

**Guidance and Procedures: 21**  
**Title: Special Subject Populations: Children**  
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## **I. Introduction**

Special considerations apply when research involves subjects who are minors (in California, under 18 years of age). Such research is important to obtain accurate data and develop optimal therapies for children. At the same time, children are inherently more vulnerable than adults, and require a higher level of protection.

Federal regulations for research with adult subjects ([Title 45-Code of Federal Regulations \(CFR\)-Part 46](#)) serve as a starting point. Additional special considerations for children are outlined in [45 CFR 46, Subpart D](#) (and [21 CFR 50 for FDA-regulated research](#)) and interpreted by UCLA's Institutional Review Board (IRB) as described below. California laws also apply to research involving children conducted in the State of California (see below). Additionally, there may be additional laws or requirements for research involving children being conducted in other states or internationally.

Both the researcher and the IRB must consider the benefits, risks, and discomforts inherent in the proposed research and assess their justification in light of the expected benefits to the children or to society as a whole. In calculating the degree of risk and benefit, both the researcher and the IRB should weigh the circumstances of the subjects under study, the magnitude of risks that may accrue from the research procedures, and the potential benefits the research may provide to the subjects or class of subjects.

The purpose of these guidelines is to assist investigators in applying for UCLA IRB approval to conduct studies involving children.

## **II. Definitions**

The following definitions are based on U.S. Department of Health and Human Services (DHHS) regulations at 45 CFR 46.402 and Food and Drug Administration (FDA) regulations at 21 CFR 50.3, and California law.

- A. **Children** are people who have not reached the legal age to consent for treatment or procedures involved in the research. In California, the legal age is usually 18, but there are important exceptions (explained in Section V or Section VI (F) of this guidance). For research conducted outside California, the process described in Section IV of this guidance will be used to decide which individuals in the local jurisdiction meet the DHHS and FDA definition of "children."
- B. **Minors** are people under 18 years of age. Because in California some people under 18 years of age can consent for themselves to some research procedures, not all "minors" meet the federal criteria for being "children."
- C. **Assent** is the term used for a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

- D. **Guardian** is an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care. The FDA definition continues with the phrase “when general medical care includes participation in research.” For research conducted outside California, the process described in Section IV of this guidance will be used to decide which individuals in the local jurisdiction meet the DHHS and FDA definition of “guardian.”

In California, a guardian may be a parent, a legally appointed guardian, a guardian *ad litem* as appointed by a court (this is an individual who may have no relationship to the minor who is appointed by the court to protect and represent the interests of the minor before the court), or others as consistent with an order of a court having jurisdiction over the minor. For wards of a court, usually an order from the judge is required in addition to permission from the person charged with care of the child.]

- E. **Emancipated minors (defined by California Family Code)** are those who are either (a) married or divorced, or (b) on active duty in the U.S. armed forces, or (c) emancipated by a court.
- F. **Self-Sufficient Minors (defined by California Family Code)** are (a) 15 years of age or older, (b) living separate from their parents/guardians, and (c) managing their own financial affairs.
- G. **Parent:** is a child's biological or adoptive parent.
- H. **Permission** is the agreement of parent(s) or guardian(s) to allow the participation of their child or ward in research.
- I. **Wards (specifically defined only by the FDA)** are children who are placed in the legal custody of the State or other agency, institution, or entity, consistent with applicable Federal, State, or local law.

### **III. Special Investigator Responsibilities when Conducting Research Involving Children:**

- A. When planning a study that will involve children, the principal investigator (PI) should first consider four main issues:
1. What is the ***rationale for including children***? What unique outcomes, benefits, and risks will come from studying children? Does the study address a condition that particularly affects children?
  2. How is the study ***risk level*** determined? What are the relevant regulations?
  3. How are study procedures different from ***standard of care*** for the subjects?
  4. What are ***consent (permission and assent) requirements*** for the study? Will permission from one or both parents be needed?
- B. The PI should familiarize him/herself with the permitted categories for research involving children, understand and follow the guidelines for obtaining permission and consent from parents and the assent of the children, and understand ???and apply the California definitions of “children” and “minors.”
- C. The PI will include the *UCLA IRB Application Supplement to Include Children in Research* with expedited or full committee applications to the IRB.

### III. Permitted Categories of Research Involving Children

A. The federal regulations require IRBs to classify research involving children into one of four categories and to document their discussions of the risks and benefits of the research study. Investigators conducting research involving children should familiarize themselves with the four categories of research involving children that may be approved by IRBs, based on degree of risk and benefit to individual subjects, are as follows:

1. **Research not involving greater than minimal risk ([45 CFR 46.404](#) and [21 CFR 50.51](#)).** If the IRB finds that the research presents no greater than minimal risk to the children, the IRB may approve the research if it finds and documents that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians.
2. **Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects ([45 CFR 46.405](#) and [21 CFR 50.52](#)).** If the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual child, or by a monitoring procedure that is likely to contribute to the child's well-being, the IRB may approve the research if it finds and documents that:
  - The risk is justified by the anticipated benefit to the subjects;
  - 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
  - Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.
3. **Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition ([45 CFR 46.406](#) and [21 CFR 50.53](#)).** If the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual child, or by a monitoring procedure which is not likely to contribute to the well-being of the child, the IRB may approve the research if it finds and documents that:
  - The risk represents a minor increase over minimal risk;
  - 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;
  - 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
  - Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians.
4. **Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children ([45 CFR 46.407](#) and [21 CFR 50.54](#)).**

If the IRB finds and documents that the research does not meet the requirements set forth in categories 45 CFR 46.404-406 and 21 CFR 50.51-53, the IRB may only approve the research if it finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children. Additionally, the research may only proceed if the Secretary of the Department of Health and Human Services (DHHS) (or, if the research is subject to FDA regulations, the Commissioner of Food and Drugs), 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, determines either: (1) that the

research in fact satisfies the conditions of 45 CFR 46.404, 45 CFR 46.405 or 45 CFR 46.406 (or 21 CFR 50.51, 21 CFR 50.52 or 21 CFR 50.53), or (2) the following:

- the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
- the research will be conducted in accordance with sound ethical principles;
- adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians as set forth in 45 CFR 46.408 (or 21 CFR 50.55).

- B. California Health & Safety Code Section 111530(b), permits use of experimental drugs in minors only when the experimental drug is related to maintaining or improving the health of the subject or related to obtaining information about a pathological condition of the subject.

#### **IV. Requirements for Permission by Parents or Guardians and for Assent by Children**

##### **A. Adequate Provisions for Child Assent.**

Adequate provisions are required in order to solicit the assent of the children. The researcher must consider and propose these provisions in the IRB application and specifically discuss whether the children are capable of understanding the nature of their participation in the research. The IRB will review the proposed provisions.

1. 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 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.

2. If either of the following to be 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 a child's dissent, which should normally be respected, may be overruled by the child's parents. This should be discussed in the IRB application and will be considered by the IRB. When research involves the provision of experimental therapies for life-threatening diseases such as cancer, however, IRBs 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.

3. 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 under circumstances in which consent may be waived 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.

#### **B. Adequate Provisions for Parent or Guardian Permission.**

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

1. **Research not involving greater than minimal risk (45 CFR 46.404 and 21 CFR 50.51).** When research is approved under this category, and permission is to be obtained from parents, the IRB may find that the permission of ***one parent is [may be] sufficient.***
2. **Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects. (45 CFR 46.405 and 21 CFR 50.52).** When research is approved under this category, and permission is to be obtained from parents, the IRB may find that the permission of ***one parent is [may be] sufficient.***
3. **Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition (45 CFR 46.406 and 21 CFR 50.53).** When research is approved under this category, and permission is to be obtained from parents, ***both parents must give their permission 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.
4. **Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (45 CFR 46.407 and 21 CFR 50.54).** When research is approved under this category, and permission is to be obtained from parents, ***both parents must give their permission unless*** one parent is deceased unknown, incompetent, or not reasonably available, or when only one parent has legal

#### **C. Waiver of Parental or Guardian Permission**

1. In accordance with the federal regulations at 45 CFR 46.116(d), the IRB may waive the requirement for parent or guardian permission if the IRB finds and documents that:
  - The research involves no more than minimal risk to the child-subjects;
  - The waiver or alteration will not adversely affect the rights and welfare of the child-subjects;
  - The research could not practicably be carried out without the waiver or alteration; and
  - Whenever appropriate, the parents will be provided with additional pertinent information after participation.
2. In accordance with the federal regulations at 45 CFR 46.408(c), if the IRB determines that the research protocol is designed for conditions or for 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 requirement to obtain parent or guardian permission provided both:

- The waiver is not inconsistent with federal, state, or local law; and
  - An appropriate mechanism for protecting the children who will participate as subjects in the research is substituted. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risks and anticipated benefit to the research subjects, and their age, maturity, status and condition.
3. Neither of the waivers described in (1) and (2) above may be granted by the IRB in its review of research that is subject to FDA regulations.

#### D. Re-Assent/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.

#### E. Documentation

1. Permission by parents or guardians shall be documented in accordance with and to the extent required by 45 CFR 46.117 [45 CFR 46.111(a)(5)] and, in the case of FDA-regulated research, in accordance with and to the extent required by 21 CFR §50.27 [21 CFR 56.111(a)(5)].
2. When the IRB determines that assent of a child is required, it will also determine whether and how assent must be documented. Assent must generally be documented according to the 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.
  - ***If the child is under the age of 7***, only parental permission is required. The Board encourages the investigator to explain, where possible and appropriate, what the child will be asked to do.
  - ***If the child is 7-12 years of age***, a child assent form is required in addition to the parental permission form. The 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.
  - ***If the child is 13-17 years of age***, a youth assent form is required in addition to a parental permission form. The youth assent form must contain all required elements of informed consent and may follow the format provided for adult consent but is

required to contain simple language written at the appropriate educational level of the youngest prospective subject in the youth age range. In some research projects, it may be necessary to utilize two assent forms written to accommodate subjects at either end of the age range.

If the IRB determines that a parental permission/adult consent form is written at an appropriate level, investigators may use a single form that serves as both the youth assent and the parental permission/adult consent.

## **V. Special Categories**

### **A. Wards of the State or Other Agency**

1. Under 45 CFR 46.409 (and 21 CFR 50.56 for FDA-regulated research), children who are wards of the state or any other agency, institution, or entity can be included in research posing greater than minimal risk with no prospect of direct benefit to subjects or requiring the approval of the HHS Secretary or FDA Commissioner (see Section III 3) and (4) above) *only* if the IRB finds and documents that such research is:
  - a. Related to their status as wards; or
  - b. Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.
2. If the IRB makes either of the above determinations, the IRB must also 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. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.
3. Investigators are responsible for awareness of and compliance with any relevant requirements of the competent court, agency, institution or entity of which the child is a ward.

### **B. Enrollment of Persons Under 18 Who Can Consent for Themselves**

1. California law defines several groups of persons under 18 years of age (referred to as "children" or "minors" in state law) who are legally able to consent to treatment or procedures involved in research. Under federal regulations (45 CFR 46.402(a) and 21 CFR 50.3(o)), these people do not meet the definition of "children" and therefore are able to consent for themselves as if they were adults.
2. ***Within California***, minors generally may not consent to medical care or treatment involving medical care or treatment without a parent or legal guardian's consent. Based on federal regulations and California law, minors are permitted to consent for themselves for research in the situations described further in section V.C below.
3. ***Outside of California***, the age of consent depends on the local jurisdiction. UCLA Researchers enrolling study participants in other states or countries will need to comply with local law.

## **C. California Law**

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.

### **1. Confidentiality of Medical Records**

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>1</sup> The same law ensures that a minor's parents do not have the right of access to medical record information 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.

### **2. Drug Research**

California law does not allow a waiver of parent-guardian permission for minors to receive experimental drugs (except in certain circumstances for drug treatment as described below).<sup>2</sup>

### **3. Device & Behavioral Research**

California law does not include restrictions similar to drug research for device or behavioral research.

### **4. 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:

- a. Married or divorced,
- b. On active duty in the U.S. armed forces, and/or
- c. 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)

### **5. Self-sufficient Minors**

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

- a. Minor is 15 years of age or older;
- b. 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*
- c. Managing her/his own financial affairs, regardless of the source of the minor's income.<sup>3</sup>

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<sup>1</sup> CA Health & Safety Code 123110(a) and 123115(a).

<sup>2</sup> CA Health & Safety Code 24175.

<sup>3</sup> CA Family Code 6922(a).

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>4</sup>

**6. *Minors may provide sole consent for the following procedures/treatments:***

Female minors of child bearing potential and pregnant minors may be considered autonomous for the purpose of providing informed consent in a research context without parent-guardian permission for specific related clinical procedures under State law. In other words, minors who have attained the legal age for consent to a type of medical treatment do **not** meet the definition of "children" for that treatment and would be considered to have autonomous rights such as an adult **only** for the purposes of that treatment(s).

- Pregnancy (Prevention or Treatment): Medical care related to prevention or treatment of pregnancy (no minimum age), except sterilization.<sup>5</sup> The health care provider is not permitted to inform a parent or guardian<sup>6</sup>,
- Contraception: Medical care related to contraception.<sup>7</sup> The health care provider is not permitted to inform a parent or guardian,<sup>8</sup>
- Abortion and related medical care<sup>9</sup>: The health care provider is not permitted to inform a parent or guardian,<sup>10</sup>
- Infectious disease, etc.: Medical care related to the diagnosis or treatment of an infectious, contagious, or communicable disease or condition that is required under State law to be reported or is a sexually transmitted disease for minors 12 years of age or older,<sup>11</sup>
- AIDS/HIV testing and treatment: 12 years of age or older.<sup>12</sup> The health care provider is *not* permitted to inform a parent or guardian without the minor's consent. The provider can only share the minor's medical record with the signed informed consent of the minor,<sup>13</sup>
- Rape: Diagnosis and treatment for rape, and collection of medical evidence for minors 12 years of age or older,
- Sexual Assault & Rape Services: Diagnosis and treatment for sexual assault, and collection of medical evidence, no minimum age,<sup>14</sup>

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<sup>4</sup> CA Family Code 6922(c).

<sup>5</sup> CA Family Code 6925.

<sup>6</sup> CA Health & Safety Code 123110(a) and 123115(a).

<sup>7</sup> CA Family Code 6925.

<sup>8</sup> CA Health & Safety Code 123110(a) and 123115(a).

<sup>9</sup> American Academy of Pediatrics v. Lungren 16 Cal.4<sup>th</sup> 307 (1997).

<sup>10</sup> CA Health & Safety Code 123110(a) and 123115(a).

<sup>11</sup> CA Family Code 6926 and CA Health & Safety Code 123110(a) and 123115(a).

<sup>12</sup> CA Health & Safety Code 121020.

<sup>13</sup> CA Health & Safety Code 123110(a) and 123115(a).

<sup>14</sup> CA Family Code 6928. The health care provider must attempt to contact the minor's parent-guardian and document other information. The requirement to inform a parent/guardian does NOT apply if the treating professional reasonably believes that the parent/guardian committed the rape or assault (This provision does not apply to minors 12 years of age or older).

- Alcohol or Drug Treatment: Medical care and counseling for diagnosis and treatment for alcohol or drug related treatment for minors 12 years of age or older, excluding participation in replacement narcotic abuse treatment using methadone or levoalphacetymethadol (LAAM),<sup>15</sup>
- Emergency Medical Services: A minor who has a condition or injury which is considered an emergency but whose parent or guardian is unavailable to give consent is permitted give consent for medical services.<sup>16</sup> The health care provider, however, is required to inform the minor's parent or guardian,
- Outpatient mental health care: For minors 12 years of age or older if both of the following requirements are satisfied:
  - a. the minor, in the opinion of the attending professional person, is mature enough to participate intelligently in the outpatient services, and
  - b. the minor would present a danger of serious physical or mental harm to self or to others without the mental health treatment or counseling, or is the alleged victim of incest or child abuse.<sup>17</sup>

#### D. Research Conducted Outside California

1. 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.
2. 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. *Please note*: 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.
3. The application to the IRB should describe the investigator's knowledge of local requirements and how appropriate consent and assent will be obtained.
4. The IRB will ensure that the investigator's plans demonstrate knowledge of local requirements. OPRS staff will confirm information provided by the investigator, with the assistance of University Counsel as needed.

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<sup>15</sup> CA Family Code 6929(e) and CA Health & Safety Code 123115(1)(2).

<sup>16</sup> CA Code of Business & Professions 2397(c)(2). An emergency situation is "a situation... requiring immediate services for alleviation of severe pain or immediate diagnosis of unforeseeable medical conditions, which, if not immediately diagnosed and treated, would lead to serious disability or death.

<sup>17</sup> CA Family Code 6924. Though California allows minors (as defined above) to provide informed consent for outpatient mental health treatment, the law prohibits their sole consent for psychotropic drugs, convulsive therapy, or psychosurgery, without the corresponding permission of the parent-guardian.

## **VI. IRB Responsibility**

### **A. IRB Expertise When Reviewing Research Involving Children**

An IRB considering a protocol involving children as participants has is required to:

1. Assess its needs for pediatric expertise among the IRB voting membership to assure that it possesses the professional competence necessary to review the specific research activities; and
2. Consider inclusion of one or more individuals who are knowledgeable about and experienced in working with children. To fulfill this requirement, the IRB may invite nonvoting individuals to assist in the review of issues which require expertise beyond, or in addition to, that available among voting IRB members.

### **B. Review**

The IRB will assess whether proposed research involving minors constitutes activities covered under 45 CFR 46 Subpart D and/or applicable California law in order to ensure that special protections are appropriately applied.

1. The IRB may determine that minors are not subject to the requirements in 45 CFR 46 Subpart D for specific interactions or interventions as allowed under California law.
2. In such cases, the IRB may determine that the minor may provide informed consent for the procedure, consistent with California law.

### **C. Informed Consent**

If the proposed research activities include interventions with minors, such as pregnancy testing, the IRB will assess whether the minor is a child under applicable federal regulations and State law for the purpose of that specific intervention.

1. If the subject is a minor as defined by State law and unable to legally participate in the procedure without parent-guardian permission, the IRB will apply all of the applicable protections at 45 CFR 46 (Subpart D).
2. If the subject is *not* a child as defined at 45 CFR 46.402 and by California law, the IRB will determine whether additional protections at Subpart D should be applied in order to ensure the research demonstrates respect for the dignity of the subject as well as minimize risks and maximize benefits, e.g., including an appropriate alternative mechanism for protecting the children, such as a subject advocate, as outlined in 45 CFR 46.408(c).

### **Regulations:**

45 CFR 46, Subpart D

45 CFR 46.408(c)

45 CFR 46.116(d)

45 CFR 46.117

21 CFR 50, Subpart D

21 CFR Parts 50, 56, and 312

California Family Code Section 6550

California Family Code Section 6910

California Family Code Sections 7000-7002, Emancipation of Minors Law

California Health & Safety Code Section 111530(b)  
California Health & Safety Code Sections 123110(a) and 123115(a)  
California Probate Code, Division 2  
California Welfare & Institutions Code, Division 2, Chapter 2  
California Code for Businesses and Professions

**References:**

OHRP (formerly OPRR), *Protecting Human Research Subjects Guidebook (1993)*, Chapter 6, Section C, "Children and Minors". [http://hhs.gov/ohrp/irb/irb\\_chapter6.htm](http://hhs.gov/ohrp/irb/irb_chapter6.htm)

OHRP Children's Special Issues Page. <http://www.hhs.gov/ohrp/children/>

OHRP Guidance: Children Involved as Subjects in Research: Guidance on the HHS 45 CFR 46.407 ("407") Review Process - May 26, 2005 [http://hhs.gov/ohrp/children/Guidance\\_407Process.pdf](http://hhs.gov/ohrp/children/Guidance_407Process.pdf)

OHRP FAQs on Research with Children <http://www.hhs.gov/ohrp/faq.html>

FDA Guidance for Clinical Investigators, Institutional Review Boards and Sponsors: Process for Handling Referrals to FDA Under 21 CFR 50.54 – December 2006.  
<http://www.fda.gov/OHRMS/DOCKETS/98fr/06d-0172-gdl0002.pdf>

American Academy of Pediatrics v. Lungren 16 Cal.4<sup>th</sup> 307 (1997)