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Initial Considerations

Special regulations outlined in 45 CFR 46, Subpart D ^[1] (and 21 CFR 50 ^[2] for FDA-regulated research) apply when research involves subjects who are children. Such research is important to obtain accurate data and develop optimal therapies for children, but children are inherently more vulnerable than adults and require additional protection.

When planning a study that will involve children, first consider four main issues:

- Rationale for inclusion: Why include children in the study? What unique outcomes, benefits and risks will come from studying children? Does the study address a condition that particularly affects children?
- Risks and regulations: How is the study risk level determined? What are the relevant regulations?
- Study procedures vs. SOC: How are study procedures different from standard of care for the subjects?
- Consent and assent: What are consent (permission and assent) requirements for the study? Will permission from one or both parents be needed?

Defining "Children" and "Minors"

Only individuals who are **children** under the federal regulations are covered by the additional protections described in 45 CFR 46, Subpart D ^[1] and 21 CFR 50 ^[2].

Who qualifies as a **child** depends on local laws for consent. In California, individuals usually can consent to treatments or procedures at age 18, but there are some exceptions ^[3].

Children	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 (per 45 CFR 46.402 ^[4] and a similar definition in 21 CFR 50.3 ^[2]).
Minors	People under 18 years of age.

Minors? Who Are Not Children? In California, certain people under 18 years of age are legally able to consent for treatments or procedures involved in research. See the Legal Exceptions Permitting Certain Minors to Consent section for more info.

Other states and countries have their own laws governing the legal age of consent for treatment or procedures involved in research.

Note: California law inconsistently uses the both of the terms **children** and **minors** to refer to people who are under 18 years of age, but they are usually considered **children** in the applicable federal regulations, with some exceptions ^[5]. Research involving children that will be conducted in whole or in part at the Veterans Affairs Medical Center ^[6] requires VA approval from Washington, DC, before children may be enrolled.

Rationale for Inclusion of Children in Research

Describe the rationale for including children in the study in the "Background" section of the IRB Application and also in the background section of the consent form. Analyze what is unique to children in formulating this rationale, as well as in assessing the risks and benefits of the study.

Examples of appropriate rationales for inclusion of children in research

The research holds out the prospect of benefit to children and involves:

- A condition uniquely affecting/manifesting in children (e.g., pediatric cancer or systemic lupus erythematosus).
- A condition affecting both adults and children, where adult studies have been done but child-specific data is still needed (e.g., many drug trial conditions).
- An area of psychology or sociology specifically related to children (e.g., adolescent depression, childhood abuse).
- A pediatric condition linked to a different adult condition, so data could inform treatment of adult condition (e.g., Down's syndrome/Alzheimer's disease).

Note: Many other examples could be listed.

Permitted Categories for Research with Children

Federal regulations classify four permissible categories for research involving children, based on degree of risk and type of prospective benefit. These categories are described in relation to minimal risk.

Minimal risk definition

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 21 CFR 50.3].

Describe the study risks in the IRB Application, clarifying what would be standard of care for the subject group(s) and how the research procedures differ from that standard of care. The consent/assent forms need only discuss in detail procedures (and their risks) that are being done specifically for purposes of the study. Also, keep in mind that what constitutes "daily life" or a "routine test" may not be constant over childhood, among children of the same age, or before and after the occurrence of a disease or condition.

Permitted Categories

Below is summarized information on these categories. For complete requirements, see the summary table [7].

1) Minimal risk [45 CFR 46.404, 21 CFR 50.51]

Description: "Research not involving greater than minimal risk."

Consent/Assent:

- Permission from ONE parent/legal guardian may be sufficient.
- Assent of child (if child is 7 years of age or older).
- See the Waiver of Consent guidance [8] for info on when the IRB may waive consent/assent for non-FDA-regulated research.

Type of Review: Generally, expedited review [9] by the IRB. See the Levels of Review [9] page

for a list of expedited review categories. Occasionally, full committee review may be required.

Examples:

- A study involving one blood draw (no more than the lesser of 50 ml or 3 ml/kg in an 8 week period) in healthy 10-year-old subjects.
- Other procedures that usually qualify as minimal risk include urinalyses, EEGs, allergy scratch tests, and minor changes in diet or daily routine.

2) Greater than minimal risk, direct benefit to subject [45 CFR 46.405, 21 CFR 50.52]

Description: "Research involving greater than minimal risk, but presenting the prospect of direct benefit to the individual subjects.?"

Consent/Assent:

- Permission of ONE parent/legal guardian may be sufficient.
- Assent of child (if child is 7 years of age or older).

Type of Review: Full committee review^[9] by IRB.

Examples:

- A study evaluating a new type of therapy to treat bulimia nervosa.
- A Phase II study using an experimental chemotherapeutic regimen for children with malignant brain tumors for whom standard therapy has failed.

Note: Although most clinical trials fall into Category 2, it is sometimes difficult to determine what the "prospect of direct benefit" is, as in a study that includes a control group whose participants face less risk than the active group but also less prospect for benefit.

3) 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]

Description: "Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about subject's disorder or condition ... the risk represents a minor increase over minimal risk."

Note: The IRB may approve the study only if the research carries *no more than "a minor increase over minimal risk,"* but the regulations do not further define this limitation. The IRB may consider societal benefits as offsetting risks within Category 3, *but only if those benefits would affect a specific group to which the subject belongs.*

Consent/Assent:

- Permission of BOTH parents/legal guardians, unless one parent is deceased, unknown, incompetent, not reasonably available, or does not have legal responsibility for the custody of the minor.

- Assent of child (if child is 7 years of age or older).

Type of Review: Full committee review [9] by IRB.

Example: A study testing new biomarkers of disease progression that involves 2 extra samples of cerebrospinal fluid over a year of therapy (beyond the 5-6 that would be done as part of the child's routine care.)

4) 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]

Description: "Research not otherwise approvable which presents opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children." The IRB must agree with this determination.

The Secretary of the U.S. Department of Health and Human Services ? after consultation with a panel of experts and following an opportunity for public review and comment ? must either approve or deny approval of the study. The OHRP website [10] includes a detailed description of this process. Note: Category 4 research is very rarely approved.

Consent/Assent:

- Permission of BOTH parents/legal guardians, unless one parent is deceased, unknown, incompetent, not reasonably available, or does not have legal responsibility for the custody of the minor.
- Assent of child (if child is 7 years of age or older).

Type of Review: Full committee review [9] by the IRB and by DHHS.

Example: A study examining sleep mechanisms in children to better understand sleep-related diseases. Involves 13- to 17-year-old adolescents undergoing 3 hospital visits for IV infusion of acetate and glucose followed by MRI, in normal and sleep-deprived groups.

Consent/Assent Process and Documentation

Federal regulations [11] include requirements for parental permission (consent) and assent from children.

Parental permission is the agreement of parent(s) or guardian(s) [4] to the participation of their child or ward in research. In most cases, you must obtain permission from one or both parents/guardians, although permission may be unnecessary or inappropriate in some circumstances.

Assent is a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent. Assent should be obtained from children capable of providing assent, "[taking] into account the ages, maturity, and psychological state of the children involved? [45 CFR 46.408 [11]]. The IRB relies on the expertise of PIs in determining the capability of particular child subject groups and individuals to assent. Assent may be unnecessary or inappropriate in some circumstances.

IRB Consent/Assent Guidelines for Children by Age Group

Age of Minor Participant	Assent Form Recommended	Separate Parental Permission Form Recommended
Infant-6 years old	No	Yes
7-12 years old	Yes	Yes
13-17 years old (Option A)	Yes	No (add line to adolescent assent form for parent(s) to sign)
13-17 years old (Option B)	Yes	Yes

Details

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.

Consent/Assent Notes:

1. Base the parental permission form on the IRB sample consent forms [12], and refer to the subject as "your child" throughout the form.
2. The signature line of this form should be preceded by an explanatory statement such as: ?The person being considered for this study is unable to consent for herself/himself because s/he is a child. By signing this form, you are giving permission for your child or ward to participate in the study.?
3. In certain cases, the PI may deem a child in this age range capable of being involved in the assent process. If so, give the child 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 you obtained verbal assent.

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. A separate, more detailed permission form will be needed for the parents or guardians.

Consent/Assent Notes:

1. A very simple assent form is needed, based on the IRB Sample Assent Form #1 or #2 [12]. Refer to the subject throughout as ?you.? The child should sign the form if possible. If not, the form or study records must still document that verbal assent was obtained.
2. Base the separate parental permission form on the IRB sample consent forms [12], and refer to the subject as "your child" throughout the form.
3. The signature line of the parent?s or guardian?s form should be preceded by an

explanatory statement such as: "The person being considered for this study is unable to consent for herself/himself because s/he is a child. By signing this form, you are giving permission for your child or ward to participate in the study."

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.

Consent/Assent Notes:

1. This assent/consent form should use clear, straightforward language (eighth-grade reading level).
2. Base the assent/consent form on the IRB sample consent forms [12], 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.
3. The signature line for parental consent/permission should follow, preceded by an explanatory statement such as: "The person being considered for this study is legally unable to consent for herself/himself because s/he is a child. By signing this form, you are giving permission for your child or ward to participate in the study."

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 Sample Assent Form #3 [12]).

Consent/Assent Notes:

1. This adolescent assent form should be simpler than the adult consent form for the same study. Base the assent form on IRB Sample Assent Form #2 or #3 [12], referring to the subject throughout as "you." Only the adolescent is asked to sign this 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).
2. Base the separate parental permission form on the IRB sample consent forms [12], and refer to the subject as "your child" throughout the form.
3. The signature line of parent's or guardian's form should be preceded by an explanatory statement such as: "The person being considered for this study is legally unable to consent for herself/himself because s/he is a child. By signing this form, you are giving permission for your child or ward to participate in the study."

Number of parent/guardian signatures required

- **Permission from one parent/legal guardian:** Generally sufficient for research in categories 1 and 2 (described above [13]), although the IRB may require permission from both parents/legal guardians in some circumstances.
- **Permission from both parents/legal guardians, unless one parent is deceased, unknown, incompetent, not reasonably available, or does not have legal responsibility for the custody of the child:** Required for research in categories 3 and 4 (described above [13]).

How to document permission and assent

Signed parental permission forms should be retained with the study records.

Document the assent of children who are deemed capable in one of several ways (upon approval by the IRB):

1. Assent form signed by child (e.g., see Adolescent Assent-Option B, Sample Assent Form #3) is retained with the study records.
2. Assent form signed by person conducting the assent discussion (PI or other study staff member) is retained with the study records.
3. Certification of discussion/assent signed by person conducting the assent discussion (PI or other study staff member) is appended to parental permission form; or retained separately with the study records.

Exceptions

When can the child's assent be waived?

In certain cases, the IRB may consider waiving the requirement to obtain children's assent, for example:

- The capability of some or all of the children is so limited that they cannot reasonably be consulted; or
- 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? [45 CFR 46.408 21 CFR 50.55]. Here the parents' right to make medical decisions for their child may come into conflict with the child's right to give or withhold assent. In this situation, assent may not be mandatory, though it always should be sought.

In such cases, the PI may propose a waiver of child's assent in the IRB application. The IRB's decision about waiver of assent will depend on the specifics of the study.

Consent/Assent Notes:

- If the child is considered capable of providing assent, always provide a simple verbal explanation of what will happen to him/her and the opportunity for questions and

discussion.

- Even if the requirement for assent is waived, it is always preferable to seek the child's assent, if possible.
- Document on the parental permission form or in the study records that the child was appropriately informed about the study.

When can parental permission be waived?

FDA-Regulated Studies

PARENTAL PERMISSION FOR CHILDREN'S ENROLLMENT CANNOT BE WAIVED.

Subpart 21 CFR 50 lacks the provision for waiver of parental permission, because the FDA says it does not oversee studies for which such a waiver is appropriate. See the section Legal Exceptions Permitting Certain Minors to Consent for info on circumstances when minors may consent to research for themselves.

For Non-FDA-Regulated Studies

See the Waiving Informed Consent page [8] for information on when consent may be waived completely for a study.

The IRB may also waive parental permission in some cases in which the study "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)." There must be "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]

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)].
- 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. Note: Some people under 18 who are living independently may be able to consent for themselves without a waiver of parental permission.

Investigators should address all such consent concerns for research with minors, including arguments for waiver of standard consent procedures in the IRB Application.

What if 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 restriction applies to all permissible categories. That is, when both parents are involved in the decision, they must agree for the child to be enrolled, even if only one parent's

signature is required.

When Can Minors Consent for Themselves?

Federal regulations ? when interpreted with California legal exceptions ? permit some minors to consent to research without a parent or legal guardian's consent. Please note that the information below only pertains to research **conducted in California**. If you are working in another state or country, consult with local collaborators and describe to the IRB how your plans to enroll children or minors will comply with laws and regulations.

Under provisions of the California Family Code ^[14], minors can consent for themselves in certain situations:

Minors (age 12+) seeking *some types of care/treatment* for mental health issues; infectious, contagious or communicable diseases; sexual assault or rape; and drug or alcohol abuse

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

- **Outpatient mental health treatment or counseling** (in limited circumstances) excluding ECT, psychosurgery or psychotropic drugs (Sec 6924);
- Medical care for the diagnosis or treatment of **reportable infectious, contagious, or communicable/sexually transmitted diseases** (Sec 6926);
- Medical care for the diagnosis or treatment of the condition and collection of medical evidence with regard to **alleged rape** (Sec 6927) or **alleged sexual assault** (Sec 2928);
- Medical care and counseling for the diagnosis and treatment of a **drug- or alcohol-related problem** (if the treating physician deems and documents that parental involvement is inappropriate), excluding narcotic replacement drugs (Sec 6929).

Prevention or treatment of pregnancy medical care

Minors may consent for themselves to medical care related to the prevention or treatment of pregnancy, but not necessarily to sterilization (Sec 6925).

Emancipated minors

Emancipated minors ? those who are either

- married or divorced, or
- on active duty in the U.S. armed forces, or
- emancipated by a court ?

have the legal right to consent on their own behalf to medical, dental or mental health treatment. 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) (Sec 7000-7143).

Self-sufficient minors

Self-sufficient minors who satisfy all the following criteria may consent to the minor's own medical or dental care (Sec 6922):

- 15 years of age or older, and
- living separate from their parents/guardians, and
- managing their own financial affairs.

The California Family Code ^[14] **includes more restrictions and exceptions than can be summarized here.** For example, in some cases, the care provider must attempt to contact the minor's parent or guardian. Consult the relevant sections of the law if you are considering enrolling subjects based on these examples. You may also call the IRB office ^[15] for help in framing a query to UCSF legal counsel.

Consent: With IRB approval, minors in these categories should provide consent and sign the consent form just as an adult would, unless the IRB approves a waiver ^[8] or alteration ^[16] of consent. The PI must ensure that any individual minor possesses the mental capacity ^[17] to consent to the research.

Additional points to consider

- 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.
- 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 (e.g., phase I or phase II trials of investigational new drugs or devices).
- Unless the PI obtains a Certificate of Confidentiality ^[18], the minor's parents or legal guardians may obtain medical information relating to the minor's drug or alcohol abuse, care even if the minor objects.

Recruitment, Discovery of Sensitive Info and Long-Term Studies

Recruitment Issues

Minimize pressure to participate

When children are asked to do something by parents, doctors, teachers or other adult authorities, they often feel implicit pressure to agree. Similar issues with social or peer pressure (e.g., for studies in educational settings) may also arise in recruiting children to participate in research.

Describe how you plan to minimize implicit pressure to participate in the "Recruitment" section

of the IRB Application. As with all consent and assent forms, the freedom to decline participation should be made clear.

Consider special arrangements for participation

In designing studies involving children, consider any special arrangements for participation, such as scheduling, parking and food, and discuss them with parents if appropriate. Though such information is not required, it could be helpful to parents in deciding about or planning for study participation.

Examples of special study arrangements to consider:

- If the subject is to receive a series of procedures or tests, can these be coordinated with school and/or work schedules?
- Are there siblings who will need childcare or other provisions made?
- What about transportation and/or parking permits for the facility where the research is being conducted?
- Will subjects or their family members need snacks or meals during the study?

Payment and reimbursement

Ethics and regulations: Ethical considerations regarding payment of subjects who participate in studies become even more complex when the research involves children. The regulations offer no specific guidance in this regard; IRBs have varying perspectives and policies. The IRB neither encourages nor prohibits payment of children in research studies, but considers such proposals on a case-by-case basis.

When evaluating this issue, the IRB will apply its usual guidelines for research subject payments [19]. The IRB will also look closely at certain factors such as age, health, socioeconomic and cultural backgrounds of the subjects to ensure that proposed payment does not constitute undue inducement to participate.

Amounts and recipients of payment: At present, \$20-\$25 (or the equivalent in tokens of appreciation) per subject visit is commonly offered as payment for studies involving children at UCSF. In most cases, the IRB recommends that payment for study participation be made directly to the subject or to both child and parent(s) at the same time, rather than to the parent(s) alone.

Reimbursement: The IRB considers reimbursement separately from payment, and recommends that study subjects or their families be reimbursed for expenses related to research (e.g., parking, travel, meals) whenever possible.

Consent/Assent Notes:

- Types, amounts and schedules of payment or reimbursement should be described in the appropriate section of the consent form.
- If subjects need to keep receipts in order to be reimbursed, this should be clearly stated.
- The form should note whether subjects who begin but do not finish a study will be paid

on a pro-rated basis.

Discovery and disclosure of sensitive information

In the course of research with minors, especially adolescents, you may discover sensitive information about subjects that is not related to the study itself. Examples of such information include sexual activity, STDs, use of illegal substances, HIV status, cancer and child abuse.

How will you maintain confidentiality?

Consider how you will handle such situations should they arise. The permission and/or assent form should describe plans for disclosure ? or non-disclosure ? of such information to parents, legal authorities and the subjects themselves.

- In some cases, it may be appropriate for the PI to seek an NIH Certificate of Confidentiality ^[18].
- As with all UCSF consent forms, complete confidentiality should never be promised. See IRB sample consent forms ^[12] for recommended wording.

Child abuse reporting requirements

Ethical and legal obligations apply whenever child abuse is discovered. Be aware that, in most cases, the same reporting expectations pertain in research settings as in clinical settings.

University researchers may fall into a category of health professionals or others listed as ?mandated reporters? under the California Child Abuse and Neglect Reporting Act (California Penal Code 11164-11174.4 ^[20]). Even if your mandated reporter status is not clear, you can make a voluntary report to the appropriate agency.

- If you are planning a study that is designed or likely to elicit information about sexual or physical abuse of a child, the application and consent/assent forms must indicate how discovery of such information will be handled.
 - If such information is discovered unexpectedly (i.e., not anticipated given the study design or subject population), seek advice from his/her department chair or dean or from the Director of the UCSF HRPP, who may refer the question to UC Legal Counsel.
-

Enrolling Children in Long-Term Studies

Long-term research studies may involve subjects who are children at the time of enrollment, but reach the age of consenting for themselves (in California, usually 18 years old) while study procedures or follow-up are still ongoing.

When will you be required to obtain new consent from such subjects?

- If there is continued interaction with subjects who were first enrolled as children, ?re-

consenting? when a subject's legal status changes will usually be required.

- If the only continuing study procedures are follow-up activities such as review of records or examination of biological specimens, the original consent may suffice.

If relevant, address the above issue in the IRB Application.

Research Involving Children in Educational Settings

When planning studies involving children in educational settings, consider the following issues:

Obtain community support

First, obtain support from the educational community of their target school/subject group. This may include contacting school district officials, the local PTA, and/or the principal of a particular school. School officials and/or teachers may approve recruitment for a study, but they do not have authority to give permission for participation of individual children in research ? only a parent or guardian, with the child's assent, can do so.

Active consent is usually required vs. implied consent

The IRB is unlikely to approve use of ?implied consent? ? e.g., a child brings home information about participating in a study at school, and absence of response is considered agreement. In most cases, obtaining ?active consent? via permission and assent procedures appropriate for the subject group(s) is required.

Comply with CA consent requirements

Parental Consent for Children to Participate in Research (§51513 [21]): For K-12 students ? tests, questionnaires, surveys, or examinations containing any questions about the pupil's or the pupil's family's personal beliefs or practices in sex, family life, morality and religion require written parental consent (permission).

Consider recruitment issues

Pay particular attention to recruitment issues such as scheduling, payment and minimizing pressure to participate, discussed in the section above.

Offer alternative activities

If the study will be conducted during school hours, an equivalent alternative activity should be offered for students who do not wish to participate.

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Links

- [1] <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartd>
- [2] <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50>
- [3] <https://irb.ucsf.edu/#consent-exceptions>
- [4] <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.402>
- [5] <https://irb.ucsf.edu/#exceptions>
- [6] <https://irb.ucsf.edu/research-sfvamc>
- [7] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/children-summary-table.pdf>
- [8] <https://irb.ucsf.edu/waiving-informed-consent>
- [9] <https://irb.ucsf.edu/levels-review>
- [10] http://www.hhs.gov/ohrp/policy/populations/guidance_407process.html
- [11] <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.408>
- [12] <https://irb.ucsf.edu/consent-and-assent-form-templates>
- [13] <https://irb.ucsf.edu/#categories>
- [14] <https://leginfo.legislature.ca.gov/faces/codesTOCSelected.xhtml?tocCode=FAM&tocTitle=+Family+Code+-+FAM>
- [15] <https://irb.ucsf.edu/contact-us>
- [16] <https://irb.ucsf.edu/verbal-electronic-or-implied-consent-waiver-signed-consent>
- [17] <https://irb.ucsf.edu/enrolling-individuals-cognitive-impairments-and-assessing-decisional-capacity>
- [18] <https://irb.ucsf.edu/certificate-confidentiality-nih>
- [19] <https://irb.ucsf.edu/research-subject-payments>
- [20] http://leginfo.legislature.ca.gov/faces/codes_displayText.xhtml?lawCode=PEN&division=&title=1.&part=52000&file=51510-51513
- [21] <http://www.leginfo.ca.gov/cgi-bin/displaycode?section=edc&group=51001-52000&file=51510-51513>