



# Research Administration

## Human Research Protection Program

### Guidance and Procedure: Obtaining and Documenting Informed Consent (updated September 3, 2020)

#### [Introduction](#)

#### [Overview of the Informed Consent Process](#)

#### [General Requirements for Informed Consent](#)

#### [Preparing Informed Consent Documents](#)

#### [Using IRB Approved Informed Consent Documents](#)

#### [Obtaining Written and Oral Informed Consent](#)

#### [Documenting Written Informed Consent](#)

#### [Required Signatures](#)

#### [Witness Signatures](#)

#### [Research Participants Bill of Rights](#)

#### [Significant New Findings and Re-Consent](#)

#### [Obtaining Informed Consent from Non-English Speaking Participants](#)

#### [Obtaining Informed Consent from Legally-Authorized Representatives](#)

#### [Obtaining Informed Consent from Participants Outside of California](#)

#### [Regulations and References](#)

### Introduction

This guidance document provides information about ***obtaining and documenting informed consent from research participants***. Investigators are required to obtain the legally effective informed consent of each participant or their legally-authorized representative, unless the IRB approves a consent procedure which does not include, or which alters, some or all of the elements of informed consent. See OHRPP Guidance, [Requesting Waivers or Exceptions to the Informed Consent Process](#) for more information.

### Overview of the Informed Consent Process

Consent for participation in research requires an ***informed consent process***. An informed consent process involves an information exchange and on-going communication that takes place between the Investigator and the potential participant. The consent process starts with the initial presentation of a research activity to a prospective participant (e.g., responding to an advertisement), requires documenting that consent was obtained and continues through the research activity until the participant decides to end his/her participation or the study closes.

An ***effective informed consent process*** involves these elements:

- Conducting the process in a manner and location that ensures participant privacy,
- Giving adequate information about the study in language understandable to the participant,
- Providing adequate opportunity for the participant to consider all options,
- Responding to the participant's questions,
- Ensuring that the participant has comprehended the information provided,
- Obtaining the participant's voluntary agreement to participate and,
- Continuing to provide information as the participant or research requires.

## General Requirements for Informed Consent

### General Requirements

- Consent documents must be in **a language understandable to participants** or representatives.
- There may be **no exculpatory language** through which participants or representatives are made to 1) waive or appear to waive any legal rights or 2) release or appear to release the investigator, the sponsor, the institution or its agents from liability for negligence.

### Basic Required Elements of Informed Consent

In seeking informed consent, the following information must be provided to each participant:

- A statement that the **study involves research**, an explanation of the **purposes of the research** and the **expected duration** of the participant's participation, a description of the **procedures** to be followed, and identification of any **procedures which are experimental**;
- A description of any **reasonably foreseeable risks or discomforts** to the participant;
- A description of any **benefits** to the participant or to others which may reasonably be expected from the research;
- A disclosure of appropriate **alternative procedures or courses of treatment**, if any, that might be advantageous to the participant;
- A statement describing the extent, if any, to which **confidentiality of records** identifying the participant will be maintained. If study is FDA regulated, add statement that the FDA may inspect the records;
- For research involving more than minimal risk, an explanation as to whether any **compensation and** an explanation as to whether any **medical treatments are available if injury occurs** and, if so, what they consist of, or where further information may be obtained;
- An explanation of **whom to contact in the case of a research-related injury** to the participant;
- **Contact information for the research team** for answers to pertinent questions about the research and **contact information for someone independent of the research team** for questions, concerns or input and for answers about **research participants' rights**; and
- A statement that **participation is voluntary**, and that **participant may refuse or discontinue participation** at any time refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled.

### Additional Elements of Informed Consent

When appropriate, one or more of the following elements of information should also be provided to each participant:

- The **approximate number of participants** involved in the study.
- A statement that the particular treatment or procedure may involve **risks to the participant** (or to the embryo or fetus, if the participant is or may become pregnant) which are **currently unforeseeable**;
- A statement that **significant new findings** developed during the course of the research which may relate to the participant's willingness to continue participation **will be provided to the participant**;
- Anticipated circumstances under which the **participant's participation may be terminated by the Investigator** without regard to the participant's consent;
- Any **additional costs to the participant** that may result from participation in the research and the **amount and schedule of payments**; and
- The **consequences of a participant's decision to withdraw** from the research and **procedures for orderly termination of participation** by the participant;

## OTHER REQUIREMENTS

California State Law, University of California and UCLA require additional elements to the consent, as appropriate:

- A disclosure statement that informs participants that *investigator(s) may have a conflict of financial interest* in the research.
- If the study has a real or foreseeable risk of biomedical harm, statement that participants will be given a copy of the consent form and *a copy of the Research Participant's Bill of Rights* in participant's own language to keep.
- **Required UCLA boilerplate sections** for tissue/blood samples, establishment of cell lines, and genetic testing.

## Preparing Informed Consent Documents

Investigators should use one of the UCLA [consent templates](#) to prepare written consent documents or study information sheets, and refer to the [UCLA Consent Form Standards and Sample Language guides](#) for specific information. A checklist of the [Criteria Required by Federal Regulation to Approve Informed Consent](#) is available on the OHRPP website.

These documents are designed to provide clear consent information to increase potential research participants' understanding of research studies and better enable them to make decisions about participation.

Follow these general instructions to help facilitate informed decision-making by participants:

- **Recommended Formatting:** Use reader-friendly formatting so the consent form *looks* easy to read.
  - Leave a 1-inch margin around the entire document.
  - Leave ample white space between headings and paragraphs, but do *not* double space within paragraphs.
  - Use subheadings, bullet lists and/or tables when appropriate.
  - Use black Arial or similar font, preferably 12-point size or larger.
- **Required UCLA Formatting:**
  - **Footer:** Leave the footer of the consent form blank. The webIRB program will automatically insert the assigned protocol number and IRB approval period in the footer.
  - **Header:** Include page numbers ("Page X of Y" format). Also include any additional information (e.g., sponsor protocol number, version) as needed. A header is not necessary on the first page.
- **Question and Answer Format:** The question and answer format is considered best practice for writing consent forms. Write the consent form in conversational style, as if you were speaking to the reader. Section headings should be in question format (see template). Answers should be in **second person** ("You" instead of "I") and **active voice** (e.g., "the Investigators will ask you to..." instead of "you will be asked to...") whenever possible to engage the reader.
- **Reading Level:** Write the consent form so it is understandable to a lay audience, e.g., 8<sup>th</sup> grade reading level; *USA Today* newspaper. The reading level of a document is more difficult if it contains long complex sentences. Whenever possible use words with three syllables or less, non-scientific/non-medical words, simple sentences and break up the text into short straightforward sections. The [PRISM Readability Tool Kit](#) is a useful resource for achieving an appropriate reading level.

- **Parental permission/child assent forms:**
  - **Adolescents ages 13-17:** Create a single document addressed to the adolescent with signature lines for assent and parental permission. An exception to this would be when parents and adolescents are being asked to undergo different procedures, in which case two forms are needed.
  - **Children ages 7- 12:** Create two documents, one for parental permission and a separate simplified assent form for children.

**IMPORTANT NOTE:** Children are not required to sign the assent form. In some circumstances children may not be able to sign the assent form, but Investigators are required to document in the research record that child assent is obtained.

## Using IRB Approved Informed Consent Documents

Investigators should always use the **most current, approved versions of informed consent documents for obtaining and documenting informed consent**. The UCLA IRB reviews and approves all materials to be used as part of the informed consent process, **including advertising and recruitment materials**, to assure that potential participants will be provided with an accurate and fair description of the risks or discomforts and the anticipated benefits of study participation.

**IMPORTANT NOTE:** Informed consent documents that have been approved by the IRB will be stamped with an official IRB approval stamp that includes the approval date. The IRB number and expiration date will also be included on each page of the document. When informed consent documents are amended or revised, IRB approval is required before they can be used.

## Obtaining Written or Oral Informed Consent

Obtaining consent involves **explaining the research and assessing participant comprehension**, using a consent document as a guide for the verbal explanation of the study.

### **IMPORTANT NOTES:**

- Principal Investigators are responsible for assuring that all Investigators obtaining consent are **qualified and appropriately trained to explain the research and assess participant comprehension** as discussed below.
- Informed consent from the participant and/or his or her legally-authorized representative must be obtained **prior to initiating any research activities**, including screening procedures.

### **Step 1- Explaining the Research**

Investigators should use these steps for orienting a potential participant to the purpose of the research and why they might wish to participate:

- Explain the study to the potential participant verbally, providing all pertinent information (purpose, procedures, risks, benefits, alternatives to participation), and allow the potential participant ample opportunity to ask questions.
- After a verbal explanation, provide the potential participant the written consent form (or information sheet when required by the IRB) and afford sufficient time to consider whether or not to participate in the research. "Sufficient time" can range from minutes to days, depending on how long it reasonably takes to evaluate the procedures, risks, potential benefits, and alternative treatments.
- After allowing the potential participant time to read the consent form/information sheet, meet with the potential participant and answer any additional questions s/he may have.

**IMPORTANT NOTE:** In-person explanations of the study may not be practicable for obtaining oral consent, such as for internet surveys. The IRB will require contact information on the survey website so participants can contact the investigator to discuss the study before agreeing to participate (e.g., introductory text before clicking the “agree” or “submit” button).

## **Step 2 - Assessing Participant Comprehension**

Investigators (not participants) have the responsibility for ensuring that a potential participant understands the research and the risks and benefits involved. Investigators should use these steps to assess participant understanding:

- Answer questions but also ask questions to further the discussion and elicit questions from the potential participant. This will prompt the potential participant to think more carefully about the study.
- Assess comprehension using open-ended and non-directive questions. Open-ended questions are those that begin with “who,” “what,” “when,” “where,” “why,” and “how often,” or “please describe.”
- Avoid or limit close-ended questions that ask for “yes” or “no” answers.
- Based upon the above, decide whether the potential participant adequately understands the study.

### ***Examples of open-ended questions:***

- “Describe in your own words the purpose of the study.”
- “Would you explain to me what you will have to do if you are in the study?”
- “Would you describe the alternatives to participation in this study?”
- “What more would you like to know about this study?”
- “What is the possible benefit to you if you participate in this study? What are the possible risks?”
- “How long does your participation in this study last?”
- “Why are you eligible to participate in this study?”
- “When does your first testing session happen?”
- “Where will the study take place?”
- “Who do you contact if you have questions or experience side effects?”

### ***Examples of closed-ended questions:***

- “Do you understand what we are asking you to do?”
- “Do you have any questions for me?”
- “Do you understand that there are some risks to taking this drug?”
- “Do you need any more information to decide whether to participate?”

**IMPORTANT TIP:** Investigators can use a [subject comprehension tool](#) to assess participant comprehension.

## **Obtaining Informed Consent by Telephone:**

It may not be possible in some situations to have an in-person discussion of the study with participants or their legally-authorized representatives, yet the criteria for a waiver of documentation of informed consent cannot be met. When approved by the IRB, documenting written informed consent in these instances must involve a process as follows:

1. The participant or their legally-authorized representative receives a copy of the informed consent document *in advance* of a telephone discussion.
2. The investigator obtains consent over the telephone using the Steps 1 and 2 for obtaining informed consent.



3. If the participant or legally-authorized representative agrees to participation, s/he signs the consent form as described below and returns it to the investigator (e.g., via fax) for signature **before** any research procedures begin.

## Documenting Informed Consent

Documenting informed consent occurs **after** explaining the research and assessing participant comprehension. At minimum, it involves obtaining the signature of the participant (or the legally-authorized representative, when IRB approved) as well as the person obtaining consent. The signature of the person obtaining consent indicates he/she has explained the research to the participant, ensured that the participant understands the research and s/he freely consent to participate.

In most cases the federal regulations require that informed consent be documented, but they also provide for some important exceptions. In some circumstances, the IRB may approve a waiver of documentation of informed consent. See OHRPP guidance, [Requesting Waivers and Exceptions to Informed Consent](#) for more information.

### Required Signatures for Documentation of Informed Consent:

- The **participant must sign and date** the consent form at the time of the consenting process and only **after** all questions are answered and s/he agree to participate in the study. Rare exceptions include blind or illiterate participants and participants unable to consent for themselves.
- The **person who has oriented and obtained consent from the participant** must also sign and date the consent form. This signature **cannot pre-date** the participant's signature.

### IMPORTANT NOTES:

- The participant should always be provided with a copy of the signed and dated consent form to use as continual reference for items such as procedure risks and/or side effects, questions and for emergency contact information.
- If the IRB requires a HIPAA Research Authorization this must also be signed and dated at the time written consent for participation in the study is obtained.

### Witness Signatures:

Witness signatures are required by federal regulations in very limited circumstances and can be required by the IRB to assure an adequate informed consent process for some research studies. Examples:

- Informed consent is obtained using a short form consent process (when approved by the IRB)
- The participant has decision-making capacity, but cannot read, write, talk or is blind.
- The participant's guardian/legally-authorized representative (LAR) cannot read, write, talk or is blind.

When required the witness must be impartial, such as an adult who is not a member of the study team. The witness must sign and date the consent form at the time the consenting process occurs. A signature of the witness means:

- The requirements for informed consent have been satisfied.
- Consent is voluntary and freely given by the participant, guardian, or legally-authorized representative.

**IMPORTANT NOTE:** The California Medical Experiment Act requires attestation that the consent form is signed and dated by a person other than the participant or the participant's guardian or legally-authorized representative who can attest that the requirements for informed consent has been met. At UCLA, the Investigator's signature serves this purpose, unless an impartial witness is required as described above.

### **Research Participants Bill of Rights:**

The California Health & Safety Code, Section 24172, describes a “Bill of Rights” that must be provided to all participants of a medical experiment for which there is ***real or foreseeable risk of biomedical harm***. This list of rights must be written in a language in which the participant is fluent.

The bill of rights document does not need to be part of the informed consent form, nor does the document need to be signed. However, the document must be provided to participants as part of the informed consent process. The fact that the document is provided should be noted in study records.

The UCLA ***IRB does not provide a copy of this document with approved informed consent documents***. For studies that require it, the IRB approval letter indicates it needs to be provided to participants as a condition of IRB approval. A standardized version of this [document](#) is available on the OHRPP website in over 30 languages and available in Braille by calling the office.

### **Significant New Findings and Re-Consent:**

Obtaining a signature on a consent form does not complete the consent process. Assuring informed consent requires that participants be ***provided with any new information*** that arises during the course of the study (e.g., changes to the research plan, change in risk/benefit profile, and the results of related research) ***that may affect a participant's decision whether or not to continue participation in the study***.

When such information arises, the Investigator should submit an amendment to revise the consent form to describe the changes to the study since the participants last provided informed consent. Alternatively, participants may be presented with an addendum to the consent form that describes what has changed since they last provided consent.

Addendum [templates](#) are available on the OHRPP website. Documenting re-consent should follow the same process described above.

The IRB may consider whether participants participating in longitudinal studies should be re-consented on an annual basis.

## **Obtaining Informed Consent from Non-English Speaking Participants**

The federal regulations require the translation of consent documents into the language that is most easily understood by research participants. A potential participant's inability to read or to read English is not an appropriate basis for exclusion from most research. The IRB approved informed consent documents should be available in English and other languages as appropriate to the participant population(s). See [OHRPP Guidance and Procedure: Special Participant Populations- Non-English Speaking Participants](#) for additional information.

## **Obtaining Informed Consent from Legally-Authorized Representatives**

***Parent/Legal Guardian Permission and Child Assent:*** Refer to the [OHRPP Guidance and Procedure: Special Participant Populations- Children](#) for detailed requirements for obtaining parental permission and child assent, and when individuals are considered “children” under federal regulations and California law.

***Surrogate Informed Consent:*** California law authorizes specific individuals to give surrogate informed consent for the enrollment of participants in limited circumstances. The law distinguishes between emergency room and non-emergency room research and describes specific surrogate

hierarchies for each environment. Please see both the [OHRPP Guidance and Procedure: Guidelines for Research Using Legally-authorized Representatives](#) as well as [OHRPP Guidance and Procedure: Special Participant Populations- Cognitively Impaired](#) for specific information.

**IMPORTANT NOTE:** IRB approval is required to use a legally-authorized representative for research involving children or participants who are cognitively or medically incapacitated.

## Obtaining Informed Consent from Participants Outside of California

When planning to conduct research outside of California, Investigators are responsible for being aware of the informed consent requirements of other states or countries. This is especially important for research that involves children and the use of legally-authorized representatives, as DHHS and FDA regulations rely on local laws for determining who meets their definitions of “children” and “legally-authorized representatives”.

## Types of Informed Consent

The table below summarizes the different types of informed consent and if that specific type of consent is allowed under DHHS and FDA regulations.

| <i>Type of Consent</i>                                | <i>DHHS allowed</i>   | <i>FDA allowed</i>  |
|---|---|---|
| <b>Standard paper written consent</b>                 | Yes   | Yes   |
| <b>Verbal Consent using an Information Sheet</b>      | Yes – if this method of consent is approved and the IRB grants a waiver | No  |
| <b>Electronic consent with no signature</b>           | Yes – if this method of consent is approved and the IRB grants a waiver | No  |
| <b>Electronic consent with electronic signatures*</b> | Yes   | Yes   |
| <b>Online consent with no signatures</b>              | Yes – if this method of consent is approved and the IRB grants a waiver | No  |
| <b>No consent</b>                                     | Yes – if this method of consent is approved and the IRB grants a waiver | Limited exceptions – only allowed under specific conditions |

\* Under California law, an "electronic signature" means an electronic sound, symbol, or process attached to or logically associated with an electronic record and executed or adopted by a person with the intent to sign the electronic record.

Research projects that are subject to FDA regulations, must comply with FDA requirements at [21 CFR Part 11](#). UCLA Office of Compliance has documented that [Epic Electronic Health](#)



Record System is 21 CFR Part 11 compliant. If you have any questions about your system, please contact the UCLA Office of Compliance.

## Regulations and References

### **DHHS Regulations and Guidance**

- General Requirements for Informed Consent; Elements of Informed Consent; Waiver or Alteration of Consent: [45 CFR 46.116](#)
- Documentation of Informed Consent; Waiver of Documentation of Informed Consent (Oral Consent): [45 CFR 46.117](#)
- [OHRP Guidance Documents on Informed Consent](#)
- [Electronic Informed Consent Guidance](#)

### **FDA Regulations and Guidance**

- General Requirements for Informed Consent: [21 CFR 50.20](#)
- Elements of Informed Consent: [21 CFR 50.25](#)
- Documentation of Informed Consent: [21 CFR 50.27](#)
- Waiver of Documentation of Informed Consent (Oral Consent): [21 CFR 56.109\(c\)](#)
- [FDA Guide to Informed Consent Information Sheet](#)
- [Electronic Informed Consent Guidance](#)

### **California Law**

- Research Participants Bill of Rights (Section 24172) and Surrogate Consent (Section 24178): [California Health & Safety Code Section 24170-24179.5](#)
- Electronic Signature (Section 1633): [Uniform Electronic Transaction Act](#)

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### **Change history:**

5/18/2020: Removed the restriction on adult family members of the participant acting as the witness for the consent conference.

07/22/2020: Added chart on types of consents allowed under FDA and DHHS regulations.

09/03/2020: Updated FDA and DHHS chart.