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Verbal, Electronic or Implied Consent (Waiver of Signed Consent)

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When Is a Waiver of Signed Consent Allowed?

Federal regulations allow the IRB to waive the requirement for obtaining signed consent if it finds that:

1. The only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality.
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. (Note: Only #2 applies to FDA-regulated studies [1].) OR
3. If the 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 risk or harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained. As set forth in [45 CFR 46.117)(c)].

The IRB can also waive signed consent in studies that meet the requirements for waiving all consent [2].

Generally when the IRB approves a waiver of signed consent, verbal consent (often with use of an information sheet) or electronic consent will still be required. In limited cases, implied consent may be allowed.

Examples of approvable waiver of signed consent

- The identities of subjects will be completely anonymous if the consent form is not signed, and there is minimal risk involved in the study.
- Obtaining signed consent is not appropriate or feasible according to the cultural standards of the population being studied, and there is minimal risk involved in the study.
- There is a possible legal, social or economic risk to the subject entailed in signing the consent form, e.g., for immigrants who might be identified as being illegal aliens.
- The study involves only use of extra blood which is taken at the time of a venipuncture being done for clinical reasons.

Verbal, Electronic and Implied Consent

Verbal Consent

Verbal consent means that the individual obtaining consent reads/explains a verbal version of a consent form (i.e. an information sheet), and subjects give their verbal consent in place of written consent to participate. Subjects should be given the opportunity to ask questions and provided with a copy of the information sheet.

If it is not feasible to provide subjects with an information sheet ? for example, the only contact is by phone ? the IRB will ask to see a *consent script* to evaluate the consent process.

Document in the research file when the consent discussion took place and if there were any issues.

See the Obtaining and Documenting Informed Consent [3] page for more information on how to conduct the consent discussion and document the consent process.

Electronic Consent

Many studies, such as online surveys, are now being conducted entirely via electronic methods. For such studies, you may choose to include the consent information (see the Information Sheets section below) in the recruitment email or at the beginning of the online survey. Subjects will consent to the research by clicking "Agree" or "Continue" (or similar) if they wish to participate.

For clinical studies or other studies that require signed consent, you may on occasion wish to use an appropriately secure electronic signature. Please refer to UCSF's Electronic Signature

information about UCSF's DocuSign. If you are using another form of electronic signature, please discuss this in your application.

Implied Consent

You may wish to replace signed consent with *implied consent* that is, a prospective subject is informed about a study where participation consists only of filling out an anonymous questionnaire. The person completes the questionnaire and, by doing so, agrees to participate in the research. The IRB will consider approving such requests in limited circumstances, based on appropriate justification and information regarding the consent process.

Information Sheets

The regulations state, "in cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research." In such cases, the IRB will usually call for use of an *information sheet* that includes most or all of the elements of a consent form [5] (e.g. purpose, procedures, risks, benefits, etc.), but not the subject's signature.

Write an information sheet using the consent and assent form templates [6]. If the study qualifies for exemption [7], use the exempt consent templates [8].

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Links

[1] <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.109>

[2] <https://irb.ucsf.edu/waiving-informed-consent>

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

[4] <https://it.ucsf.edu/services/electronic-signature>

[5] <https://irb.ucsf.edu/consent-guidelines>

[6] <https://irb.ucsf.edu/consent-and-assent-form-templates>

[7] <https://irb.ucsf.edu/levels-review>

[8] <https://irb.ucsf.edu/exempt-consent-templates-and-guidance>