



Guidance and Procedures: Obtaining Child Assent and Parent Consent in Research

(05/03/2023)

Overview

Research with children requires additional considerations to ensure the rights and welfare of children are upheld during the course of human subjects research. By definition, children are unable to provide informed consent to participate in research, although they might be able to give their assent. Federal regulations task Institutional Review Boards (IRBs) with determining if the age, maturity and psychological state of the children allows for the children to assent to their participation in the research. If the children are found to be able to assent, adequate provisions must be put in place to solicit assent from the children prior to participating in research. The federal regulations also mandate that parents/guardians be notified of the research and provided the opportunity to consent to their child's participation, unless the IRB finds that obtaining parent/guardian permission could put the child at additional risk (example, neglected or abused children).

What is child assent?

The federal regulations defines **children** as persons who have not attained the [legal age](#) for consent to treatment or procedures involved in research, under the applicable law of the jurisdiction in which the research will take place. By definition, children are unable to provide informed consent to participate in research, although they might be able to give their assent. **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 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 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. 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).

How should child assent for research participation be documented?

The 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 will 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. For children with potential reading difficulties, the written consent document may be read aloud exactly as written and approved by the IRB. If the child participants are of varying ages, it is appropriate to submit different versions of the form.

If a child is capable of assent and the IRB requires that assent be sought, it must be obtained before the child can participate in the research activity. Thus, if the child dissents from participating in research, even if his or her parents or guardian have granted permission, the child's decision prevails. However, the federal regulations state that the IRB may waive the assent requirements if the intervention or procedure involved in the research holds out the prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of research. Usually, TAMU does not conduct this type of medical or psychological research. Conversely, if a child assents to participate in research, and parental permission has not been waived by the IRB, the permission of the parents or guardian is also required before the child can be enrolled in the research.

Children up to 7 years old

In most cases, children this young will not be able to participate in the assent process, and only a permission form for the parents or legal guardians will be needed ([Parent Permission](#)).

- In certain cases, the PI may deem a child in this age range capable of being involved in the assent process. If so, the child should be given a simple verbal explanation of what will happen to him/her, and then document on the parental permission form or in the study records that verbal assent was obtained ([Assent Script](#)).

Children 7 to 12 years old

In most cases, children this age will be able to participate in the assent process, using a simplified assent form ([Assent Form](#)). A separate, more detailed permission form will be needed for the parents or guardians ([Parent Permission](#)).

- The assent form should be brief and study specific, with subheadings or numerical paragraphs, and contain language that is both appropriate to the child's development and age. The assent form should have a simple format that is easy to read and when possible, limited to one page. The use of larger type, simple schema, and pictures will facilitate the child's understanding of the text.

Adolescents 13 to 17 years old

In most cases, adolescents should be fully informed about a study and give assent to their own participation in the research. There are two ways to document their assent.

Adolescent Consent Documentation-Option A

Option A is usually preferred. One form is written for the adolescent subject and the parents or guardians.

- This assent/consent form should use clear, straightforward language (eighth-grade reading level).
- Base the assent/consent form on the [Informed Consent Document for Social and Behavioral Research](#), referring to the adolescent subject throughout as “you.” Both the adolescent and the parents or guardians are asked to sign this form, with a signature line for the adolescent first.
- For online survey research that does not collect sensitive information, it is appropriate to use a [Simple survey consent script](#) to obtain assent and parent permission, where both the child and the parent will be asked to indicate whether or not they agree to the research.

Adolescent Consent Documentation-Option B

A simplified assent form is written for the adolescents. A separate, more detailed permission form is written for the parents or guardians.

Option B is reserved for studies where Option A is not feasible or appropriate. This option can be used for studies with a very complex protocol and/or involving adolescent subjects whose medical condition demands a simpler form than the adult’s form, even when the adult’s form is written at an eighth-grade level (e.g., see [Assent Form](#)).

- This adolescent assent form should be simpler than the adult consent form for the same study. Base the assent form on [Assent Form](#). (Note that assent forms written for 7-12 year olds are often too simple for adolescents, but can be expanded upon or adapted as appropriate).

Avoiding Undue Influence: Because children are more vulnerable to persuasion than adults, researchers must take special care for no undue influence during the assent process. This is especially important if the investigator is in a position of authority over the child such as a teacher. Language such as “You will be helping me” or similar appeals to their sense of fun, fairness, or obedience should be avoided. Likewise, promises of tempting rewards to induce participation should be avoided. Additionally, care should be taken in choosing the setting in which children are asked for their assent. For example, if they are asked in the company of other children, they may be subject to peer pressure; and if asked individually by an adult or in the presence of a parent, they may feel pressure to obey. On the IRB application form, researchers should indicate steps to be taken to mitigate these effects.

When can child assent be waived?

The IRB is responsible for deciding whether child assent is required in proposed research activities. The IRB requires 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 [HRP 411 Checklist Waiver or Written Documentation of Consent](#).

Does parental permission and child assent for research involving children have to occur at the same time or in any particular order?

In general, parental or guardian permission should be sought before seeking the assent of a child, particularly in more than minimal risk research, unless the requirement for obtaining parental or guardian permission can be waived.

However, there might be some cases involving minimal risk research, where it would be reasonable to seek child assent prior to seeking parental permission. For example, a school-based study of minimal risk (e.g., investigating children's responses to music), could be posed to children in the school setting. Children could be asked if they wanted to participate and if so, sent home with a request for parental or guardian permission. In all cases, except when the requirement for obtaining parental or guardian permission can be waived, parental or guardian permission, even if sought after child assent is provided, is required before the child can be enrolled in the study.

Importantly, any research conducted in schools must be accompanied by a [school permission letter](#) from each participating school with the assurance that participating school(s) complies with the [Family Educational Rights and Privacy Act](#) (FERPA) and [The Protection of Pupil Rights Amendment](#) (PPRA). Researchers are required to adhere to regulations when student records and activities subject to FERPA and PPRA are involved. These regulations exist separately from IRB decisions.

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

Unless the IRB has waived the requirement to obtain parent consent, permission by parents or guardians must be documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the parent(s) or legal guardian.

- **Permission** means the agreement of parent(s) or guardian to the participation of their child or ward in research.
- **Parent** means a child's biological or adoptive parent.
- **Guardian** means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.
 - When research is conducted in Texas, in accordance with state law, a guardian means a person who is appointed by the court to protect for the person of one who does not have the capacity to protect his or her own interests [HRP 013 SOP LARS, Children, and Guardians](#)

Obtaining parental permission recommendations:

- Parents should be told if the child's assent will or will not be requested, and if so, that both parent and child agreement are required
- Give complete, specific details and concrete examples of what children will be expected to do to provide data for the study and how the data will be collected. If an experimental model will be used, both the control and experimental procedures should be described (or use separate consent/assent forms)
- If recordings or photographs will be made of children or their work, the Parental Consent Form should specifically ask for the parent's agreement. If the recordings or photographs will be used in presentations or publications, it may be appropriate to use a separate release form.
- For research in classroom settings, describe what, if anything, will be expected of students who do not participate. It may be appropriate to include wording such as "Even if your child does not participate in the study, he or she will still receive the required instruction and be expected to complete the required assignments and tests."

Do both parents need to provide permission for their child to participate in the research?

It depends. In general, permission should be obtained from both parents before a child is enrolled in research. However, the IRB may find that the permission of one parent is sufficient for research to be conducted under 46.404 or 46.405. When research is to be conducted under 46.406 and 46.407 permission must be obtained from both parents, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

Permissible Research with Children			
45 CFR 46 (OHRP) 21 CFR 50 (FDA)	Category	Requirements The IRB must decide the following before children may be involved as subjects:	Parental Permission
46.404, 50.51	Research not involving greater than minimal risk ¹	Adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in 46.408 and 50.55.	Permission from one parent may be sufficient
46.405, 50.52	Research involving greater than minimal risk but presenting the prospect of direct benefit ² to the individual subjects	a. The risk is justified by the anticipated benefit to the subjects; b. The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and c. Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in 46.408 and 50.55.	Permission from one parent may be sufficient
46.406, 50.53	Research involving greater than minimal risk ¹ and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition	a. The risk represents a minor increase over minimal risk; b. The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social or educational situations; c. The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and d. Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in 46.408 and 50.55.	Permission must be obtained from both parents ³
46.407, 50.54	Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children	a. The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and b. The Secretary of DHHS or Commissioner of Food and Drugs for the FDA, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either: 1. That the research in fact satisfies the conditions of 46.404 and 50.51, 46.405 and 50.52, or 46.406 and 50.53, as applicable, OR 2. The following:	Permission must be obtained from both parents ³

		<p>i. The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health and welfare of children;</p> <p>ii. The research will be conducted in accordance with sound ethical principles; iii. Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in 46.408 and 50.55</p>	
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1. "Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests," 45 CFR 46.102

2. "The prospect of direct benefit" means the intervention or procedure holds out the possibility of direct benefit to the individual subject, or the study involves a monitoring and diagnostic procedures that may contribute to the subject's care or well-being." 45 CFR 46.405, 21 CFR 50.52

3. When research is to be conducted under 46.406 and 46.407 permission must be obtained from both parents, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

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

Yes, under certain circumstances. The IRB may waive the requirement for obtaining parental or guardian permission if it makes and documents the findings that:

- (i) The research involves no more than minimal risk to the subjects;
- (ii) The research could not practicably be carried out without the requested waiver or alteration;
- (iii) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
- (iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
- (v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

In addition to the provisions for waiver contained in the federal regulations, 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.

The FDA's regulations do not have a comparable waiver of parental permission to match 45 CFR 46.408(c). The FDA's regulations do permit waiver of consent but only under the narrow exception for emergency research meeting the requirements of [21 CFR 50.24](#). In addition, under their [Guidance issued in July 2017](#), the FDA also indicated that it would use regulatory discretion and allow IRB's to waive the requirements for consent for "minimal risk" clinical investigations.

Do I still need to obtain signed parent permission if I am conducting a simple online survey?

For some research projects, the IRB may approve a request to waive the documentation of informed consent. This means that the researcher still provides the parent(s) or legal guardian with the required

consent information, but the researcher is not required to obtain the parent(s) or legal guardian's signature(s) on the informed consent document.

A **waiver of documentation** of informed consent is permissible when:

1. The signature on the informed consent document would be the only record linking the subject to the research and the principal risk of harm to the subject would be a breach of confidentiality. For example, for research on sensitive topics, such as domestic violence or illegal activities;
2. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context. For example, minimal risk research that involves surveys/interviews conducted via telephone or online; or
3. The participants are members of a cultural group in which signing forms is a not a normal/acceptable practice.

Can parental permission ever be “passive” or “implied”?

The term “passive consent” is sometimes used in research with children to describe situations in which the investigator can assume that a parent is permitting a child to participate. For example, researchers collecting survey and behavioral data from children at school provide parents with information regarding the study by mail and ask the parent(s) to return a form if they do not want their child to participate. Sometimes this practice is referred to as an opt-out procedure, which is not consistent with the regulatory requirement for seeking and obtaining parental permission. If the IRB determines that the conditions for waiver of parental permission can be met, then the IRB could waive the requirement for parental permission under [45 CFR 46.408\(c\)](#) or [45 CFR 46.116\(f\)\(3\)](#). Even though not required by the regulations, an IRB may require that parents be given the opportunity to refuse permission even when the IRB has waived the regulatory requirement to obtain parental permission. All research conducted in schools must be accompanied by a [school permission letter](#) that assures that the proposed research activities, including the “passive” consent protocol, are consistent with FERPA and PPRA regulations. More guidance on “passive” consent and PPRA requirements can be found [here](#).

Passive parental consent procedure is commonly used in school settings where the following conditions are met:

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.
4. Subject selection is based on classroom membership and not exclusionary.
5. All children that are capable and will provide assent.

The investigator must provide the parent(s) with a written document containing all the required elements of informed consent that gives parents the opportunity and sufficient time to opt-out of providing permission. The protocol application should explain how the written document will be distributed to parents/guardians (e.g. the letter will be mailed/emailed by the school, the letter will be distributed at parent-teacher conferences, etc.). The letter should be sent to parents/guardians **at least two weeks before research activities begin**.

Please be aware that some school districts require active parental consent regardless of whether IRB waiver of documentation of consent is appropriate, so the researcher must check with the participating school district(s) prior to the development of a passive consent process. The researcher must provide a written statement from the school/district's leadership that they are in agreement with the research and any opt-out consent procedures during IRB review.