

All research involving children or adults with diminished decision-making capacity requires adequate provisions for soliciting the assent of each participant unless the board waives this requirement. Additionally, parental permission or legal authorized representative (LAR) consent must accompany assent unless the board waives this requirement.

Federal regulations require IRBs to determine in their review that adequate provisions are made for soliciting the assent of children who possess assent capacity. This means that both the researcher and the IRB must consider the age, maturity, and psychological state of eligible children. If some or all children lack the capacity to give assent, the IRB may grant a waiver.

Whether the IRB requires documented (signed) or strictly oral assent depends on potential participants' ages and levels of mental development, considered together with the complexity of the study under review. It's common for IRBs to require the assent of participants age 7 and older, although there are exceptions. IRBMED recommends that child participants age 9 and older provide documented assent when research involves drug or pregnancy testing and/or recommends use of birth control during participation. IRBMED guidance offers a general outline of which assent plans, including waivers of assent, the IRB commonly finds appropriate within various age ranges.

Whereas an assent document designed for elementary- and middle-school-age readers may omit much of the detail included in the parental permission document, adolescent readers generally possess the reading and comprehension skill to warrant inclusion of most of the detail in an adult's document. In fact, it's common for researchers to prepare a single document for use in both the consent of adults and the assent of older minors, although some of the information in IRBMED's consent template—notably financial and HIPAA-related details—may be less relevant to minors.

The IRB may determine in which order researchers should seek assent and parental permission, given the research and the context in which it will be conducted. OHRP guidance recommends that, in general, parental or guardian permission should be sought before assent, particularly in research posing greater than minimal risk.

Federal regulations require parental permission from both parents unless research involving minors presents no more than minimal risk and/or offers the potential for direct benefit, in which case the IRB has the option to require only one parent's permission. If two parents' permission is required but one parent has sole legal custody of the participant, or if the other parent is deceased, unknown, incompetent, or not reasonably available, the IRB may decide on a case-by-case basis to allow permission from only one parent. The researcher should indicate clearly in the study record why the second parent did not sign.

When children enrolled in research reach the legal age of consent, legally effective informed consent must be obtained for these now-adult participants to permit any ongoing research activity, unless the requirement for informed consent is waived by the IRB.

Part Two of this presentation will focus on assent considerations and requirements in research involving adults with cognitive impairment.

Contact the IRB for more information about assent and parental permission.