

Guidance: Research Involving Visually and/or Hearing Impaired Participants or Participants Who Are Illiterate

(Last updated June 10, 2016)

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Introduction

Investigators are required to obtain the legally effective informed consent of each participant or his or her 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. This guidance document provides information about obtaining informed consent from participants who are visually or hearing impaired, or who cannot read or write. Please refer to UCLA OHRPP guidance documents for obtaining and documenting informed consent as well as research involving those who do not speak or understand English. Links are located at the end of this document.

Obtaining Consent from Visually-Impaired Participants

Methods of Obtaining Consent

- The appropriate UCLA consent form should be presented orally.
- Use of an audio recording of the informed consent document is acceptable as part of the consent process.
- Sufficient time should be allowed for questions to be asked and answered, both by the participant, and by the person obtaining consent to ensure the subject comprehends the consent information.
- For biomedical studies in which there is a **real or foreseeable risk of biomedical harm**, California law requires that research participants receive a copy the Participants Subjects Bill of Rights in a language in which they are fluent. A standardized version of this document is available in English in Braille by calling the UCLA OHRPP.

Documenting Informed Consent

- If capable of doing so, the participant should sign and date the consent form (California State Law recognizes “X” or any mark as an acceptable signature).

- Person obtaining consent should sign and date the consent form.
- PI may request a waiver for signed consent (refer to guidance listed below).
- Participant must be given a copy of the signed consent as well as a copy of the Research Participants Bill of Rights in Braille (when appropriate).

Obtaining Consent from Hearing-Impaired Participants

Methods of Obtaining and Documenting Informed Consent

- For hearing-impaired participants who can read and write, the standard guidelines for obtaining and documenting informed consent should be followed.
- For hearing-impaired participants who cannot read or write, the guidance for obtaining and documenting informed consent for those who cannot read or write should be followed. Links to this guidance are located below.
- Hearing impaired participants may want or need a sign language interpreter present. The UCLA Health System website provides information on obtaining these services. <https://www.uclahealth.org/Pages/patients/patient-services/interpreter-services.aspx>

Obtaining Consent from Participants Who Cannot Read or Write

Methods of Obtaining Consent

- The appropriate UCLA consent form should be presented orally.
- Use of a video or audio recording of the informed consent document is acceptable as part of the consent process.
- Sufficient time should be allowed for questions to be asked and answered, both by the subject, and by the person obtaining consent to ensure the subject comprehends the consent information.
- For biomedical studies in which there is a **real or foreseeable risk of biomedical harm**, California law requires that research participants receive a copy the Participants Subjects Bill of Rights in a language in which they are fluent. A copy of the Bill of Rights is available in English and several translations on the OHRPP website (see below).

Documenting Informed Consent

- If capable of doing so, the subject should sign and date the consent form (California State Law recognizes “X” or any mark as an acceptable signature).
- Person obtaining consent should sign and date the consent form.
- PI may request a waiver for signed consent (refer to guidance)
- Participant must be given a copy of the signed consent as well as a copy of the Research Participants Bill of Rights, if appropriate.

Related Guidance, References and Regulations

UCLA OHRPP Guidance and Procedures

- [Obtaining and Documenting Informed Consent](#)
- [Requesting Waivers and Exceptions to Informed Consent](#)
- [Child Assent and Permission by Parents or Guardians](#)
- [The Use of Legally Authorized Representatives or Surrogate Consent](#)
- [Research Involving Persons with Cognitive Impairments](#)
- [Research Involving Non-English Speaking Research Subjects](#)
- [Research Participants Bill of Rights](#) (in English and 36 translations)

DHHS Regulations

- General Requirements for Informed Consent - [45 CFR 46.116](#)
- Documentation of Informed Consent - [45 CFR 46.117](#)

FDA Regulations

- 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\(c\)](#)

California Law

- Research Participants Bill of Rights ([Section 24172](#))

Change history:

6/9/2016: Updated link