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### *Did you know the HRPP website has...*

- Detailed information about how to prepare an informed consent document?
- Guidance for simplifying medical terminology to lay language?

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# The Informed Consent Process

Both written consent and verbal consent for participation in research must involve an informed consent process. Informed consent involves an **education and information exchange** that takes place between the researcher and the potential subject. The entire informed consent process involves giving a subject adequate information concerning the study, providing **adequate opportunity for the subject to consider all options**, responding to the subject's questions, ensuring that the subject has comprehended this information, obtaining the **subject's voluntary agreement to participate** and, continuing to provide information as the subject or situation requires. To be effective, the process should provide ample opportunity for the Investigator and the subject to exchange information and ask questions.

Sometimes the information to be imparted to potential subjects is complex or possibly distressful and may require some time for it to be absorbed and appreciated. In these circumstances, the researcher should present the information and discuss the issues with potential subjects on more than one occasion, or **allow a period of time to elapse** between imparting the information and requesting a signature on the consent form. During this waiting period, potential **subjects should be encouraged to discuss their possible participation with family members, close friends, or trusted advisors**. With IRB approval, other approaches to communicating complex information can be used, including the use of audio-visual materials and brochures.

**Verbal Consent Process:** In most cases the federal regulations require that informed consent be documented (i.e., a signed consent form), but they also provide for some important exceptions. In some circumstances, the IRB may waive the requirement for written consent and allow researchers to obtain verbal consent. A waiver of documentation of informed consent must be approved by the IRB in order to obtain verbal consent from potential subjects.

**Written Consent Process:** Obtaining written informed consent from a potential subject is more than just a signature on a form. The consent document is to be used as a guide for the verbal explanation of the study and serves as the basis for a meaningful exchange between the Investigator and the subject.

Documentation involves the use of a written consent form containing all the information to be disclosed and signed by the subject or the subject's legally authorized representative (LAR). The subject or LAR who signed the consent form must be given a copy as a reference and reminder of the information conveyed. Use of a LAR (surrogate) for obtaining consent for minors or subjects who are cognitively or medically incapacitated requires prior IRB approval.

# Informed Consent Waivers Simplified...

There is often confusion about the two types of waivers that can be approved by the IRB. Each type of waiver must satisfy specific regulatory criteria in order to be approved.

**Waiver of Informed Consent:** For this type of waiver, the IRB waives the requirement to obtain informed consent from subjects. This type of wavier is used sparingly and typically is granted for studies that involve no subject interaction, such as use of existing subject identifiable data and records.

**Waiver of Documentation of Informed Consent:** For this type of waiver, the IRB waives the requirement to have subjects sign a consent document. Verbal consent must still be obtained and often the IRB will require a study information sheet be provided to the subjects. This type of waiver routinely is granted for research that involves no more than minimal risk and falls into one or more Expedited research categories.

**Requesting Waivers from the IRB:** In the procedures section of the application there are two appendices for requesting waivers. Appendix O is for requesting a waiver of informed consent, and Appendix P is for requesting a waiver of documentation of informed consent. Appendices O and P are not used for requesting consent waivers for Exempt research studies, as the regulatory criteria for granting a waiver do not apply.

## Use of Surrogate Consent

If a prospective subject cannot consent on his/her own behalf, federal regulations permit researchers to obtain consent from a legally-authorized representative. CA Health & Safety Code 24178 defines the categories of individuals who are legally authorized in California to provide surrogate consent for research. Surrogate consent may be permitted by the IRB only in research studies relating to the cognitive impairment, lack of capacity, or serious or life-threatening diseases and conditions of the research subjects. Detailed information about requesting and obtaining surrogate consent is available on the HRPP website.

- No surrogates may be asked for consent unless the IRB has specifically approved use of surrogates in the research study.
- The protocol should include a process for formal assessment and evaluation of the prospective subject's ability to participate in the consent process.
- If a subject in any way objects to or resists study participation or the use of surrogate consent, that subject may not be included in the study.
- Determining who could be the surrogate decision maker is different in emergency room and non-emergency room settings (see website for details).
- Surrogates may not give consent for inpatients in a psychiatric ward or mental health facility or on psychiatric hold.
- The surrogate must complete the "Self-Certification of Surrogate Decision Makers for Participation in Research" as an attachment to the informed consent document for the research study.

- ***Informed consent involves an education and information exchange that takes place between the researcher and the potential subject.***
- ***It is critical that the Investigator not only field questions, but also asks questions to assess comprehension.***

## Informed Consent Do's and Don'ts

1. **Do** assure subjects understand that research is voluntary.
2. **Do** provide the subject with the Subject's Bill of Rights, when required by the IRB.
3. **Do** involve a witness in the consent process , when required by the IRB.
4. **Do** provide subjects adequate time to decide whether they wish to participate.
5. **Do** assure subject comprehension before completing the informed consent process.
6. **Do** ensure all required signatures are obtained.
7. **Do not** use an unapproved (unstamped) consent form.
8. **Do not** use a consenting process that is not approved by the UCI IRB.
9. **Do not** use an expired consent form. Check the IRB approval and expiration dates on the consent document before using it.
10. **Do not** verbally interpret the English version of the consent form into other languages, unless IRB approved to use short form consent.
11. **Do not** have investigators pre-sign or date the consent form before the subject.
12. **Do not** alter an informed consent document without IRB approval.

## Consenting Subjects Who Cannot Read, Speak or Understand English

As part of the IRB application process, investigators should estimate the likely proportions of non-English-speaking-people who may be encountered as eligible subjects for a proposed study. The United States Census Bureau provides overall demographic characteristics of counties and areas served by the UCI research community.

There are two methods for obtaining and documenting informed consent for research subjects who do not read, speak, or understand English. The preferred method is to provide consent forms written in the subject's language. For the occasional and unanticipated non-English-speaking subject, an alternative "short form" method is allowed [21 CFR 50.27(b)(2) and 45 CFR 46.117 (b)(2)] with prior IRB approval. For biomedical research, the Experimental Subject's Bill of Rights must still be provided in the language in which the subject is fluent. Routine use of this method is strongly discouraged by the University and federal regulators.

See the HRPP website for detailed information and flow diagrams for consenting subjects who cannot read, speak or understand English.