

Informed Consent and Assent:

This appendix provides background information and instructions for the CalProtects protocol sections #12 Informed Consent and #13 Informed Assent. In these sections of CalProtects, describe the procedures to be used in obtaining and documenting prior informed consent and assent. Any non-English versions of the consent form must also be attached, along with the documented qualifications of the translators {e.g., CVs, certifications).

Every potential research subject {or their legally authorized representative) has the right to be fully informed of the procedures, risks, and other aspects of the research before voluntarily choosing to participate. The potential research subject {or legally authorized representative) must be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. The information provided for informed consent and assent must be in language that is fully understandable to the subject or the legally authorized representative. Informed consent may not include exculpatory language through which the subject or the representative waives or appears to waive any legal rights, or that releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Children 7-17 years of age must provide informed assent {as distinguished from "consent"1) to participate in research even if their parents or guardians have given permission for their participation through informed consent. The required elements of informed assent are very similar to the required elements of informed consent {see below).

1. Two Procedures for Written (Documented) Informed Consent and Assent

- a. Regular {or "long") form. This is the usual type of informed consent or assent in which the subject is presented with a detailed, printed form to read and sign that provides complete information about all required elements of consent. Regular {or "long") form consent is designed to be fully informative.
- b. Short" form. In this type of informed consent or assent, the required elements of consent are explained orally to the subject by the investigator and the subject is asked to sign a form that summarizes the elements of consent. A witness must be present for the oral presentation and sign a copy of the summary. The protocol must contain a verbatim transcript of the oral information to be presented to the subject {or legally authorized representative).

In general, the choice of "long" or "short" form consent or assent is to be decided by the Principal Investigator based upon the risk of the research, the methodology of the research, and the characteristics and needs of the human subjects. If "short" form consent is chosen, the principal investigator must provide solid justification in the protocol.

2. General Principles of Written (Documented) Informed Consent and Assent

- a. The informed consent form must begin with the official title of the research project.
- b. The title should reflect the purpose and intent of the study.

- c. The form should next identify the principal investigator and the institution conducting the research.
- d. The body of the form (elements 1-11) should be written using the pronoun "you", while the pronoun "I" should be used for the signed consent section (element 12). Because the purpose of the consent form is to obtain consent, as well as to confirm it, the body of the informed consent form must be written in conditional language that does not read as if the potential subject has already agreed to participate.
- e. The form must be written in language that is fully understandable to the potential subjects. Scientific and technical terms should be avoided if simple but equivalent words are available.

3. Required Elements of Informed Consent and Assent

An Informed Consent Form, which lists the required information and headings, is located on the CPHS Website at www.oshpd.ca.gov/Boards/CPHS/forms.html#consent.

1. Purpose, Participation, and Procedures

This section should provide: a statement that the study involves research; an explanation of the purposes of the research; an explanation of how the potential subject was selected; an approximate number of subjects to be involved; the expected duration of the subject's participation; a description of the procedures to be followed; and identification of any procedures which are experimental.

2. Description of Risks

This section should provide a description of any reasonably foreseeable risks or discomforts to the subject. Risks may be physical, psychological, social, or economic. An assessment should be provided of the likelihood, severity, and duration of such risks. Levels of potential risk or discomfort must be accurately and clearly represented to potential subjects, and should not be unduly minimized. Any risk described in the project protocol should be addressed clearly in the informed consent form. A description should be provided of any less risky methods that were considered along with an explanation of why they will not be used. Research projects that collect or analyze personal information involve some degree of risk of loss of confidentiality for subjects. As with other risks, this should be accurately described to potential subjects.

3. Confidentiality

This section should provide a description of any measures that will be undertaken to protect the confidentiality of human subjects involved in the research. In general, statements guaranteeing complete confidentiality should not be made to potential subjects. If records may be subject to legal challenges, or certain information must be reported to law enforcement officials, this should be stated. If a federal certificate of confidentiality will be obtained, it should be described in this section.

4. Description of Benefits

This section should provide a description of any benefits to the subject or others that may be reasonably expected to result from the research. Neither compensation for participation in the activity nor the absence of costs or charges to subjects may be portrayed as benefits. If no benefits for the subjects are expected, that should be clearly stated.

5. Alternative Procedures

This section should describe any similar or equivalent procedures or treatments that may be available to potential research subjects who do not choose to participate in the research. For example, potential subjects may be able to request a similar test or treatment from their personal physician. If no alternative procedures or treatments are available, that should be stated.

6. Compensation

This section should clearly describe the value and circumstances for receipt of any money or other compensation for participation in the study. If no compensation is to be received, this should be stated. The absence of costs or charges to the subject cannot be considered compensation.

7. Treatment for Injury

If the research is greater than minimal risk, describe any treatment that will be available if any injury occurs to the subject as a result of the research. Provide information about where treatment information may be obtained and who will be responsible for any costs related to the treatment. If treatment will not be available, this should be stated.

8. Potential Conflict of Interest and Funding

This section should describe any financial or other relationship interests the researcher may have that may potentially affect the performance of the research or how results of the research are interpreted. In addition, the funding source or sponsor of the research must be identified.

9. Questions

This section should provide information about: 1) who to contact with questions about the research (usually the principal investigator), and 2) who to contact with questions about research subjects' rights (usually an institutional review board, an ethics board, or other oversight panel). If another board or panel is not reviewing the project, the subjects may be instructed to contact: Administrator, Committee for the Protection of Human Subjects, California Health and Human Services Agency (916-326-3660 or cphs-mail@oshpd.ca.gov) for information about research subjects' rights.

10. Voluntary Participation

This section should provide a clear statement that participation in the research is voluntary and that refusal to participate or withdrawal from the research at any point will not result in any penalty or loss of benefits to which the subject is otherwise entitled.

11. Research Participant's Bill of Rights

This section should include a statement that the subject is being given a copy of the Research Participant's Bill of Rights in addition to the informed consent form. For medical experiments, California law (Health and Safety Code, Section 24172) requires that the "California Research Participant's Bill of Rights" be used. English and Spanish versions of these forms are available on the [CPHS Forms](#) page. Medical experiments are defined in Section 24174 as:

"(a) The severance or penetration or damaging of tissues of a human subject or the use of a drug or device, as defined in Section 109920 or 109925, electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a human subject in the practice or research of medicine in a manner not reasonably related to maintaining or improving the health of the subject or otherwise directly benefiting the subject.

(b) The investigational use of a drug or device as provided in Sections 111590 and 111595.

(c) Withholding medical treatment from a human subject for any purpose other than maintenance or improvement of the health of the subject."

For non-medical research, the "Research Participant's Bill of Rights for Non-Medical Research" (Appendix IV) should be used. The Spanish version of this document is also included in Appendix IV. The researcher may submit alternative versions of the bill of rights for non-medical research for CPHS approval.

A copy of the approved medical or non-medical bill of rights must be attached to the consent form given to the subject.

12. Consent Statement and Signature

This is a signed and dated statement that the subject gives consent to participate in the research study and has received a copy of the Research Participant's Bill of Rights. For this statement the pronoun "I" should be used. If applicable, space should be provided for the signature of a witness. In certain circumstances the signatures of both parents may be required for children who are involved in research (see CFR §46.408).

4. Additional Elements of Informed Consent and Assent

When appropriate, information on one or more of the following elements should be included in the consent form:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without the subject's consent.
3. Any additional costs to the subject that may result from participation in the research.
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
5. A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject.
6. For research involving subjects with severe psychiatric disorders: a statement regarding (a) whether the treating psychiatrists are also members of the research team, and (b) whether study medications are determined by clinical need or dictated by the research protocol.
7. For research involving test articles regulated by the Food and Drug Administration (FDA): a statement that the purpose of the study includes evaluation of both the safety and the effectiveness of the test article.
8. Specifics on the methods, amounts, and timing of any proposed taking of blood or any other human materials, and their subsequent disposal.
9. Details regarding authorization for access to the subject's personal records (school, university, hospital, and employment, or others).
10. Details regarding the use of tape recorders or other audio or visual recordings, and an explanation of the proposed uses and disposition of such materials.
11. Assurance that should the investigator discover any untoward medical condition or inheritable disorder in the subject, this will be brought, if possible, to the attention of the subject's own physician, or the subject will be informed of the condition and advised to seek proper assistance.

5. Additional Requirements for Informed Assent

The same *Required Elements of Informed Consent*, listed above, must be used for the Informed Assent form. Because some children cannot read through as long a form as an adult, assent forms may be shortened to facilitate reading and understanding by children. However, all of the required elements of the informed consent still must

be adequately addressed. Also, the informed assent form must be written at a level that is understandable to potential subjects who are children 7-17 years of age. Different informed assent forms may be needed if the study involves children of significantly different ages.

6. Waiver or Alteration of Informed Consent and Assent

The CPHS may approve the use of a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent if Criteria A or Criteria B (below) apply.

Criteria A

1. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
(a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs; and
2. The research could not practicably be carried out without the waiver or alteration.

Criteria B

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver or alteration;
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Waiver of Written Informed Consent and Assent

CPHS may grant a waiver of the requirement for written informed consent or written informed assent under carefully justified circumstances as follows:

1. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject must be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
2. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Examples of projects for which the CPHS may consider requests for waivers of written consent or assent include: projects in which the research subjects are illiterate; projects in which the risks (usually psychological risks) inherent in asking subjects for their signatures outweigh the risks of not obtaining the signatures; projects in which requests for signatures demonstrably violate or distort the subjects' perceptions of the nature and the purpose of the investigation; and interview studies in which the subjects will read and keep the information contained in a consent document.

The waiver of written informed consent does not eliminate the investigator's ethical and legal obligation to obtain the prior consent of subjects for participation in the research activity. The protocol must explain how this consent will be obtained.

b. Guidance for Using Small Numbers or Small Cells:

1. Definition of a small cell or a small number

- (1) A *cell* is the intersection of a row and a column in a table, a spreadsheet, or in any matrix of numbers. For example, a table with four rows and three columns has twelve cells;
- (2) The CPHS considers a cell *small* when it contains 1 to 15 research subjects;
- (3) Some projects do not report data as tables but still might describe the characteristics of *small numbers* of subjects. Whenever a project describes 1 to 15 subjects, it is important to be especially careful that the identities of all subjects are protected from possible disclosure.

2. Why small numbers or small cells are potential problems

A *small number* of subjects in a descriptive report or *small cells* in a table could potentially lead to the unintended identification of a research subject's identity. With a small study population, or with a small subset of a larger population, researchers should be careful about possibly identifying subjects. For example, research subjects in a rural community might be easily identified because their community has only one or two instances of a particular disease. Similarly, multiple tables describing an urban community might allow for the deduction of a subject's identity through a process of subtraction involving cells if the numbers in them are sufficiently small.

3. Suggested methods for dealing with small cells or small numbers

1. Eliminate tables with *small cells* or data descriptions with *small numbers*: Within a table, combine (collapse) the row (or column) containing a *small cell* with another row (or column) to increase cell size;
2. Combine the different time periods, such as fiscal years, represented by two or more tables (or descriptions) into a single table (or description) to increase cell size (or number size);
3. Suppress a *small cell* with a non-numeric symbol that hides the number of subjects, for example {sc}. To prevent the identification of a small cell through subtraction, the suppression symbol should appear at least twice in the row and column of each of its intersections, as in the following example.

| | > 65 yrs. | 18-64 yrs. | < 18 yrs. | TOTAL |
|------------------|-----------|------------|-----------|-------|
| Agree | {sc} | 30 | {sc} | 60 |
| Neutral | {sc} | 60 | {sc} | 150 |
| Disagree | 70 | 90 | 80 | 240 |
| Undecided | 0 | 0 | | 0 |
| TOTAL | 120 | 180 | 150 | 450 |

Use of these suggested methods is recommended but not required by the CPHS. Researchers may request approval from CPHS for using alternative methods to protect subject identity when using small cells or small numbers.

c. HIPAA Waiver or Alteration of Authorization

Researchers may request a waiver or alteration of patient authorization under the Health Insurance Portability and Accountability Act (HIPAA). HIPAA waivers or alterations of authorization are only required when protected health information is first being requested and when there are any changes to the study that affect the HIPAA waiver or alteration. Only one IRB approval of waiver or alteration of patient authorization is required. If another IRB has approved the waiver or alteration, indicate that in the protocol and include that documentation in the Attachment section.

A statement specifying that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by HIPAA.