Northeastern University
Human Research

Guidance: Research Involving Minors

Overview

The Northeastern IRB follows state and federal regulations for research involving children. Studies that enroll children must consider a plan for obtaining minor assent and parental permission/legal guardian permission. There are criteria by which these can be waived. This document outlines these expectations.

Definitions *(Federal regulations under CFR 46.402)*

Who is a child or minor?

Children are 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.

Massachusetts state law (MGL c. 4, § 7) defines the age of majority as 18 years old. This means that, for most non-medical research conducted in MA, anyone under 18 is considered a child. For research conducted outside MA, please review the state or regional laws that define the age of majority.

Who is a parent or legal guardian?

Parent means a child's biological or adoptive parent.

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

For the purposes of research with unemancipated minors, parental or legal guardian permission can be obtained from:

1. The parent or parents who have custody of the child,
2. The legal guardian of the child, or
3. Any person or judicial or other body authorized by law to provide consent on behalf of the child for participation in human subjects research.

If permission is from someone other than a biological or adoptive parent, investigators must verify legal guardianship or the legal authority of that individual or other body to provide consent on behalf of the minor.

What is parental permission and how does it differ from consent?

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

"Parental permission" or "consent on behalf of the child" should generally not be shortened to "informed consent," as "informed consent" refers to an adult giving consent on their behalf. It is encouraged to refer to the process as "parental permission" or "consent on behalf of the child".

What is minor assent?

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

Children are expected to be part of a discussion about the research and asked if they agree to take part. This agreement to take part in research is referred to as "assent." While not legally binding, it is expected that a child voluntarily agrees to take part in research that impacts them even if their parent has agreed.

Assent should respect a child's growing sense of autonomy and ability to voluntarily take part in activities such as research. In general, the IRB expects that assent be obtained from any children 4 or older, unless there are developmental issues that might make this inappropriate.

The assent process should be similar to a consent process, but often has to take into account the child's cognitive capability. Assent, like consent, is expected to be an ongoing process. Even if a child assents and expresses desire to stop at a later point, that decision should be respected, and the child should be withdrawn.

Exempt Research Involving Minors

Can research involving children qualify for exempt review?

Research with minors does qualify for exemption in some limited situations. For complete details of exemption categories, please review the Exemption guidance. Generally speaking, exempt research involving minors consists of educational research (for example, studying a new 9th grade math curriculum) and secondary data research under Exempt 4. Research involving minors outside of these narrow situations requires Expedited or Full Board review.

Please note that minor assent and parental permission is still expected for Exempt research with minors that involves intervention or interaction with minors. Activities that do qualify for exemption but do not obtain minor assent and parental permission will be reviewed, at the discretion of the DHR, as non-exempt research.

Non-Exempt Review and Regulatory Requirements

Assent

- Assent is required for children capable of providing assent unless it is waived (see waiver of assent below). In general, assent is expected for children age 4 or older.
- Assent should generally be read aloud to younger children and can be a document more like a consent form for older children.
- The assent process should prompt the child to ask questions and confirm the child understands.
- The assent process should match the child's maturity and developing sense of autonomy.
- Studies including a broad age range should use multiple assent processes.
- The assent process should take into account and mitigate parental pressure.

Documentation of Assent and the Assent Script/Form

- Signed assent is not required. It is often impractical for younger children, but is generally recommended for older children.
- Assent materials (forms, verbal scripts, or other aids) will need to be submitted and approved by the IRB. Please label the age range for each version of assent materials.
- The assent form may be combined with a parental permission form for older children. In such cases, a separate signature line for minor assent should be included on that form.
- If signatures are not collected, it is best practice for study teams to document who, on the study team, conducted and verified assent.

When Assent is Required

- Even if the requirement for assent is waived, it is always preferable to explain the research to the child and take their wishes into account before deciding whether to enroll them.
- The IRB may not require assent under one of the following conditions: 45 CFR 46.408, 21 CFR 50.55
    - Some or all of the children will not be capable of providing assent based on their ages, maturity, psychological state, and other factors. The IRB relies on the PI's professional expertise for determining this, and may require that the application include documentation of the rationale for the determination.
    - 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.
    - The same conditions under which consent and parental permission can be waived apply (see 45 CFR 46.116 and 21 CFR 50.55(d) for FDA regulated research).

Parent/Guardian Permission

- Parental permission follows standard informed consent regulations. All elements of consent will need to be included unless a waiver or alteration is granted.
- An "opt out" process does not meet the requirements for parental permission. Studies wishing to use an "opt out" parental permission process will need meet the criteria for a waiver of parental permission.
- The parental permission process will need a mechanism to confirm the individual signing or agreeing is the parent of legally authorized representative of the child. Sending a permission slip home with a child and confirming it is returned with some signature on it does not meet this threshold.

Documentation of Parent/Guardian Permission

- Permission from one parent/legal guardian: Generally sufficient for most minimal risk research or greater than minimal risk research that proposes a direct benefit to the child. The IRB may require permission from both parents/legal guardians in some circumstances.
- Permission from both parents/legal guardians, unless one parent is deceased, unknown, incompetent, not reasonably available, or does not have legal responsibility for the custody of the child: Required for most research that is greater than minimal risk.
- Signature will need to be a legally valid signature (i.e. either a "wet" signature or an signature using a digital platform consistent with state or regional laws).

Parental Permission and Assent Requirements based on Study Details

Risk Level	Benefit	Requirements
No more risk than daily life	No direct benefit needed	Parental permission (one parent) & child assent (if appropriate). (see §46.404)
More than minimal risk	Direct benefit to the child	Parental permission (one parent) & child assent. (see §46.405)
Slightly more than minimal risk	Helps understand the child's condition	Parental permission (two parents) & child assent. (see §46.406)
More than minimal risk, doesn't fit other categories	Addresses serious child health issue	Requires expert review & HHS approval. Parental permission (two parents) & child assent. (see §46.407)

Waivers of Parental or Legal Guardian Permission

The IRB may waive parental permission under one of the following conditions:

- The IRB determines that, based on the conditions or population, parent/guardian permission is not a reasonable requirement in order to ensure the protection of the research participants (for example, neglected or abused children). *Note that this does not apply to FDA-regulated research.*
- The same conditions under which a waiver of consent applies (see 45 CFR 46.116 and 21 CFR 50.55(d) for FDA-regulated research [link DHR guidance on waivers]).

Children who Reach Adulthood

- When a child participant who was enrolled in research with parental/legal guardian permission reaches adulthood (i.e. the age of majority which is 18 in MA) before the research ends, it is required that the participant be re-consented as an adult for their ongoing participation.
- This is because the prior parental permission and child assent are not equivalent to legally effective informed consent for the now-adult participation.
- Please note that ongoing participation includes analyzing identifiable data. If a study is in data analysis and is using identifiable data, the now adult participants will need to agree to continue to allow their data to be analyzed.
- If re-consent is not possible, an IRB-approved waiver of informed consent may apply. The waiver would use standard consent waiver criteria and review process for adults.

Frequently Asked Questions (FAQs)

What if I'm enrolling both a child AND their parent?

Research that primarily involves children may also include procedures for the parent/guardian. Consent should be obtained and documented from the parent/guardian as well as permission for their child to participate in the study.

What should be included in an assent form or script?

There are no definitive guidelines about what an assent form should include as it varies depending on the cognitive and reading ability of the child. Assent forms or scripts for 4-year-olds are often very short (2-3 sentences) while assent forms for 17-year-olds are often identical to a consent form for adults. In general, an assent form should describe:

- what the study is about,
- why the child is eligible to participate for the study,
- what the child will be asked to do or what procedures will be performed,
- potential risks and discomforts.

What if two parents disagree about allowing their child to take part?

If there are two parents available to give permission but they disagree about allowing their child to participate in the study, the child may not be enrolled unless that disagreement can be resolved. This restriction applies to all permissible categories — that is, when both parents are involved in the decision, they must agree for the child to be enrolled, even if only one parent's signature is required.

What if a parent and child disagree about taking part?

If a parent wants a child to take part in the study, but the child does not want to take part in the study (and assent was determined by the IRB to be required), the child should not be enrolled in the study. If assent was waived or not required, the decision is deferred to the parent(s), but the parent(s) should be encouraged to take their child's preference into account.

When can minors consent for themselves?

There are situations where a minor is authorized to consent for themselves. For examples, minors who are deemed to be "self-sufficient", minors who have been legally emancipated, or for certain healthcare operations. These situations are defined by state or regional law and vary from situation to situation. Researchers who believe their minor participants are legally able to consent for themselves should work with Northeastern's Office of General Council to determine which laws apply and why. Documentation should be provided to the IRB as part of a submission.