

# Vulnerable Populations – Children

## Background

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Federal regulations include additional protections for children involved as subjects in research. Generally, regulations allow child participants if study procedures pose no greater than minimal risk, and researchers obtain informed consent from a parent or legal guardian and informed assent from the child. For research posing greater than minimal risk, additional protections apply. This document defines terms and explores considerations for research involving children.

## Definitions

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### What is a child?

**Children** are persons who have yet to attain the legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research takes place.

The definition of a child, or minor, varies by state and country. In general, a person is deemed a child if they have not reached the age of majority (18 years old in Iowa). When developing study materials and preparing the IRB application, establish the relevant age of majority based on your research location.

### What is a parent or guardian?

A **Parent** is a child's biological or adoptive parent.

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

Caretakers such as childcare providers, grandparents, etc., may only provide consent on behalf of a child if they are legally authorized representatives.

### Consent

When enrolling children in research, there are generally two required components of informed consent: parental permission and child assent.

**Permission** is the agreement/consent of parent(s) or guardian(s) to the participation of their child or ward in research.

**Assent** is a child's affirmative agreement to participate in research. Failure to object should not be construed as assent; affirmative agreement is required.

Please refer to the [regulations \[45 CFR 46.401\(a\)\]](#) for more information.

# General Considerations

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## Parent/Guardian Permission

Permission from a parent or guardian is a key element of protecting children, and thus is nearly always required for a child to participate in research. In low-risk research, permission from one parent/guardian is sufficient; permission from both parents may be necessary in higher-risk research.

Regulations allow the IRB to waive the parent consent requirement under [certain circumstances](#). Researchers must provide compelling justification for a waiver in the IRB application.

Parent permission must be “active”—that is, a parent/guardian must affirmatively agree, usually via signing a parent consent form. “Passive” consent, where parent permission is presumed unless the parent takes action to opt-out, does not constitute parent permission and is allowable only if the parent consent requirement is waived by the IRB.

As with consent from adult research subjects, parent/guardian permission must be freely given and based on sufficient information provided in a language understandable to the parent. See our guidance [Consent Process](#) information. Parent/guardian consent [templates](#) are also available.

## Ethics

Because children are vulnerable populations, IRB applications need to include the rationale for their inclusion (e.g., the study addresses a condition that particularly affects children, etc.). Further, researchers should identify any unique outcomes, benefits, or risks related to studying children.

At the same time, regulations require the equitable selection of research participants. If the research may offer a benefit for children, researchers need to provide justification for their exclusion. While in some research settings obtaining parental consent might pose a significant administrative burden, in general, a desire to avoid obtaining parental consent is not an adequate rationale to support the exclusion of children.

## Privacy

As noted in our related [Tipsheet](#), privacy protections must be carefully designed to maximize people’s ability to control access to themselves in the specific context of a study. Even after a parent or guardian has provided informed consent for a child to enroll in research, investigators are responsible for respecting each child’s autonomy.

There are no one-size-fits-all methods; needs vary depending on the nature and context of each study. Researchers must find a balance between protecting the privacy of child participants with having parents present for protection. Research that involves asking children to disclose highly personal, private, or risky information (e.g., about illegal activities, sexual behaviors, sensitive family information, physical or mental health, etc.) must proactively address both parental and child privacy protections.

One-on-one interactions with children should be avoided. Researchers must plan to have more than one adult present or within eyeshot during research interactions with children. The second adult may be another member of the approved research team, the child’s parent, teacher, or childcare provider, a program or group staff person, or other person as appropriate for the research setting, the age of the child, and privacy and confidentiality protections.

## Recruiting and Research Locations

For many studies involving children, recruitment begins with obtaining permission from an existing institution or program, such as a childcare facility, school district, summer program, etc., to conduct the research. Schools, for example, often have standard procedures for reviewing and approving research involving enrolled students and preferences related to communicating with parents/guardians and obtaining permission.

When conducting a study outside of the structure of a program or school, researchers often recruit directly through parents/guardians, using flyers, email messages, etc., to share information about the study with adult decision-makers.

Researchers need to describe plans to properly care for and supervise children in the related IRB application. This might involve confirming that a member of the research team will escort children from their classroom to the in-school study location and back, for example. Research activities conducted outside of existing institutions or programs require more extensive safety plans. More information is available in the Operations section of the [Youth Program Procedures](#) webpage.

## Background Checks

[ISU policy](#) requires that background checks be completed for all researchers and key personnel who will have any contact with children involved in this research project. This includes collaborating researchers from other institutions when applicable. Information on the background check process can be found [here](#). *Principal Investigators and Supervising Investigators are responsible for ensuring that background checks are completed **BEFORE** researchers or key personnel may have any contact with children.*

Records documenting completion of the background checks must be kept with other records (e.g., signed informed consent documents, approved IRB applications, etc.) and may be requested during any audits or Post Approval Monitoring of your study.

## Assent

Except in highly unusual circumstances, researchers must obtain assent (or affirmative agreement) from each child, in addition to the consent of their parent or legal guardian. Assent is required unless:

- The children are not capable of providing assent based on their age, maturity, or psychological state; or
- The research intervention or procedure holds out the prospect of direct benefit that is important to the health or well-being of the child and is available only in the research context; or
- The IRB waives the requirement for assent (when the children are otherwise capable of providing assent).

Assent may be obtained verbally in many cases, or it may be documented with the child's signature. The key factor is assuring that the child affirmatively agrees - the simple lack of disagreement is not affirmative agreement.

Consider the following when developing child assent procedures and materials:

- Make it easy for children to understand what they are being asked to do. Children must be able to freely and voluntarily choose whether to take part in the research. Multiple assent processes/documents may be needed for studies that involve children of varying ages.

- While regulations specify elements that must be included in adult/parent consent materials, there are no such specifications for assent materials. The children’s age, maturity, and/or psychological state should guide assent content.
- Use accessible language in assent materials.
  - Microsoft Word includes a [Readability Statistics](#) function which provides a rating and a Flesch-Kincaid Grade Level for any document.
  - ISU currently provides free access to [Grammarly](#), a digital writing support platform that evaluates writing for several factors, including clarity.
- Determine an appropriate means of obtaining assent from children. Written signatures on a hard copy or electronic consent form may be appropriate for children able to read the form and sign their names. Other options include:
  - Children click a response option within an online survey.
  - In some settings, verbal assent is appropriate.
  - Researchers working with very young children might simply ask permission to engage in the research activity. For example, “May I read to you?” or “Do you want to play a game?” are both viable options. While infants and toddlers may not be able to grant affirmative assent, researchers must respect refusal. If a child is crying, not interested in research intervention, or otherwise uncomfortable, do not force their participation.
- Determine how to ensure and document that BOTH parent/legal guardian consent and child assent are obtained.
  - Ask the parent/legal guardian to write the child’s name on their consent forms to facilitate matching with child assent forms.
  - Ask the child to print their names on the child assent form, as signatures may not be legible.
- Avoid real or perceived pressure or coercion to enroll in the research.
  - Convey that parental consent does not mean the child has to agree.
  - Children might feel pressure to please their teachers, coaches, or other mentors. If enrolling kids in research when important adults are present (e.g., in school, before practice, during an after-school program, etc.) work with the organization in advance to reinforce that research is truly voluntary.
  - When these important adults are members of the research team, or even present during recruitment or data collection, tell children that these adults will support anything the child decides (enrolling, withdrawing early, not enrolling in the research). In other words, help kids understand that no one will be mad if they don’t want to be in the study.
  - If possible, create a process in which these trusted adults will never know who has enrolled in the study.
  - Work with schools/programs to protect children from social isolation or other negative consequences related to their decision to not enroll in or withdraw early from the research.
  - Ensure that research conducted during school or other programs has an alternative activity for children who choose not to enroll (or whose parents do not consent to their participation). During the assent process, provide clear examples of those alternatives.
  - More information is available in the guidance on [Vulnerable Populations – Subordinates](#).

# Additional Considerations

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## Research in Schools

Work with school or system decision-makers in advance to obtain permission to conduct your research. Administrators may have requirements or preferences in terms of how you communicate with parents, obtain parental consent, and collect data, etc. In addition, detailed and proactive communication with school leaders can protect participating teachers or other staff members, especially if the research involves altering curricula or teaching methods.

Regulations that may apply to research conducted in educational environments include the following:

- [Family Educational Rights and Privacy Act \(FERPA\)](#)
- [Protection of Pupil Rights Amendment \(PPRA\)](#)
- Additionally, some states may have laws pertaining to collecting data from children in school settings.

## Wards of the State

Regulations limit the kind of research activities in which children who are wards of the state can participate and, in some cases, require the appointment of an advocate to act in the best interests of the child. For more information, visit [45 CFR 46.409](#).

## Research with Children Federal FAQs

The [Office for Human Research Protections \(OHRP\)](#) has extensive information available online, including answers to [frequently asked questions about research with children](#).

### Document History

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