

## **Guidance and Procedures: Child Assent and Permission by Parents or Guardians** (last updated June 9, 2016)

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#### **Overview**

Research with children involves more complex considerations with respect to assuring the voluntary participation of research participants than research with adults. As described below, there are issues of assent, consent, and parental permissions that must be considered. Federal regulations do not provide many specifics but they do include parental permission requirements, also discussed below. The Federal regulations also charge that “adequate provisions [be] made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent...[taking] into account the ages, maturity, and psychological state of the children involved” [\[45 CFR 46.408\]](#).

#### **How Does Assent Differ from Consent?**

Though children do not have the legal capacity to “consent” to participate in research, they should be involved in the process if they are able to “assent” by having a study explained to them and/or by reading a simple form about the study, and then giving their verbal choice about whether they want to participate or not. They may also provide a written assent if they are older. Circumstances in which a child's assent may be unnecessary or inappropriate are discussed below under [Waiver of Child's Assent](#).

#### **Process for Obtaining Child Assent and/or Parental/Guardian Permission**

##### **The Process**

The process for obtaining oral and/or written consent for children and minors is similar to that of obtaining consent for adults. An *effective informed consent process* involves at minimum these elements:

- Conducting the process in a manner and location that ensures participant privacy,
- Giving adequate information about the study in a language understandable to the participant,
- Providing adequate opportunity for the participant to consider all options,
- Responding to the participant's questions,
- Ensuring the participant has understood the information provided,
- Obtaining the participant's voluntary agreement to participate, and
- Continuing to provide information as the participant or research requires.

A complicating factor for the children and adolescents assent is the requirement to also consider parental permission—discussed below.

### Assent from Children or Minors

Researchers should carefully consider and propose adequate provisions for obtaining the assent of children prior to their participating in research. The IRB application should address whether the intended subject population of children would be capable of understanding the nature of their participation in the research, and if so, whether or how assent will be obtained.

- In determining whether children are capable of assenting, the ages, maturity, and psychological state of the children involved should be taken into account. This determination may be made for all children and adolescents to be involved in research under a particular protocol, or for each child, as appropriate. An assent process that takes into account the child's experience and level of understanding, assures an element of cooperation and a feeling of inclusion on the part of the child, and also illustrates the investigator's respect for the rights and dignity of the child in the context of research.
- Out of respect for children as developing persons, they should be provided with essential information and asked whether or not they wish to participate in the research, particularly if the research: (a) does not involve interventions likely to benefit them; and (b) the children can comprehend and appreciate what it means to be a volunteer for the benefit of others.

### Permission from Parents or Guardians

Adequate provisions must also be made for soliciting the permission of each child's parents or legally authorized representative or guardian, as noted below. At a minimum, the federal requirements for consent indicated below must be met. However, the researcher or the IRB may determine that more stringent requirements are appropriate.

Regulatory Category of Permitted Research with Children	One Parent's or Both Parents' Permission Required?
Minimal Risk (45 CFR 46.404, 21 CFR 50.51)	<b>One parent/legal guardian</b> <i>may</i> be sufficient
Greater than Minimal Risk, Direct Benefit to Subject (45 CFR 46.405 21 CFR 50.52)	<b>One parent/legal guardian</b> <i>may</i> be sufficient but IRB must determine whether one or two is required
Greater than Minimal Risk, No Direct Benefit to Subject, but Likely to Yield Generalizable Knowledge about Subject's Condition (45 CFR 46.406 21 CFR 50.53)	<b>Both parents/legal guardians</b> , unless one parent is deceased, unknown, incompetent, not reasonably available, or does not have legal responsibility for the custody of the child.
Greater than Minimal Risk, No Direct Benefit to Subject, but Results May Alleviate Serious Problems of Children's Health or Welfare (45 CFR 46.407 21 CFR 50.54)	<b>Both parents/legal guardians</b> , unless one parent is deceased, unknown, incompetent, not reasonably available, or does not have legal responsibility for the custody of the child.

## When One Parent's Permission Is Sufficient

For research that falls into risk-benefit Category 1 [[45 CFR 46.404](#) [21 CFR 50.51](#)] or 2 [[45 CFR 46.405](#) [21 CFR 50.52](#)], the IRB may determine that permission from only one parent is sufficient. The Committee will find that permission of one parent is sufficient unless the nature of the study seems likely to provoke disagreements about participation among two parents, in which case permission from two parents may be required unless one parent is deceased, unknown, incompetent, not reasonably available, or does not have legal responsibility for the custody of the minor. Research that falls into Category 3 [[45 CFR 46.406](#) [21 CFR 50.53](#)] or 4 [[45 CFR 46.407](#) [21 CFR 50.54](#)] requires permission from both parents, unless one parent is deceased, unknown, incompetent, not reasonably available, or does not have legal responsibility for the custody of the child [[45 CFR 46.406 or 407](#), [21 CFR 50.55\(e\)](#)].

**IMPORTANT NOTE:** When there is only one living parent or guardian or one parent has sole custody after a divorce, the investigator may determine that single-parent or single-guardian permission is sufficient.

## When Parents Disagree

If there are two parents available to give permission but they disagree about allowing their child to participate in the study, *the child may not be enrolled unless that disagreement can be resolved*. This applies to all permissible categories--even if only one parent's signature is required, when both parents are involved in the decision, they must agree for the child to be enrolled. If a parent who was not involved or available for the original consent later becomes involved or available, the two parents must then agree.

## Documentation of Assent and/or Parental Permission

Assent and/or Parental Permission should be documented according to the table and standards below, although the IRB may modify the standards based on age, maturity, developmental status or other considerations that may determine the appropriateness of a given approach. Parental Permission should be obtained with the use of a modified Adult Consent Form, based on the UCLA OHRPP [consent template](#).

## Assent Guidelines for Children by Age:

*Table of Assent and Parental Permission Requirements*

Age of Minor Participant	Assent Form Recommended	Separate Parental Permission Form Recommended
Infant-6 years old	No	Yes
7-12 years old	Yes	Yes. see <a href="#">child assent form</a> for model
13-17 years old (Option A)	Yes	No. Create a single document addressed to the adolescent with signature lines for assent and parental permission.
13-17 years old (Option B)	Yes. See <a href="#">adolescent assent form</a> as model	Yes

- The [UCLA sample consent and assent forms](#) can be adapted for use in most studies, using these guidelines as a basis.
- See discussion about “Waivers of Assent” and “Waivers of Parental Permission” below for exceptions to these guidelines.
- See also “Legal Exceptions Permitting Certain Minors to Consent” below.

## Discussion of Guidelines, and Signature and Documentation Requirements

**For children under 7:** Only parental permission is required.

- In certain cases, the investigator may deem a child in this age range is capable of being involved in the assent process. If so, make sure the child is given a simple verbal explanation of what will happen to him or her or what he or she will be asked to do. Document this discussion on the parental permission form or in the study records.
- Use the parental permission form on the [OHRPP website](#). Within the parental permission form, refer to the subject throughout as “your child” or “your infant.”
- If parents are also part of the study, one consent/permission form may be used to describe the study procedures for both the child as well as the parent(s). See the [OHRPP website](#).

**For children 7-12 years of age:** In most cases, children this age will be able to participate in the assent process, using a simplified assent form. A separate, more detailed permission form will be needed for the parents or guardians.

- Create two documents: a simplified [child assent form](#) and a separate parental permission based on the [UCLA consent templates](#).
- 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.
- Children are not required to sign the assent form, but investigators are required to document in the research record that child assent has been obtained either on the parental permission form or retained separately within the study records.
- If parents are also part of the study, a consent/permission form may be used to describe the study procedures for both the child as well as the parent(s), though the child would also have an assent form.
- **Option A** (usually preferred):
  - Write one consent form for the adolescent subject and the parents or guardians.
  - Use clear, straightforward language written at the 8<sup>th</sup> grade reading level.
  - Base the form on the [UCLA consent template](#).
  - Address the form to the adolescent with signature lines for assent and parental permission. The adolescent should be asked to sign first.
  - Precede the signature line for parents with the wording above.
- **Option B** 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.
  - A simplified assent form is written for the adolescents. A separate more detailed permission form is written for the parents or guardians.
  - Base the forms on the [UCLA consent template](#).
  - Only the adolescent is asked to sign the assent form.
  - Precede the signature line for parents with the wording above.

**IMPORTANT NOTE:** In some research projects, it may be necessary to use two assent forms written to accommodate subjects at either end of the age range or to accommodate different maturity levels of the participants.

## Re-Assent and Consent at Youth and Adult Milestones

The researcher and the IRB should consider whether re-assent of children who are participating in longitudinal research or **written consent of children who turn 18 years of age during study participation is required**.

- When appropriate, the researcher and the IRB need to determine that adequate provisions are made for soliciting the assent of children who reach seven years of age during study participation.
- When appropriate, the researcher and the IRB need to ensure an ongoing assent process with continuing subjects by requiring the re-assent of subjects who turn 14 years of age.
- The researcher and the IRB need to ensure that adequate provisions are made for soliciting the consent of children who turn 18 years of age during study participation. If the child participated in a study in which the only remaining procedures are data analysis, consent may not be required.

## Waiver of Child Assent

Even in cases in which the researcher and the IRB determine that the children are capable of assenting, the IRB may grant a waiver of the assent requirement in accordance with [45 CFR 46.116\(d\)](#). Such waiver of the assent requirement by the IRB is also allowed under [21 CFR 50.55\(d\)](#) for research subject to FDA regulations.

Alternatively, if either of the following are true then the assent of the children is not a necessary condition for proceeding with the research:

- The capability of some or all of the children is so limited that they cannot reasonably be consulted;  
or
- The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research.

In such circumstances as a child's dissent, which should normally be respected, the dissent may be overruled by the child's parents. This should be discussed in the webIRB application and will be considered by the Committee. When research involves the provision of experimental therapies for life-threatening diseases such as cancer, however, researchers should be sensitive to the fact that parents may wish to go to extremes, even when the likelihood of success is marginal and the probability of extreme discomfort is high. Should the child not wish to undertake such experimental therapy, and if, for example, the child is a mature adolescent and death is imminent, the child's wishes should be respected.

## Waiver of Parental Permission

In certain cases, research may be designed for conditions or for a subject population for which parental permission for inclusion in research is not a reasonable requirement to protect the subjects (e.g., neglected or abused children). More detailed examples are given below ([45 CFR 46.408](#)).

### For FDA-Regulated Studies

FDA regulations (Subpart 21 CFR 50) lack the provision for waiver of parental permission. This is because the FDA does not believe it oversees studies for which such a waiver is appropriate. Researchers who believe it appropriate to include selected groups of adolescents in research involving FDA-regulated articles should consider the section below titled Legal Exceptions Permitting Certain Minors to Consent.

### For Non-FDA-Regulated Studies

The IRB may waive parental/guardian permission provided “an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, State, or local law” ([45 CFR 46.408](#)).

**APPLICATION NOTE:** In such cases, the PI may propose a waiver of parental consent/permission under [45 CFR 46.408\(c\)](#) or [45 CFR 46.116](#) in the webIRB application.

The IRB will consider all other requests for waiver of parental permission on a protocol-by-protocol basis.

### Examples where parental permission *MAY* be waived

Research on child abuse or neglect, or research that is reasonably likely to elicit information identifying child abuse or neglect, where there is serious doubt as to whether the parents’ interests reflect the child’s interests. [[45 CFR 46.408\(c\)](#)].

This type of study is difficult to pursue and thus rarely comes before the IRB. Since the federal regulations specifically refer to “research on neglected or abused children” as an instance where “parental or guardian permission is not a reasonable requirement to protect the subjects,” the IRB would be likely to waive parental permission in such a case, provided the other requirements of the regulations [45 CFR 46.408\(c\)](#) are met.

Research on people under 18 who are in circumstances where they are clearly outside of parental influence or control.

The IRB would evaluate each study carefully to determine whether parental permission is not a reasonable requirement to protect the subjects.

Researchers also should be aware that some people under 18 who are living independently may not fit the federal definition of “children” and are able to consent for themselves without a waiver of parental permission. See Legal Exception Permitting Certain Minors to Consent below.

**APPLICATION NOTE:** Investigators should address all such consent concerns for research with minors, including arguments for waiver of standard consent procedures in the webIRB Application.

## Legal Exceptions Permitting Certain Minors to Consent

### LEGAL EXCEPTIONS IN CALIFORNIA

In California, minors (those under 18 years of age) generally may not consent to medical care or treatment, or research involving medical care or treatment, without a parent or legal guardian’s consent. However, federal regulations, when interpreted with California legal exceptions, permit some minors to consent to research.

**IMPORTANT NOTE:** The [California Family Code](#) is complex and includes more restrictions and exceptions than can be summarized here. Researchers considering enrolling subjects based on the following examples should consult the relevant sections of the law. This section provides only a brief overview.

The following outlines California laws that provide minors with autonomy regarding access to medical and mental health care, the confidentiality of their medical records, and the legal authority for the minor to provide consent for such treatments without the permission or knowledge of the parent/guardian.

## Emancipated Minors

Under California Family Code (Section 7000-7143), minors who fit into any of the following categories have the legal right to consent on their own behalf to medical, dental, or mental health treatment:

- Married or divorced,
- On active duty in the U.S. armed forces, and/or
- Emancipated by a court.

They also have extensive other rights to enter into legal and business arrangements, and so can consent to be included in other research (such as surveys or interviews)

## Self-Sufficient Minors

Under California Family Code (Section 6922), minors who satisfy all of the following criteria may consent to their own medical or dental care:

- Minor is 15 years of age or older;
- Living separate and apart from the minor's parents or guardian, whether with or without the consent of a parent or guardian and regardless of the duration of the separate residence, *and*
- Managing her/his own financial affairs, regardless of the source of the minor's income.<sup>1</sup>

The researcher must describe in the protocol and the informed consent documents the limits to the minor's confidentiality. California law stipulated that a physician, surgeon or dentist *may*, with or without the consent of the self-sufficient minor patient, advise the parent-guardian of the treatment given or needed if the physician, surgeon, or dentist has reason to know, on the basis of the information given by the minor, the whereabouts of the parent-guardian.<sup>2</sup>

## Medical Care Related to the Prevention or Treatment of Pregnancy

A minor may consent to medical care related to the prevention or treatment of pregnancy (no minimum age), but not to sterilization or necessarily abortion (Section 6925).

## Minors 12 Years or Older

Minors 12 years of age or older may consent on their own behalf for:

- **Out-patient mental health treatment or counseling** (in limited circumstances) excluding ECT, psychosurgery or psychotropic drugs (Section 6924)
- Medical care related to the diagnosis or treatment of **reportable infectious, contagious, or communicable/sexually transmitted diseases** (Section 6926)
- Medical care related to the diagnosis or treatment of the condition and collection of medical evidence with regard to **alleged rape** (Section 6927)
- Medical care and counseling relating to the diagnosis and treatment of a **drug- or alcohol-related problem** (only if treating physician deems and documents that parental involvement is inappropriate), excluding narcotic replacement drugs (Section 6929)

## California Minor Consent Laws and Providers' Confidentiality Obligations

The National Center for Youth Law has published a very useful table entitled "[Which minors can consent for what services and providers' confidentiality obligations.](#)" The table provides citations to

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<sup>1</sup> CA Family Code 6922(a).

<sup>2</sup> CA Family Code 6922(c).

various relevant California laws and the requirements for confidentiality and/or the informing obligation of the health care provider.

California law provides minors with the protection of the confidentiality of their medical records to which the minor is legally authorized to consent for the treatment or procedure.<sup>3</sup> The same law ensures that a minor's parents do not have the right of access to medical record information without the minor's consent in some cases or even with the minor's consent if the provider determines that such access would be detrimental on the provider's professional relationship with the minor patient or would be detrimental to the minor's physical safety or psychological well-being in others. See the above chart for a list of the different types of services and confidentiality requirements.

### **Consent Process for Minors Who Can Consent For Themselves**

The IRB carefully evaluates all studies targeting subjects under 18 to ensure they are properly protected. With IRB approval, for the above categories a minor should provide consent and sign the consent form just as an adult would, unless the IRB approves a waiver or alteration of the usual consent standards for adults.

### **LEGAL EXCEPTIONS OUTSIDE OF CALIFORNIA**

***Other states and countries specify their own specific legal exceptions***, if any, to the definition of children and who may be permitted to consent for themselves for medical treatment or research. UCLA researchers *enrolling research participants in other states or countries* should take care to comply with local law.

- In all cases, if the prospective subjects *cannot* legally consent for the treatments or procedures involved in the study because they are too young, they are considered "children" by federal regulations.
- If they *can* consent for the treatments or procedures, they are *not* "children" by federal regulations.

***Researchers working in other states or countries should consult with their local collaborators about applicable laws and regulations.***

- For research involving children that will take place outside California, the investigator is responsible for researching local requirements regarding who qualifies as a "child" or "guardian" under the federal definitions provided in Section II, and whether local requirements provide any other unique protections to children. Another jurisdiction's definition of "guardian" in and of itself does not mean a "guardian" under the federal definition. The federal definition hinges on whoever may, under local requirements, provide consent on behalf of the child for general medical care.
- Researchers may also call the [OHRPP](#) for help in framing a query to UCLA Legal Counsel.

***The application to the IRB*** should describe the investigator's knowledge of local requirements and how appropriate consent and assent will be obtained. The IRB will assess whether the investigator's plans demonstrate knowledge of local requirements.

### **IRB CONSIDERATIONS:**

- While the IRB is not legally required to apply the special protections of Subpart D for children set forth in 45 CFR 46 and 21 CFR 50 for research involving the categories of minors above, the IRB may apply special protections depending on the specific research study.
- Further, in certain cases, the IRB may determine that certain groups of minors that otherwise may legally consent should be excluded from a research study in light of potential risks or due to the investigational nature of the trial.

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<sup>3</sup> CA Health & Safety Code 123110(a) and 123115(a).



**IMPORTANT NOTE:** Even if the IRB approves minor consent for the specific study, the principal investigator must also ensure that any individual minor possesses the mental capacity to understand the risks, benefits and the consequences of the decision to participate in research.

## References

### California Statutes and Guidance

- [California Minor Consent Laws](#), National Center for Youth Law, 2003.
- [Understanding Confidentiality and Minor Consent in California: An Adolescent Provider Toolkit](#)

### DHHS Regulations and Guidance

- [45 CFR 46, Subpart D: Additional Protections for Children Involved as Subjects in Research](#)
- [45 CFR 46.408\(c\): Requirements for Permission by Parents or Guardians and For Assent by Children](#)
- [45 CFR 46.116\(d\): General Requirements for informed Consent](#)
- [45 CFR 46.117: Documentation of Informed Consent](#)
- [OHRP \(formerly OPRR\), \*Protecting Human Research Subjects Guidebook \(1993\) Chapter 6, Section C, "Children and Minors."\*](#)
- [OHRP Children's Special Issues Page](#)
- [OHRP FAQs on Research with Children](#)

### FDA Regulations and Guidance

- [21 CFR 50, Subpart D: Additional Safeguards for Children in Clinical Investigations](#)
- [FDA Guidance for Clinical Investigators, Institutional Review Boards and Sponsors: Process for Handling Referrals to FDA under 21 CFR 50.54](#) – December 2006.

### UCLA OHRPP Guidance

- [Research Involving Children and Minors](#)
- [Obtaining and Documenting Informed Consent](#)
- [Requesting Waivers and Exceptions to Informed Consent](#)

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### Change history:

6/9/2016: Updates to links and references