

**Quick Reference Guide
Children as Research Subjects**

This guide is a supplement to: POLICY HRP-021: LARs, Children, and Guardians; INVESTIGATOR GUIDANCE HRP-802: Informed Consent; and CHECKLIST HRP-310: Children

1. When are subjects under age 18 considered “children” in human research?

Per **POLICY HRP-021: LARs, Children, and Guardians**, subjects under 18 are children in **all cases EXCEPT** the following:

- Legally emancipated minors, regardless of age or type of research
- Married individuals, regardless of age or type of research
- Individuals of any age if the research procedures involve medical care related to the diagnosis or treatment of venereal disease
- Individuals of any age if the research procedures involve birth control information or services
- Individuals 14 years of age or older if the research procedures involve outpatient diagnosis or treatment of a mental or emotional disorder or chemical dependency, excluding methadone maintenance
- Individuals 15 years of age or older if the research procedures involve hospital care or medical or surgical diagnosis or treatment

2. What are the consent/parent permission and assent requirements for the study?

<p>Are the subjects legally considered children per Section 1 above and POLICY HRP-021: LARs, Children, and Guardians?</p>	<p>Yes: Who must provide consent/parent permission?</p>	<p>Study is minimal risk or holds out prospect of direct benefit: One parent/guardian.</p>	<p>Is assent required?</p> <ul style="list-style-type: none"> •No: Subjects do not have capacity to assent. •No: Study holds out prospect of direct benefit, is important to subjects' health/well-being, is only available in the study. Subjects may be asked to assent at investigator's discretion. •Yes: The above two do not apply.
	<p>No: Subjects can consent for themselves. Parent(s)/guardian may also participate in the consent process and sign the consent form.</p>	<p>Study is greater than minimal risk with no prospect of direct benefit: Two parents/guardians, unless one is not reasonably available.</p>	<p>Is assent required?</p> <ul style="list-style-type: none"> •No: Subjects do not have capacity to assent. •Yes: Subjects have capacity to assent.

Note: The IRB can waive parent permission and/or assent requirements if appropriate in light of the nature of the study and the subject population. If you are requesting this, include justification in your protocol.

3. When required, what are the appropriate procedures for obtaining assent from the child subjects?

*The IRB uses age as a general guideline in determining appropriate assent procedures, but it is ultimately **up to the investigator to assess what is appropriate for the study population and describe these procedures in the protocol, providing justification for any deviations from these guidelines.***

Children younger than 7 years: Assent is not required because the subjects are so young they cannot reasonably be consulted. However, a simple verbal explanation of the study procedures should be given if appropriate.

Children ages 7 – 14 years: Researchers may obtain assent verbally and document this on the consent form or elsewhere in the research record, or researchers may ask the subject to sign an assent form after discussing the study with the subject at a level appropriate to the subject’s understanding. Researchers may use the OHSU assent template or create their own.

Children ages 15 – 17 years: The subject may sign the consent form along with his or her parent(s) or guardian as documentation of assent. A separate assent form is not needed.

EXCEPTION to assent requirement for children ages 7 – 17: If the research study holds out a prospect of direct benefit that is important to the health or well-being of the child subjects and is available only in the context of the research, assent is not required. However, researchers should explain the study to the subject at a level appropriate to his or her understanding. Researchers may obtain assent if there is a reasonable opportunity and they feel it is appropriate.

Subjects under 18 who are not “children” per Section 1 above: Subjects may provide their own informed consent to participate in the research. The subject’s consent alone is sufficient, but often, the subject’s parent(s) or guardian will also give permission and sign the consent form.

TIP for all subjects ages 15 – 17: Refer to the IRB’s suggested consent form signature templates. Options are provided for studies where subjects in this age group are considered “children” and studies where they can consent for themselves.