

Federal regulations outline requirements for obtaining the assent of subjects under 18, as well as the permission of their parents or legal guardians. Depending on the circumstances of the study, the IRB may decide to require either oral or written assent, and assent documents may contain less detail than adult consent documents do. Parental permission documents, on the other hand, must contain all of the federally required elements of informed consent; for this reason, most are structured identically to adult consent documents.

An IRB may waive the requirement that researchers obtain minor subjects' assent

- if subjects are incapable of providing assent;

or

- if the study at hand offers subjects the potential for direct benefit unavailable outside the research.

When determining whether subjects ought to provide their assent, IRBs should consider subjects' age, maturity, and psychological state.

Even when minor subjects are capable of assenting, an IRB may grant a waiver of assent if the study meets the criteria for a waiver of consent. Those four criteria are

- that the study presents no more than minimal risk to subjects;
- that the waiver does not adversely affect subjects' rights or welfare;
- that the research could not be conducted without a waiver;

and

- that, where appropriate, researchers will provide subjects with pertinent information after study participation.

If a study involving minors presents no more than minimal risk, or if it offers subjects the potential for direct benefit, federal regulations allow IRBs to require only one parent to sign the parental permission document. If, however, the study presents more than minimal risk and does not offer direct benefit, federal regulations require signatures from both of a subject's parents. If one parent has sole legal custody of the subject, 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 one signature on the parental permission document, although the researcher should

U-MIC TRANSCRIPT

Assent Requirements and Waivers

indicate clearly in the study record why the second parent did not sign. Contact the IRB for guidance.

If an IRB determines that parental permission is not a reasonable requirement to protect subjects—for example, in the case of child subjects who are abused or neglected—Department of Health and Human Services regulations permit the IRB to grant a waiver of parental permission, provided that

- there is an appropriate substitute mechanism to protect minor subjects;

and

- the waiver is consistent with federal, state, and local law.

Keep in mind that this provision does not apply to research under FDA oversight.

Researchers involving wards of the state as research subjects should work closely with the IRB to ensure compliance with all laws and requirements for obtaining both assent and the permission of legal guardians.

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

Posted: 9/18/2013