

## INFORMED CONSENT

*This guidance document is intended for investigators who plan to conduct research involving informed consent. (For research with minors/children as subjects, also see [CPHS Guidelines on Child Assent and Parent Permission](#).) Should you need additional assistance, please contact OPHS at 510-642-7461 or [ophs@berkeley.edu](mailto:ophs@berkeley.edu).*

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### **A. Basic Principles**

In accordance with federal regulations on human subjects in research (45 CFR 46), as well as the guiding principle of “respect for persons” contained in the [Belmont Report](#), the investigator, in almost all cases, must obtain the informed consent of the subject before that individual may participate in the research. If the subject is not legally competent to give consent, consent must be obtained from the subject's legally authorized representative such as a parent, guardian, or conservator. The investigator should seek such consent only under circumstances that give the prospective subject or representative sufficient opportunity to consider the matter carefully and that minimize the possibility of coercion or undue influence. The information that is given should be in language that is understandable to the subject or representative. It should be a full, clear, but succinct explanation, without jargon or technical terms. (For most non-minor subject populations, it should be written at an 8th-grade reading level.)

No informed consent, whether oral or written, may include any language through which the subject or representative is made to waive or appear to waive any of the subject's legal rights, including release of the investigator, the sponsor, the University, or its agents from liability for negligence.

### **B. Elements of Informed Consent**

In addition to the general requirements described above, federal regulations specify eight required elements of informed consent as well as six additional elements to be used when appropriate. The CPHS has incorporated federal and University guidance to provide the following outline of necessary elements for CPHS consent forms:

#### **1. Heading, Title, and CPHS protocol ID Number:**

The consent form should be presented on UC Berkeley letterhead. Insert a heading such as “Consent to Participate in Research” as well as the specific study title at the top of the form. If the study has more than one subject group/consent form, designate appropriate sub-group after study title, e.g., “*Title of Study (Controls)*.” The CPHS protocol ID number, once assigned, must be included in the footer of each page (or if the consent form will be in an online format and thus not include footers, note the CPHS number at the top of the form).

## 2. Key Information:

A brief description of key information must appear at the beginning of the consent form and should be organized and presented in a way that facilitates comprehension. These elements include:

- The fact that consent is being sought for research and that participation is voluntary.
- The purpose(s) of the research, expected duration of the prospective subject's participation, and study procedures.
- Reasonably foreseeable risks or discomforts to the prospective subject.
- Reasonably expected benefits to the prospective subject or others from the research.
- Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject.

## 3. Introduction/Identification of Investigators/Researchers:

The Principal Investigator (PI)'s name, title/degree, and affiliation with the University should be stated. (The title of "Dr." should be used only for those with medically based degrees, e.g., M.D., F.A.A.O.) If there is a Student Investigator (SI) in addition to the PI/Faculty Sponsor and/or multiple investigators, see [CPHS Informed Consent templates](#) for how to correctly list them.

## 4. Invitation to Participate:

State why the individual is being asked to take part in the study, using language that avoids any connotations of requirement or demand.

## 5. Purpose:

Explain the overall purpose of the study, including the fact that the study involves *research*. If appropriate, note the approximate number of subjects anticipated to take part in the study.

## 6. Procedures:

- Give a full description of the research procedures (first describing any *screening* procedures done for purposes of the study, unless there is a separate consent form for screening).
- If the study involves direct interaction or intervention with the subject, describe what the subject will be expected to do, who will conduct the procedures, where and when they will take place, how often they will be performed, and how much time will be required for each procedure. Explain randomization and/or placebo if included in the study.
- State the *total time* expected for the subject's study participation.
- Identify any study procedures that are *experimental*. Make a clear distinction between those procedures that are in the interests of research and those that are part of standard treatment.
- Prospective respondents to surveys or interviews should be warned of any personal and/or sensitive questions. Describe any photographing or audio- or video-recording of the subject.
- For clarity, discuss procedures in chronological order (i.e., in the same order that the subject would undergo them), and use separate paragraphs with numbers or bullets for each procedure description.
- If an investigator is to seek data about the subject *indirectly*, such as inspecting private records, describe the data and how it will be obtained.

## 7. Benefits:

- Provide a clear description of any direct benefits to the subject and/or "general" benefits to others (e.g., groups of subjects/patients, society) that may reasonably be expected from the research.

- If no direct benefit to the individual subject is anticipated, state this.
- **Note:** *Compensation/payment for participation is not considered by CPHS as a “benefit,” but should be described instead in its own section (see “Compensation/Payment” below).*

8. Risks/Discomforts:

- Provide a clear description of any reasonably foreseeable risks or discomforts (physical, psychological, or social) to the subject, noting probability and magnitude of potential harm.
- Discuss measures that will be taken to minimize risks/discomforts.
- If appropriate, indicate any procedures that may involve risks to the subject (or embryo or fetus) that are currently unforeseeable/unknown.
- If appropriate, note that the investigators will inform subjects about any significant new findings developed during the course of the research which may relate to their willingness to continue participation in the study.
- Include risk of breach of confidentiality, and refer subject to next section for more detail.

9. Confidentiality:

**Note:** See CPHS website for [Data Security Guidelines](#) before completing this section.

- Provide an explanation of the extent to which the confidentiality of private data identifying the subject will be maintained. Since complete confidentiality of research data cannot be guaranteed, avoid any wording that implies such assurance. Instead, use language such as:

Your study data will be handled as confidentially as possible. If results of this study are published or presented, individual names and other personally identifiable information will not be used [*if accurate*].

Explain how investigator will minimize the risks to confidentiality (e.g., storage of data, coding, password protection, encryption, limited access to study records, etc. should be described).

Also, *if applicable*, indicate any organizations that may look at or copy research records, e.g., study sponsor, FDA, etc. (*Note:* Although FDA usually will not record individually identifiable data, it does have this authority. For FDA-regulated studies, the consent form must include a statement about FDA access to research records.)

- If the investigator wishes to retain the human subjects data after the immediate project is completed for possible use in future projects by the researcher or others, this should be clearly discussed, including planned length of record retention. Note: Investigators are encouraged to include language that allows for data sharing in the future.
- If collecting private information or identifiable biospecimens for future research, one of the two following statements must be included:
  - Identifiers might be removed and the de-identified information or biospecimens used for future research without additional informed consent from the subject; or
  - The subject's information or biospecimens will not be used or distributed for future research studies even if identifiers are removed.

- If collecting biospecimens subjects must be informed that while there may be future commercial use of their biospecimens/samples or genetic data, subjects will not receive any profits if this occurs. Recommended language to convey this information, also known as the “[Moore Clause](#),” is:

“Biospecimens (such as blood, tissue, or saliva) collected from you for this study and/or information obtained from your biospecimens may be used in this research or other research, and shared with other organizations. You will not share in any commercial value or profit derived from the use of your biospecimens and/or information obtained from them.”

As applicable, include a statement regarding whether clinically relevant research results, including individuals research results, will be disclosed to subjects, and if so, under what conditions?

As applicable, include a statement indicating whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

- As applicable, address special confidentiality issues pertaining to use of photographs, audiotapes, or videotapes; HIPAA-related data; reportable information; Certificate of Confidentiality; etc. (See [CPHS guidelines](#) and [consent form templates](#) for further details on many of these issues.)

#### 10. Alternatives:

If applicable, state appropriate alternative procedures or courses of treatment that might be advantageous to the subject.

#### 11. Discontinuing Study Participation:

- If appropriate, indicate if there could be negative consequences or restrictions should a subject decide to withdraw from the research, and describe procedures for stopping participation in a safe/orderly manner.
- If appropriate, describe circumstances under which the subject’s participation may be ended by the investigator, regardless of subject’s consent (e.g., if the investigator believes it is in their best interest, if the subject does not follow the study rules, if the study is stopped).

#### 12. Compensation/Payment of Subjects:

Describe any compensation/payment to be offered subjects, including amount, type (monetary or non-monetary [e.g., course credit]), terms, and schedule by which it will be provided.

#### 13. Costs to Subjects:

If appropriate, describe any costs/charges which subjects or their insurance carriers will be expected to pay. If there are no costs to subjects or their insurers, this may be stated here (but only if costs to subjects would usually be involved with the procedures; otherwise, no statement is needed).

#### 14. Treatment and Compensation for Injury:

*If the study involves more than minimal risk*, the consent form must include information regarding availability of medical treatment and compensation for the costs of such treatment if injury occurs. The following statement, in accordance with University of California policy, must be used:

It is important that you promptly tell the researcher [*investigator’s name*], if you believe that you have been injured because of taking part in this study. You can tell the researcher in person or call him/her at [*telephone number*].

If you are injured as a result of taking part in this study, University of California will provide necessary medical treatment. The costs of the treatment may be billed to your insurer just like other medical costs,

or covered by the University of California or the study sponsor [*sponsor name*], depending upon a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information, call OPHS at (510) 642-7461.

15. Voluntary Nature of Research Participation:

The consent materials must clearly state that *participation in research is voluntary*, and that the individual is free to refuse participation altogether or to discontinue it at any time without penalty or loss of benefits or services to which s/he is otherwise entitled.

16. Questions:

The form must include contact information for subjects in case they have any questions about the study or about their rights as a research subject. Provide the telephone number(s) and/or email addresses of the PI and/or student investigator (SI) (if only one, it should be the individual who will interact/be most directly involved with the subjects). This section should also provide contact information for the OPHS, should the subject wish to speak to someone other than the researchers about study concerns or their rights as a research subject (see CPHS consent form templates). Note: If the researcher is not within the local calling area of subjects, provisions should be made to allow calling without long distance charges to subjects.

17. Consent/Signature Section:

Unless waiver of signed consent has been requested from the CPHS (see discussion below), the form should end as follows:

- State that the person will be given a copy of the consent form to keep. If applicable, also state that they will be given a copy of the Medical Research Subject's Bill of Rights.
- The form should then indicate that if the individual has considered the information presented and wishes to participate in the study, s/he should indicate agreement by signing the form. Labeled lines for signature and date should be provided.
- Additional lines may be added for signature of parents/guardians, legally authorized representatives, persons obtaining consent, etc., when appropriate.
- Include footers which contain the CPHS protocol ID number (as above) and page numbering (e.g., "Page x of y").

### C. Obtaining Documented Consent

Unless waived, the investigator must document informed consent by use of a written consent form, including all of the elements described above, to be signed by each person agreeing to participate.

After the investigator goes through the informed consent document with the subject (including oral presentation/explanation as appropriate), the prospective subject or their legally authorized representative must be given adequate opportunity to consider the information presented and express any questions or concerns.

If a decision to participate is made, the form will then be signed and dated by the subject or legal representative. A copy of the consent form (and Medical Research Subject's Bill of Rights, if applicable) should be given to the person signing the form.

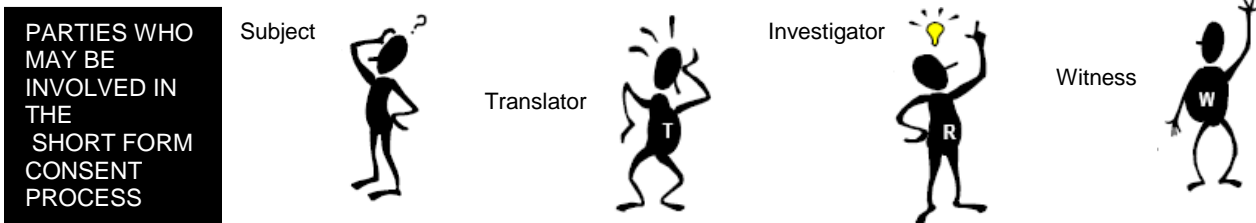
The investigator should safeguard the signed consent forms and retain them for at least three years after the end of the last CPHS approval period. (See CPHS Data Security Guidelines and Risk Assessment Matrix for more detail about investigators' research records retention.)

**D. Oral Consent Presentation and the Short Form**

As an alternative to the standard written informed consent documents, the required consent information may be presented orally and the subject given a written “Short Form” consent document, stating that the elements of informed consent have been presented orally to the subject. When this method is used, the following conditions apply:

- The investigator must have an Oral Script of the consent information to be presented orally.
- The oral presentation and the Short Form must be in the subject’s native language.
- A witness to the oral presentation is required. The witness must sign both the Short Form document and a copy of the Oral Script. If an interpreter/translator will be employed to assist with the consent process, the translator may serve as the witness. The study investigator may not serve as the witness.
- The subject must sign the Short Form. Adult subjects who are competent to provide consent, but are illiterate or unable to talk or write, may indicate their agreement to participate by making their mark (e.g., an X or a thumbprint) on the Short Form, when consistent with applicable local law.
- The person obtaining consent (e.g., the investigator) must sign a copy of the Oral Script. The person obtaining consent may not also serve as a witness.
- These consent documents (Short Form and Oral Script) with original signatures must be retained by the investigator. The subject must be given copies of the Short Form and the Oral Script to keep.

The CPHS application should provide a detailed description of the informed consent process, including who will conduct the oral presentation, who will serve as the witness, and whether or not an interpreter/translator will be used. In addition, the investigator should submit for review both English and foreign language versions of the Short Form, along with his/her affirmation of the accuracy of the translations, and an English version the Oral Script.



	<b>Subject</b>	<b>Translator</b>	<b>Investigator</b>	<b>Witness</b>
<b>Needs to Sign</b>	Short Form	Nothing <b>UNLESS</b> also serving as the witness	Oral Script	Oral Script and Short Form
<b>Keeps</b>	Copy of Short Form and Oral Script	Nothing	Original signed Short Form and Oral Script	Nothing

**E. Waiver of Informed Consent**

According to HHS federal regulations (45 CFR 46.116), the CPHS may waive the requirement to obtain informed consent, or it may approve a consent procedure that alters some of the elements of informed consent described above.

However, the CPHS must first be satisfied that:

1) The research

- (a) presents no risks of harm, considering probability and magnitude, greater than those ordinarily encountered in daily life or during the performance of routine examinations or tests; and
- (b) the research could not practicably be carried out without the waiver or alteration; and
- (c) if the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format; and
- (d) the waiver or alteration will not adversely affect the rights and welfare of the subjects; and
- (e) whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

OR

- 2) 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 the research could not practicably be carried out without the waiver or alteration.

**Note:** Consent waiver is not allowed for FDA-regulated research. In addition, if an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens, and refused to consent, consent may not be waived for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

**Deception in research:** Informed consent implies that subjects will be correctly informed and not deliberately misled about a study. In certain cases, the CPHS may allow an investigator to give subjects incomplete or even misleading information about the nature of the research. However, to obtain such approval, the investigator must justify use of incomplete disclosure or active deception according to the criteria above for waiving some or all elements of informed consent. Usually, the investigator will be required to give the subject a debriefing form after study participation to correct the misleading information, and in certain cases, will need to offer the subjects an opportunity to reaffirm or withdraw their consent for use of data obtained in this manner.

**Note:** See CPHS website for CPHS guidelines on [Deception and Incomplete Disclosure in Research](#).

## F. Informed Consent Exception

Information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects may be obtained without the informed consent of the prospective subjects or the subject's legally authorized representative, if either of the following conditions are met:

- (a) The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative; or
- (b) The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

## G. Waiver of Documented Consent

According to federal regulations (45 CFR 46.117(c)), the CPHS may waive the requirement for the investigator to obtain documented (i.e., signed/ written) consent for some or all subjects. However, the investigator must first satisfy the CPHS that either:

1. The only record in the investigator's possession linking the subject and the research would be the consent document, and the principal risk of the study would be potential harm resulting from a breach of confidentiality. Each subject must be asked whether they want documentation linking them with the research, and the subject's wishes will govern; or
2. The research presents no risks of harm, considering probability and magnitude, greater than those ordinarily encountered in daily life or during the performance of routine examinations or tests, and the research involves no procedures for which written consent is normally required outside of a research context; or
3. If subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risks of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

*Note: When the documentation requirements are waived, the CPHS will usually require that the investigator provide subjects or legally authorized representatives with a written statement containing the elements of informed consent, as appropriate.*

**For more detail and examples, see [Consent Form Templates/Samples](#).**

## **H. Posting Clinical Trial Consent Forms**

1. For clinical trials conducted or supported by a Federal department or agency, an IRB-approved informed consent form used to enroll subjects must be posted by the awardee or the Federal department or agency component conducting the trial on a publicly available Federal Web site (e.g. [clinicaltrials.gov](http://clinicaltrials.gov)) that will be established as a repository for such informed consent forms.
2. If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal Web site, such Federal department or agency may permit or require redactions to the information posted.
3. The informed consent form must be posted on the Federal Web site after the clinical trial is closed to recruitment and no later than 60 days after the last study visit by any subject, as required by the protocol.