parents or guardians.

1.2 Research or clinical investigations involving greater than minimal risk, but prospect of direct benefit (45 CFR 46.405, 21 CFR 50.52)

The IRB may approve research involving greater than minimal risk, but the prospect of direct benefit to subjects, provided that:

- adequate provisions are made to solicit the assent of the children and the permission of at least one of their parents or guardians;
- the research intervention or procedure has the potential for direct benefit to subjects, or a monitoring procedure is likely to contribute to the subject's well-being;
- the risk is justified by the anticipated benefit to subjects; and
- the risk/benefit ratio of the research is at least as favorable for subjects as available alternatives

1.3 Research or clinical investigations involving greater than minimal risk, with no prospect of direct benefits (45 CFR 46.406, 21 CFR 50.53)

The IRB may approve research involving greater than minimal risk, with no prospect of direct benefit to subjects, provided that:

- adequate provisions are made to solicit the assent of the children and the permission of both parents or guardians;
- the research intervention or procedures is likely to yield generalizable knowledge about the subject's disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition;
- the risk represents a minor increase over minimal risk;
- the research intervention or procedures present experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;

1.4 Research or clinical investigations on serious problems affecting the health or welfare of children (45 CFR 46.407, 21 CFR 50.54)

Research that is not otherwise approvable under any of the 3 categories above requires review by the Secretary of the US Health and Human Services (HHS), (and the Commissioner of Food and Drugs, if applicable) in addition to local IRB review. In reviewing research under this category:

- 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; and
- the HHS Secretary (and Commissioner of Food and Drugs, if applicable), after consultation with a panel of experts in pertinent disciplines and following opportunity for public review and comment, has determined either:
 - 1) that the research satisfies the conditions of 46.404 (50.51), 46.405 (50.52), or 46.406 (50.53), or:
 - 2) (i) the research presents an opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
(ii) the research will be conducted in accordance with sound ethical principles; and
(iii) adequate provision are made for soliciting the assent of children and the permission of their parents or guardians.

HRPP staff will forward the protocol and supporting documentation for review by the applicable federal agency (OHRP or FDA) using each agency's published procedures. The agency will post the materials for public comment, requesting recommendations from a panel of experts. Following the review, the agency may either find that the research is approvable under one of the 3 allowable categories, or that the research may be approved under this category.

2.0 IRB review.

The IRB reviews research involving children by a variety of methods.

2.1 Exempt categories of research.

The IRB may determine that a research project involving children is eligible for one or more of the categories of exemption. Exempt categories 1 and 3 -6, as well as category 2 regarding educational tests may be applicable to research involving children. However, category 2 for research involving survey or interview procedures or observations of public behavior does not apply to research involving children, except for observation of public behavior when the investigators do not participate in the activities being observed. Refer to *7.1 Exempt Determinations* for more information.

2.2 Review by the expedited method.

The IRB may review research involving children using the expedited method, provided that the research qualifies as minimal risk, under one or more of the allowable categories of research. Refer to *7.3 Expedited Review* for more information.

2.3 Review at a convened meeting.

The IRB may review research involving children at a convened meeting. Refer to *7.4 Full Board Review* for more information.

3.0 Informed consent requirements.

Investigators must make adequate provisions to solicit the assent of children, as well as the permission of their parents or guardians prior to the child's participation in research, unless the IRB has waived this requirement. Refer to *9.4 Children as Research Participants* for more information.

4.0 Wards of the state.

Children who are wards of the State or any other agency, institution, or entity may be included in categories of research or clinical investigations described in sections 1.3 or 1.4 above only if such research is:

- related to their status as wards
- conducted in schools, camps, other settings in which majority of children are not wards

The IRB requires that an advocate be appointed for each ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. A single individual may serve as an advocate for more than one child. The advocate should have the background and experience to act in the best interests of the child for the duration of their participation in the research. They must not be associated with the research, the investigator(s) or the guardian organization.

5.0 Research conducted in public or private schools.

Research conducted in public or private schools may be subject to other laws or school policies that would affect collection of data from students, and/or the requirement to obtain written permission from parents or guardians.

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 requires the signed permission of a parent or guardian (if the student is a minor) or signed consent of the student. Refer to *11.1 Use of Confidential Records* for more information.

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)

6.0 Mandated reporting responsibility for child abuse or neglect.

Investigators may be required to report cases of suspected child abuse or neglect. If that type of information is likely to be revealed during the conduct of the research, parents or guardians should be informed (in the permission form) that the researcher will be required to report 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; however this varies 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: the agreement of parent(s) or guardian(s) 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 with 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

Informed Consent Waiver Request Attachment

Child/Youth Assent templates

Parent/Guardian permission templates

RELATED HRPP SECTIONS:

7.1 Exempt Determinations

7.3 Expedited Review

7.4 Full Board Review

9.1 Consent Process

9.2 Documentation of Informed Consent

9.3 Waiver or Alteration of Informed Consent Requirements

9.4 Children as Research Participants

11.1 Use of Confidential Records