

**Scope**

This guidance includes parental and guardian permission, when a child may consent for themselves, types of surrogate decision makers for children and their authority, and required documentation. It also covers:

- [Waiver of Parental or Guardian Permission](#)
- [Assent](#)
- [Special Circumstances](#)
  - Parents or Guardian Are Unavailable
  - Children Who Are Wards
  - Guardians – Restrictions on Authority
  - Minors who may Consent as Adults, including Emancipated Minors
  - Research at VA Facilities
- [Mandatory Reporting of Child Abuse and Neglect](#)

**Definitions**

**Assent:** A child's affirmative agreement to participate in research. Absent affirmative agreement, mere failure to object is not assent.

**Children:**

**[DHHS and FDA]** Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. Subpart D of the DHHS must be applied only if an individual involved in the research meets this definition.

**[California law]** The legal age for consent to treatments or procedures involved in research is generally 18, but there are important exceptions (see Minors Who May Consent as Adults, Including Emancipated Minors).

**[Other jurisdictions]** Contact the Stanford University General Counsel's Office for guidance.

**Minors:** Persons under 18 years of age. Because some minors can consent for themselves to some research procedures, not all "minors" meet the federal criteria for being "children."

**"Emancipated" Minors** must meet one of the following requirements:

- a. have entered into a valid marriage whether or not it has been dissolved, or
- b. be on active duty with the armed forces, or
- c. have received a court declaration of emancipation.

See [Resources](#) below for applicable CA laws

**Guardian:** An individual or official appointed through a state or local law, a court order, or upon the death of a parent through the parent's will to have custody of a child, either temporarily or permanently, with the associated rights to make decisions on behalf of the child. (Normally, the authority of a parent ceases upon the court appointment of a guardian).

**In California** a guardian has the authority to consent on behalf of a child to general medical care (and therefore meets the DHHS and FDA definition of "guardian") when his or her court issued letters of guardianship include the authority to consent on behalf of a child to general medical care. This authority, however, is subject to restrictions (see **Guardians – Restrictions on Authority** below.)

**Ward:** (defined by FDA) a child who is placed in the legal custody of the State or other agency, institution, or entity, consistent with applicable Federal, State, or local law.

### Waiver of Parental or Guardian Permission

- Under OHRP 45 CFR 46.116(e) (f), and (g), and [FDA Guidance](#), the IRB may waive parental or guardian permission if the conditions for waiver of consent are met, including that the research represent no more than minimal risk to human subjects; or
- when the emergency exception applies.

Parental or guardian permission is not a reasonable requirement to protect the children and an appropriate mechanism is substituted; for example, if the study:

- focuses on a condition or is a study of such a private and sensitive nature that it is not reasonable to require permission, (for example, adolescents in studies concerning treatment of sexually transmitted disease); or
  - involves a subject population such as abused or neglected children. [45CFR 46.408(c)]
- A request for a waiver (or partial waiver) will be considered for research conducted *in a classroom*, if the research is minimal risk and meets the other waiver requirements.
  - Research is *generally not suitable for a waiver* if it involves:
    - parental political affiliations or beliefs,
    - mental or psychological problems,
    - sexual behavior or attitudes,
    - illegal/antisocial/self-incriminating behavior,
    - appraisals of other individuals with whom the minor has a familial relationship,
    - relationships legally recognized as privileged (lawyers, doctors, clergy), or
    - religious affiliations or beliefs.

### Assent

The IRB must determine whether researchers have adequate provisions to solicit assent, when the children are capable of providing it. The researcher must inform the IRB how the affirmative assent of the child will be documented, e.g., by signature on assent form, documented by the researcher, or other. In California, an researcher for an experimental drug study must normally obtain the assent of any child participant 7 years or older. For studies involving children *7 to 17 years*, the IRB recommends that researchers document the child's willingness to participate with a signed assent document. A child's capacity to assent must be evaluated on an individual basis.

#### Assent Document

- Should include any information that can affect a child's decision to participate - an explanation of the proposed research procedures (procedures that are not part of the child's care should be described as optional), the research purpose, and any discomforts.
- Should use language that is geared to the cognitive level of participating children. The language used in the parental consent document might also be suitable for an older teen.
- Might more appropriately be obtained orally (omission of signature) for younger children (younger than 7 years but old enough to be consulted about participating in research).

See [Assent Form Template](#) on the Human Subjects Research website.

#### Assent Not Required or Waived

At the request of a researcher, the IRB may determine no assent is required in one or more of the following circumstances (including FDA regulated protocols):

- Children are not capable of assenting, after taking into account the ages, maturity, and psychological state of the children involved, either for all the children or for each child.
- 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.

- Customary conditions for waiver or alteration of consent are satisfied (45 CFR 116 or 21 CFR 50.55(d)).

## Special Circumstances:

### 1) Parents or Guardian Are Unavailable

Generally, a researcher may not involve a child in research if the parent(s) or guardian are not available to provide permission and the IRB has not waived parental or guardian permission.

**In California**, a researcher may be able to involve children for research involving treatment:

- Under certain circumstances where (i) the child is residing with a non-parent relative, (ii) the care of the child has been entrusted by a parent or guardian to an adult, or (iii) the child is in the custody of foster parents, a juvenile court, a social worker or probation officer, and
- When certain conditions are satisfied, e.g. completion of a "Caregiver's Authorization Affidavit," issuance of a court order.

**These laws are complex:** Contact the Stanford General Counsel's Office for guidance.

### 2) Children Who Are Wards

- Laws limit research with children who are "wards" of the State or other agency, institution or entity.
- The IRB may approve a protocol that involves wards and research involving greater than minimal risk with no prospect of direct benefit to participants (under 45 CFR 46.406 or 21 CFR 50.53) or not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (under 45 CFR 46.407 or 21 CFR 50.54) only if the study is:
  - 1) related to their status as wards, or
  - 2) conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of the participating children are not wards.

If the research is approved under the above conditions, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child in a study.

*Note:* The above does not apply for research approved under 46.404 or 405, 50.51 or 52.

**Who may be an advocate?** An advocate: i) has the background and experience to act in (and agrees to act in) the best interest of the child for the duration of the research, and ii) is not associated in any way with the research (except as an advocate, or member of the IRB), the researchers, or any guardian association.

- Researchers are responsible for: i) informing the IRB when the study intends to include children who are wards; and ii) compliance with any relevant requirements of the competent court, agency, institution, or entity of which the child is a ward.
- For *research involving medical care* for wards of a court, an order from the judge is often required, in addition to permission from the person charged with the care of the child. Lucile Packard Children's Hospital (LPCH) *Legal Guardianship & Consent* policy provides guidelines for authority to consent for medical treatment for various categories of minors, including wards of the state, such as wards of the court, dependents, minors placed for adoption, minors living in foster care, etc.

### 3) Guardians – Restrictions on Authority

**Medical Care (no research involved):** In California, a guardian normally has the same authority with respect to the child as a parent having legal custody, except as limited by statute or court order (e.g. the legal document establishing the guardianship).

**Research Involving Medical Care: A guardian's authority to consent is restricted** in the following circumstances (in the absence of an affirmative court order):

- terms of any letters of guardianship issued by a court (a certified copy of which should be obtained and placed in the medical record),
  - surgery on a child 14 years or older, unless (i) the child also consents, (ii) the guardian obtains a court order, or (iii) the guardian has determined based on medical advice that an emergency exists in which the child faces loss of life or serious bodily injury if the surgery is not performed,
  - administering an “experimental drug”; e.g., FDA investigational drug), unless a 7 years or older child also consents and the drug is related to maintaining or improving health or obtaining information about a pathological condition of the child,
  - authorizing electro-convulsive treatment,
  - admitting the child to a “mental health treatment facility” without the child’s consent,
  - authorizing antipsychotic drugs except under certain circumstances,
  - authorizing an elective procedure performed primarily for the purpose of rendering the child sterile (i.e., not treatment which secondarily results in sterilization),
  - authorizing psychosurgery under any circumstances.
- See [Resources](#) below for applicable CA laws.

#### 4) Minors who may Consent as Adults, including Emancipated Minors

**In California**, minors may consent to participation in research without parental or guardian permission if legally emancipated and in certain treatment circumstances. An “emancipated minor” may consent to participation in any type of research.

In addition, *for research involving treatment* certain **un-emancipated minors** may consent to research involving specific types of medical treatment, including:

- Outpatient mental health treatment for a minor 12 years or older when certain criteria are met,
- Hospital, medical or surgical care related to prevention or treatment of pregnancy for minors (any age),
- Medical care related to diagnosis/treatment of a communicable reportable disease or condition,
- Hospital, medical or surgical care related to rape for a minor 12 years or older,
- Hospital, medical or surgical care related to sexual assault but must attempt to contact parent/ guardian unless reasonably believe involved,
- Care for alcohol or drug abuse.

See [Resources](#) below for applicable CA laws

#### 5) Research at VA Facilities

Research involving children must not be conducted by VA while on official duty or at VA hospital or approved off-site facilities, unless a waiver has been granted by the VA Chief Research and Development Officer. Waivers are granted only when the study poses no more than minimal risk. Contact (202) 254-0183 for more information on obtaining a waiver.

#### Mandatory Reporting of Child Abuse and Neglect

Stanford has strict requirements for the reporting of child abuse and neglect. Researchers should be aware of Stanford requirements and their obligations under California law. See [Resources](#) below.

<b>Resources: Regulations and Guidance</b>	
California Law	<ul style="list-style-type: none"> <li>• Family Code <a href="#">6920</a>; <a href="#">6924</a> ; <a href="#">7002</a> Emancipated Minors; Unemancipated minors’ consent for research</li> <li>• <a href="#">Health &amp; Safety Code Section 111515</a> Experimental drug definition</li> <li>• <a href="#">Probate Code 2356(a)</a> Mental health treatment facility definition</li> <li>• <a href="#">Welfare &amp; Institutions Code Section 5325</a> Electro-convulsive treatment definition</li> </ul>
FDA	<ul style="list-style-type: none"> <li>• <a href="#">21 CFR 50 Subpart D</a> Additional Safeguards for Children in Clinical Investigations</li> <li>• <a href="#">21 CFR 50.55(d)</a> Waiver or alteration of consent</li> </ul>

Stanford University <b>HRPP Policy Guidance</b>	<b>Children and Consenting Minors Consent and Assent; Mandatory Reporting</b>	GUI-C24 5/5
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OHRP	<ul style="list-style-type: none"> <li>• <a href="#">45 CFR 46 Subpart D</a> Additional Protections for Children Involved as Subjects in Research</li> <li>• <a href="#">45 CFR 46.116(c) or (d)</a> General requirements for informed consent.</li> <li>• <a href="#">45 CFR 46.408(c)</a> Requirements for permission by parents or guardians and for assent by children</li> <li>• <a href="#">Children Involved as Subjects in Research</a>: Guidance on HHS 45 CFR 46.407 ("407") Review Process</li> </ul>
<b>Resources: Other References</b>	
Stanford HRPP	<ul style="list-style-type: none"> <li>• <a href="#">Ch 9.3</a> Risks to Vulnerable Populations</li> <li>• <a href="#">Ch 12.2.3</a> Children and Consenting Minors</li> <li>• <a href="#">Ch 14.4</a> Recruitment</li> <li>• <a href="#">GUI-1</a> Additional Protections for Inclusion of Children (&lt;18 years) in Research – OHRP</li> <li>• <a href="#">GUI-9</a> Additional Safeguards for Inclusion of Children (&lt;18 years) in Research – FDA</li> <li>• <a href="#">GUI-C34</a> Parental Permission</li> <li>• <a href="#">Assent Form Template</a></li> </ul>
Other Stanford resources	<ul style="list-style-type: none"> <li>• <a href="#">Mandatory Reporting of Child Abuse and Neglect</a> (Stanford University Human Resources)</li> <li>• <a href="#">Child Abuse and Neglect Reporting</a> (Office of the Chief Risk Officer)</li> </ul>