

ASSENT GUIDANCE

The HRPP/IRB is responsible for reviewing informed consent procedures and materials to ensure the protection of the rights and welfare of human subjects and equitable participant enrollment. Research involving children is subject to additional protections outlined in [45 CFR 46 Subpart D](#), since children are considered a vulnerable subject population. When children are the focus population, they must provide assent to participate in the research. According to [45 CFR 46.402\(b\)](#), **Assent** is a child's affirmative agreement to participate in research.

Procedures for Obtaining Assent

- When a human subject participant is below the legal age of consent, the researchers must obtain assent from the child. In the US, participants under the age of 18 cannot provide consent, and instead provide assent.
- Parental permission from one or both parents (or from a legal guardian) is also required.
- Permission from both parents are required when
 - 1) The research is greater than minimal risk where there is no prospect of direct benefit to the child, per [45 CFR 46.406](#), and
 - 2) The research is not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children, per [45 CFR 46.407](#)
- When conducting research with participants who are children, the parent(s) of the child should typically be approached first. Parent permission must be obtained **before** child assent is obtained.
- Both parent permission and child assent must be provided before research activities can begin.
- If the child does not assent but the parent provides permission, the child must not participate in the research. Similarly, if the child provides assent but the parent does not provide permission, the child must not participate.
 - Note: There are some instances in which the parent may provide permission without the child's assent, but this is uncommon. If you are unsure if this may apply to your research, please contact HRPP at irb@wsu.edu.
- If a participant reaches legal age while the study is still being conducted, the participant must re-consent to study procedures as an adult. Parental permission is no longer required.

Resources for Developing Equitable Assent and Parent Permission Forms

- Assent and Parent Permission templates are provided by the WSU HRPP/IRB as a starting point for developing your materials. Please visit our [Forms Index](#) webpage to find the assent or parent permission form(s) relevant to your subject population.
- Materials should be created to match the reading level of your prospective participants whenever possible. Resources for analyzing grade level appropriate language include but are not limited to:
[Readability Calculator](#)
- If enrolling Non-English or English as a second language (ESL) participants, translations should be created and included in your submission packet for review. Resources for translation services include, but are not limited to:
[WSU Translation Services](#)
- Assent and Parent Permission materials should be created to be accessible to all whenever possible. Resources for how to format and create accessible materials, especially for people who use assistive devices include, but are not limited to:
[Creating Accessible Materials](#)

The following additional requirements for assent should be provided in the form:
A statement that the parent(s) are aware that the child is being asked about the research.
A statement that the child may refuse to participate, even if the parent(s) provided permission.
A description of the research data, if any, that will be shared with the parent(s).
A statement about the requirements for mandatory reporting of child abuse.
Tips:
Ensure language utilized is grade level appropriate. An assent form for 15 to 17-year olds may include more complex language than an assent form for 8 to 10-year olds.
Consider using pictures to demonstrate study procedures when obtaining assent from younger children.
Utilize free online resources for simplifying language, such as Rewordify.com .
Calculate the readability of your assent form using Microsoft Word's Flesch-Kincaid grade level test and Flesch-Kincaid Reading Ease test.
Behavioral assent (nodding of the head, verbal assent) may be an appropriate form of assent for younger children (ex: 4-6 years of age).