

Summary of Office for Human Research Protections “Research with Children FAQs”

Are the exemptions different for research involving children?

One of the six exemptions of research involving human subjects is narrowed in scope by Subpart D’s additional protections for research involving children. The other five exemptions apply to research involving children as human subjects in the same way that they apply to research involving adults.

The narrowed exemption is the exemption at [45 CFR 46.101\(b\)\(2\)](#), which generally applies to research involving educational tests, interviews or survey procedures or observation of public behavior, if the data are recorded without individual identifiers, or if disclosure of the recorded responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation. Where children will be involved as research subjects, however, the use of survey or interview procedures is eliminated from this exemption, and so is research involving the observation of public behavior if the investigators participate in the activity being observed.

In other words, the only research activities involving children that may fall under this exemption are those involving educational tests or observation of public behavior where the investigators do not participate in the activity being observed. To be exempt, these activities must also meet the condition that the data are recorded without individual identifiers, or the condition that disclosure of the recorded responses would not place the subjects at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation. Otherwise, all the requirements of the human subjects regulations apply.

What is parental permission in the context of research involving children?

By definition, children are unable to provide informed consent to participate in research, although they might be able to give their [assent](#). The IRB should determine that unless parental permission can be waived adequate provisions are made for soliciting the permission of the parent(s) or legal guardian(s). The regulations define “permission” at 46.402(c) as the “agreement of parent(s) or guardian to the participation of their child or ward in research.” The term “parent” means a “child's biological or adoptive parent.” The term “guardian” means “an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.”

Can parental or guardian permission for research involving children be waived?

Yes, under certain circumstances. An Institutional Review Board (IRB) may waive the requirements for obtaining parental or guardian permission if it makes and documents the findings under either [45 CFR 46.116\(c\) or \(d\)](#).

46.116 (c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practicably be carried out without the waiver or alteration.

46.116 (d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

In addition to the provisions for waiver contained in 46.116(c) and (d), if the IRB determines that a research protocol is designed to study conditions in children or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the parental permission requirements provided that an appropriate mechanism is in place to protect the children, and provided that the waiver is not inconsistent with federal, state, or local law ([45 CFR 46.408\(c\)](#)). The choice of an appropriate substitute mechanism (for example, appointing a child advocate or an assent monitor) for protecting children participating in research would depend on the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and the child's age, maturity, status, and condition (45 CFR 46.408(c)).

How should parental permission for research involving children be documented?

Permission by parents or guardians shall be documented in accordance with and to the extent required by [46.117 of subpart A of 45 CFR part 46](#). Essentially, parental permission should be documented in a manner similar to that used to document informed consent. An Institutional Review Board (IRB) may find that waiver of documentation of informed consent is appropriate under the HHS regulations at 46.117.

§46.117 Documentation of informed consent.

(a) Except as provided in paragraph [\(c\)](#) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph [\(c\)](#) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by [§46.116](#). This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by [§46.116](#) have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

What is child assent, and how do the requirements vary with the age of the research subjects?

Assent” is defined by the regulations as follows:

“Assent” means a child’s affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent. ([45 CFR 46.402\(b\)](#)).

This means the child must actively show his or her willingness to participate in the research, rather than just complying with directions to participate and not resisting in any way. When judging whether children are capable of assent, the Institutional Review Board (IRB) is charged with taking into account the ages, maturity, and psychological state of the children involved. The IRB has the discretion to judge children’s capacity to assent for all of the children to be involved in a proposed research activity, or on an individual basis.

The IRB should take into account the nature of the proposed research activity and the ages, maturity, and psychological state of the children involved when reviewing the proposed assent procedure and the form and content of the information conveyed to the prospective subjects. For research activities involving adolescents whose capacity to understand resembles that of adults, the assent procedure should likewise include information similar to what would be provided for informed consent by adults or for parental permission. For children whose age and maturity level limits their ability to fully comprehend the nature of the research activity but who are still capable of being consulted about participation in research, it may be appropriate to focus on conveying an accurate picture of what the actual experience of participation in research is likely to be (for example, what the experience will be, how long it will take, whether it might involve any pain or discomfort). The assent procedure should reflect a reasonable effort to enable the child to understand, to the degree they are capable, what their participation in research would involve.”

When does child assent have to be obtained for research and can it be waived?

The Institutional Review Board (IRB) is responsible for deciding whether child assent is required in proposed research activities. The IRB should require child assent unless it can be appropriately waived, or if the child is not capable of providing assent.

The regulations at 45 CFR 46.408(a) identify three types of circumstances where the IRB may determine that waiver of children’s assent is appropriate:

1. if the capability of some or all of the children is so limited that they cannot reasonably be consulted;
2. if the intervention or procedure involved in the research holds out the prospect of direct benefit to the health or well-being of the children and is available only in the context of the research.
3. if the research meets the same conditions as those for waiver or alteration of informed consent in research involving adults, as specified in the regulations at either [45 CFR 46.116\(c\)](#) or [45 CFR 46.116\(d\)](#).

How should child assent for research participation be documented?

The HHS regulations do not require documentation of assent. The Institutional Review Board (IRB) has the discretion to determine the appropriate manner, if any, of documenting child assent. Based on such considerations as the child's age, maturity, and degree of literacy, the IRB should decide what form of documentation, if any, is most appropriate. If adolescents are involved in research where a consent form would have been used if the subjects were adults, it would generally be appropriate to use a similar form to document an adolescent's assent.

If young children are involved who are as yet unable to read, documentation should take a form that is appropriate for the purpose of recording that assent took place. The IRB may also decide that documentation of assent is not warranted.