

## A. MINOR PARTICIPANTS WHO ARE CHILDREN

By regulatory definition, “children” are persons who have not attained the legal age for consent to treatments, procedures, or other activities involved in research under the applicable law of the jurisdiction in which the research will be conducted. In California, a person under 18 years old is considered a “child,” and may not generally consent to participate in research. Some exceptions allow a person under 18 to consent, and they are explained below in Section B, Minors Who May Consent as Adults, Including Emancipated Minors. The term “minor” generally means a person under 18 in one of those exceptions.

Since children are considered a vulnerable population, the IRB imposes additional protections on research involving children, in accordance with the Common Rule (45 CFR Part 46, Subpart D) and FDA regulations (21 CFR Part 50, Subpart D). This includes the investigator obtaining the permission of parents or guardian through the consent process and of the assent of the child, and the IRB being able to make certain findings based on the level of risk and benefit of the research.

### 1. Obtaining Parental Permission

The IRB requires the investigator to obtain the permission of the child's parent(s) or guardian before enrolling the child in a study. This typically involves a discussion that covers all of the elements of informed consent and having the parent(s) or guardian sign an informed consent document that looks like the typical adult research consent document, except that the document is not directed to the parent as a participant in research.

For parents, adequate provisions are made for soliciting the permission of both, unless one parent is deceased, unknown, incompetent, or not reasonably available or when only one parent has legal custody for the child. See guidance [Parental Permission](#).

### 2. Waiver of Parental or Guardian Permission

If the research is not regulated by the FDA, the IRB may waive parental or guardian permission if:

- a. the regular conditions for waiver of consent are met (see 45 CFR 46.116(c) or 46.117(d)); or
- b. the study focuses on a condition for which parental or guardian permission is not a reasonable requirement to protect the children and an appropriate mechanism is substituted, e.g. is of such private and sensitive nature that it is not reasonable to require permission, (for example, adolescents in studies concerning treatment of sexually transmitted disease); or
- c. a subject population for which parental or guardian permission is not a reasonable requirement to protect the children and an appropriate mechanism is substituted, e.g. is such that parental permission is not a reasonable requirement to protect the participants, (for example abused or neglected children). (See 45 CFR 46.408(c))

*Research regulated by the FDA is not eligible for waiver of parental or guardian permission unless the emergency exception applies.*

The Classroom. The IRB will consider a request for a waiver or partial waiver of parental

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permission for research to be conducted in a classroom, provided the research is minimal risk and meets the other waiver requirements.

Parental/ Guardian Waiver Not Suitable. Research is ordinarily not suitable for a waiver of permission if it involves any of the following issues:

- parental political affiliations or beliefs
- mental or psychological problems
- sexual behavior or attitudes
- illegal, antisocial, or 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.

If the IRB waives the requirement for parental or guardian permission, the IRB normally devises an alternative mechanism to protect the child participants (e.g., appoint a qualified child advocate).

In accordance with the federal regulations, the IRB requires that the investigator obtain the assent of the children, if the children are capable of providing assent, and it is not waived.

### 3. Obtaining Assent

The IRB must determine whether investigators have adequate provisions to solicit assent, when the children are capable of providing it. See 45 CFR 46.408; 21 CFR 50.55. The term “assent” refers to a child’s affirmative agreement to participate in research. Absent affirmative agreement, mere failure to object is not assent. The IRB also needs to know how the affirmative assent of the child will be documented, e.g., signature on assent form, documented by the investigator, or other.

In California, an investigator for an experimental drug study must normally obtain the assent of any child participant 7 years or older. For that reason, for all studies involving children 7 to 17 years, the IRB recommends that investigators document the child's willingness to participate with a signed assent document.

The IRB requires the language of the assent document to be geared to the cognitive level of the children being asked to participate in the research study. Procedures that are not part of the child's care need to be described as optional. Any information that can affect a child's decision to take part should be included. The child should be given an explanation of the proposed research procedures, the purpose of the research, and any discomforts, in a language appropriate to the child's age, experience, maturity, and condition. (See the *Assent Questions and Assent* form templates on the IRB website).

A particular child participant's capacity to assent must be evaluated on an individual basis. For example, it may be entirely suitable to use the language in the parental consent document as an assent document for an older teen. However, in children younger than seven years of age but old enough to be consulted about participating in research, it may be more appropriate to obtain the child’s assent orally and omit any signature.

### 4. Assent Not Required Or Waived

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An investigator may request that the IRB not require assent in one or more of the following three circumstances, including FDA regulated protocols:

- The IRB determines that the 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.
- The IRB determines that 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.
- Even if the IRB determines that assent is appropriate, it may waive the requirement if the customary conditions for waiver or alteration of consent are satisfied (45 CFR 116 or 21 CFR 50.55(d)).

## 5. Guardianship

A “guardian” is 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). Under California law, such 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 the restrictions discussed below.

Limits on Guardian Authority for Medical Care. 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). This includes the authority to consent on behalf of the child to general medical care.

For research that involves medical care, however, a guardian’s authority to consent or require is restricted, in the absence of an affirmative court order, in the following circumstances:

- by the terms of any letters of guardianship issued by a court (a certified copy of which should be obtained and placed in the medical record),
- for 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 advise that an emergency exists in which the child faces loss of life or serious bodily injury if the surgery is not performed,
- from administering an “experimental drug” (defined in Health & Safety Code Section 111515; 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,
- from authorizing electro-convulsive treatment (defined in Welfare & Institutions Code Section 5325),

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- from admitting the child to a “mental health treatment facility” (defined in Probate Code 2356(a)) without the child’s consent,
- from authorizing antipsychotic drugs except under certain circumstances,
- from authorizing an elective procedure performed primarily for the purpose of rendering the child sterile (i.e., not treatment which secondarily results in sterilization),
- from authorizing psychosurgery under any circumstances.

### 6. Children Who Are Wards

Legal requirements limit the circumstances for research with children who are “wards” of the State or any other agency, institution or entity. The IRBs may approve a protocol that involves wards and research involving greater than minimal risk but presenting the prospect of participant direct benefit (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 research is: (i) related to their status as wards, or (ii) conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of the participating children are not wards, and
- The research appoints an advocate for each child, who: (i) may be the same individual for all of the children, (ii) 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 (iii) is not associated in any way with the research (except as an advocate), the investigators, or any guardian association.

Additionally, for research involving medical care for wards of a court, often an order from the judge is required, in addition to permission from the person charged with the care of the child.

### 7. Children’s Whose Parents or Guardian Are Unavailable

An investigator may not normally involve a child in research if the parent(s) or guardian are not available to provide permission and the IRB has not waived permission of the parent(s) or guardian. In California for research involving treatment, however, an investigator may be able to involve children:

- 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. An investigator who intends to rely on one or more of them should contact the IRB legal advisor in the General Counsel’s Office for guidance.

## 8. Children in Research At VA Facilities

The VA is authorized to care for veterans and to conduct research that supports the mission of the VA and enhances the quality of health care delivery to veterans. As a result, research involving children must not be conducted by VA investigators while on official duty or at the VA hospital or approved off-site facilities, unless a waiver has been granted by the VA's Chief Research and Development Officer.

Waivers are granted only if the study poses no more than minimal risk. If a waiver is granted, the IRB requires that the research must be in accordance with STANFORD's standard policies and procedures. For more information on obtaining a waiver from the VA, contact (202) 254-0183.

## B. MINORS WHO MAY CONSENT AS ADULTS, INCLUDING EMANCIPATED MINORS

Under California law, minors may consent to participation in research without parental or guardian permission (i.e., as if adults) if legally emancipated and in certain treatment circumstances.

### 1. Any Type of Research

The IRB interprets California law relating to emancipated minors as authorizing an "emancipated minor" to give consent to participation in research. To be emancipated, the minor must meet one of the following requirements set out in California Family Code 7002:

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

### 2. Research Involving Treatment

In addition, the IRB interprets a variety of other California statutes as authorizing certain unemancipated minors to consent to research involving specific types of medical treatment, including:

- Outpatient mental health treatment by a minor 12 years or older when certain criteria are met (Family Code 6924),
- Hospital, medical or surgical care related to prevention or treatment of pregnancy for a minor of any age (Family Code 6925),
- Medical care related to diagnosis/treatment of a communicable reportable disease or condition (Family Code 6926),
- Hospital, medical or surgical care related to rape for a minor 12 years or older (Family Code 6927),
- Hospital, medical or surgical care related to sexual assault (Family Code 6928) but must attempt to contact parent/ guardian unless reasonable believe involved,
- Care for alcohol or drug abuse (Family Code 6902 and 6929).

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