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Informed Consent

Based on the governing principles of human research outlined in "The Belmont Report ^[1]," investigators have key responsibility for ensuring *voluntary participation* of research subjects. The recruitment plan and consent process must be carefully designed so that subjects' consent will be well-informed and freely given.

Any prospective research subject (or his/her legally authorized representative) should be able to understand ^[2] as completely as possible what procedures, risks, benefits, alternatives and rights are involved, and make the choice about being in the study without pressure or undue inducement to participate. Free and informed consent is not one-time event, but an ongoing process.

With few exceptions, researchers must obtain and document consent ^[3] from the prospective research subject *before* initiating any screening or study procedures. Any exceptions must be reviewed and approved by the IRB beforehand.

Federal Requirements and Elements of Consent

OHRP and the FDA enforce federal regulations covering informed consent in research involving human subjects ? 45 CFR 46, Section 46.116-117 [4] and? 21 CFR 50 [5], respectively. These regulations are applied to all human research at UCSF.

45 CFR 46.116 describes general requirements for informed consent.

Except for when waivers are granted by the IRB, before involving a human subject in research covered by this policy, the investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative (LAR). An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the representative.

The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information. Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension. Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.

No informed consent, may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Elements of Consent: The regulations stipulate what basic required elements of informed consent and additional elements that may be added to a consent form when appropriate. The Federal Requirements for Approving Consent Forms Checklist [6] describe the elements of informed consent and local consent requirements. Use the UCSF consent and assent form templates [7], which satisfy federal and institutional consent requirements.

As a reminder, the consent form is one part of the entire consent process [3]. The consent document serves as a written summary of the information that was presented and is a useful reference for the subject and the investigator.

Consent Process

Documentation

In general, informed consent is documented [3] with a written consent form approved in advance by the IRB and incorporating the required elements of consent. See the Obtaining and Documenting Informed Consent [3] page for detailed information on how to conduct the consent discussion and document the consent process.

Exceptions to informed consent requirements

The IRB may approve exceptions or alterations to the general rule for informed consent, including a waiver of all consent [8]; surrogate consent [9] for individuals who can give informed consent for themselves; verbal, electronic or implied consent [10]; or use of a short-form process [11] for subjects who cannot read English. *You must justify any exception in your IRB Application.*

Vulnerable populations

There are special consent considerations and requirements for research that involves certain vulnerable populations [12], such as children or pregnant women.

Other IRBs? Consent Form Requirements

The UCSF IRB is willing to rely on other specified IRBs [13] in limited circumstances. The IRB also is willing to consider accepting and reviewing consent forms not written in the UCSF format [7] in certain circumstances in which the form has been or will be approved by another duly constituted IRB.

Use the **Consent Form Checklist for Using a Non-UCSF Consent Form** [14] when modifying the consent forms, assent forms, information sheets and recruitment materials. The consent document must meet the federal criteria for IRB approval of a consent form [15], and the minor changes described in the checklist [14] provide local context and meet California legal and University of California requirements.

In the Section 1.8 of the Initial Review Submission Packet (special processing instructions), explain your request to use a consent form in a non-UCSF format. See Working With Other Institutions [16] for additional information.

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Links

[1] <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>

[2] <https://irb.ucsf.edu/enrolling-individuals-cognitive-impairments-and-assessing-decisional-capacity>

[3] <https://irb.ucsf.edu/obtaining-and-documenting-informed-consent>

[4] <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116>

[5] <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50>

- [6] <https://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/consent-approval-criteria.pdf>
- [7] <https://irb.ucsf.edu/consent-and-assent-form-templates>
- [8] <https://irb.ucsf.edu/waiving-informed-consent>
- [9] <https://irb.ucsf.edu/surrogate-consent>
- [10] <https://irb.ucsf.edu/verbal-electronic-or-implied-consent-waiver-signed-consent>
- [11] <https://irb.ucsf.edu/consenting-non-english-speakers>
- [12] <https://irb.ucsf.edu/special-consent-requirements-vulnerable-populations>
- [13] <https://irb.ucsf.edu/relying-other-irbs>
- [14] <http://hrpp.ucsf.edu/sites/hrpp.ucsf.edu/files/checklist-non-ucsf-consent.pdf>
- [15] <https://irb.ucsf.edu/#federal>
- [16] <https://irb.ucsf.edu/working-other-institutions>