Obtaining and Documenting Informed Consent

Consent Discussion (ongoing) ? Give Experimental Subjects Bill of Rights (if applicable) ? Sign Consent Form ? Sign HIPAA Authorization (if applicable) ? Consent Documentation (ongoing)

Informed Consent Overview

Consent for participation in research requires *an informed consent process.* This process involves an information exchange and on-going communication that takes place between the investigator (researcher) and the potential research participant (subject).

The consent process starts with the initial presentation of a research activity to a prospective subjective (including advertisements and notices), continues with a discussion and information exchange between the researcher and the prospective subject, and requires documenting that consent was obtained. The process may also be ongoing through the research activity until the participant decides to end his or her participation or until the study closes.

An *effective informed consent process* involves these elements:

- Conducting the process in a manner and location that ensures *participant privacy*
- Obtaining the prospective *subject voluntary agreement* to participate

- Giving adequate information about the study *in a language understandable* to the potential subject
- *Documenting the consent* appropriately

- Providing adequate opportunity for the potential *subject to consider all options*
- *Providing copies* of the consent documents to the subjects

- Responding to the potential *subject questions* and/or concerns
- *Continuing to provide information* as the subject or research requires

- Ensuring the potential *subject comprehension* of the information provided

Key Considerations

Several key considerations for obtaining informed consent are described below:

Timing

Informed consent from the subject and/or his legally authorized representative must be obtained prior to initiating any research activities, including screening procedures unless the IRB grants a waiver to do otherwise.

Ongoing conversation

While the initial verbal explanation and dialogue with the subject are critical so that subjects know what they are agreeing to before they consent (see below), ideally the consent process should be an ongoing conversation throughout the course of the study. Throughout the study, make yourself available to answer questions and encourage subjects to ask questions or voice concerns, tell subjects about changes in the study procedures or risks or alternatives, and allow subjects to withdraw from the study for any reason at any time.

Additional approaches

With prior IRB approval, other methods of communicating information about a study may be used to supplement the consent process, or in rarer cases, substitute for a consent document. These approaches include the use of audio-visual materials, brochures, drawings and information posted on a specific website.

Qualifications of person obtaining consent

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 described below. Any person who may obtain consent in a study should be listed in the IRB application as key personnel, though the person need not be listed as an investigator in the consent document itself.

Subject ability and willingness to consent

- **Decision-making capacity**: Subjects should be able to understand the nature and consequences of the study [1]. If they cannot, surrogate consent [2] may be required. See general discussion of subject comprehension assessment below.
- **Voluntariness**: Subjects should be free from coercion when deciding to participate. This requires that researchers carefully evaluate, plan and implement the recruitment, consent documents, and the consent process as described below.

Obtaining Written or Verbal Informed Consent

Obtaining consent involves explaining the research and assessing participant comprehension using a consent document, usually a written consent form [3] or information sheet, as a guide for the verbal explanation of the study. Informed consent from the participant and/or his or her legally-authorized representative (surrogate) [2] must be obtained prior to initiating any research activities, including screening procedures.

See **Quick Guide: How to Consent, Assess Comprehension, and Document Informed Consent for Clinical Research** **[4]** for a summary of the info below.

Step One: Explaining the Research

Explain the study to the potential subject verbally

Explain the study to the potential subject verbally, providing all pertinent information (purpose, procedures, risks, benefits, alternatives to participation), and allow the potential participant ample opportunity to ask questions or voice concerns. Do not read the consent document verbatim but, rather, paraphrase the information checking for comprehension and allowing for questions throughout the process. For some studies, it would be appropriate to include family members or close friends in the process.

After a verbal explanation, provide the potential subject the written consent form or information sheet

After a verbal explanation, ***provide the potential subject the written consent form or information sheet***(as required by the IRB), and afford sufficient time to absorb and appreciate the information to consider whether or not to participate in the research.

The time needed will vary depending on the complexity and/or nature of the research. Potential subjects, particularly those in higher risk studies, may need a waiting period and should be encouraged to discuss their possible participating with family members, close friends or trusted advisers.

Meet with the potential participant and address questions or concerns

After allowing the potential participant time to read the consent form/information sheet, ***meet*** with the potential participant ***and address any additional questions*** or concerns he or she might have.

Important notes on consenting vulnerable populations and other unique situations

1. Special considerations for surrogate consent [2] and consent involving other vulnerable populations [5] including children and prisoners are discussed elsewhere on this website.
2. If subjects cannot read the consent form, review this guidance [6].
3. If subjects are non-English speakers, review this guidance [7].
4. See also Verbal, Electronic or Implied Consent [8] for additional approaches.

Step 2: Assessing Subject Comprehension

The responsibility of ensuring that a potential subject understands the research and the risks and benefits involved falls primarily upon the investigator, not the potential subject.

Ask and answer questions

Answer questions, but also *ask questions* to further the discussion and elicit questions from the potential participant. This will prompt the potential subject to think more carefully about the study.

Ask open-ended and non-directive questions

Open-ended questions are those that begin with ?who," ?what,? ?when,? ?where,? ?why,? ?how often,? or ?please describe?.?

Examples of open-ended questions:

- ?Describe in your own words the purpose of this study.?
- ?Would you explain to me what you will have to do if you are in the study??
- ?Can you tell me some other options for your care you would have if you decide not to participate in this study??
- ?What else would you like to know about this study??
- ?What is a possible benefit to you if you participate in this study??
- ?What are the possible risks to you if you participate in this study??
- ?How long does participation in this study last??
- ?Why are you eligible to participate in this study??
- ?Where will the study take place??
- ?Will you receive the investigational drug if you are in this study??
- "Whom should you contact if you have questions or experience side effects once the study begins??

Avoid/limit questions that ask for ?yes? or ?no? answers

Avoid or limit close-ended questions that ask for ?yes? or ?no? answers. *Examples of closed-ended questions:*

- ?Do you understand what we are asking you to do??
- ?Do you have any questions??
- ?Do you understand there are risks to taking the study drug??

Assess whether the potential participant adequately understands the study, using a decision-making capacity tool if needed

Based upon the above, *assess* whether the potential participant adequately understands the study.

Consider using this *decision-making capacity tool* [9] if needed to assess subject comprehension. Other tools and information about this topic may be available in your department and are also available on other UC IRB websites and elsewhere.

Documenting Informed Consent

Consent Discussion [10] (ongoing) ? Give Experimental Subjects Bill of Rights [11] (if applicable) ? Sign Consent Form [12] ? Sign HIPAA Authorization (if applicable) ? Consent Documentation [12] (ongoing)

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 or parent(s), when approved) as well as the person obtaining consent. The person obtaining consent indicates he/she has explained the research to the participant, ensured that the participant understand the research and that the subject freely consents to participate.

In most cases, the federal regulations require that informed consent be documented, but they also provide some important exceptions. See Verbal, Electronic or Implied Consent [8] for more information.

Consent Documentation

Use the approved version

Ensure subjects sign the currently approved consent form by printing the stamped copy from iRIS (not required, but strongly encouraged).

Required signatures

- Once subject agrees (or legally authorized representative [LAR] or parent(s) agrees on

subject behalf) to participate in study, subject (or LAR or parent(s)) should sign and date the consent form.
- The person who has oriented and obtained consent should also sign and date consent form, after subject signs.
- A witness signature is *not* required except in limited circumstances as described below.

Give a copy, keep a copy

Give subjects a signed copy and keep the original signed copy in your research file.

Research file notes

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

Medical record documentation

Include a copy of the consent form in the medical record when study may affect subject?s health/treatment, and it would be helpful to share research-related treatment information with UCSF providers who may not be aware of the subject?s study participation. Also document when the consent process took place in the medical record.

Important Note*: No changes may be made to the consent form (including crossing out or striking through the consent form text or making any changes in the wording) with out prior approval* [13] *from the IRB.*

Witness signature requirements

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 [7] (when approved by the IRB).
- The participant has decision-making capacity, but cannot read, write, talk or is blind [6].
- The participant?s guardian/legally-authorized representative cannot read, write, talk or is blind [6].

When required the witness must be impartial, such as an adult who is not a member of the study team and preferably who is ***not*** a family member of the participant (unless the person is a health professional or otherwise knowledgeable about research). 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 UCSF, the Investigator's signature serves this purpose, unless an impartial witness is required as described above.

Additional Forms Required for Clinical Research

Experimental Subjects Bill of Rights (BoR)[14]

California state law (Health & Safety Code, Section 24172) requires that an ?experimental subject?s bill of rights? be provided to all participants in a medical experiment. The IRB has interpreted ?medical experiments? to include almost studies involving biomedical procedures, placebo controls, innovative therapy and/or normal volunteer subjects in studies involving more than minimal risks [15].

This list of rights must be written in a language in which the participant is fluent. Several translations [14] are available.

If subjects should receive the Bill of Rights ?

Consent form template language

Include template language [3] about the Bill of Rights in the ?Consent? section of the consent form.

No signature required

This form does **not** need to be signed, unless the study is being done under the auspices of the UCSF Helen Diller Family Comprehensive Cancer Center.

Do not submit to the IRB

You do not need to submit this form to the IRB.

Document distribution

Give each subject a copy of the Bill of Rights. Then document that you gave the BoR to each individual subject by one of the following methods:

- Keep a copy of the BoR in the subject?s study file with the signed consent form (and HIPAA authorization if applicable), *OR*
- Write a note that the subject received the BoR on the consent form (study file copy) OR
- Write a note in the subject?s research record *OR*
- Add a subject signature line to the BoR and keep a copy in research file.

Important Note: The Cancer Center requires that subjects sign the BoR and that a signed copy is given to the subjects and kept in the file.

HIPAA Authorization Form [16]

HIPAA allows researchers/UCSF personnel to access, use, create or disclose the individual's protected health information (PHI) for research purposes. **Check your approval letter (initial or continuing review) to see if subjects need to sign aHIPAA authorization form[16]!**

If subjects need to sign a HIPAA authorization ?

Consent form template language

Include HIPAA-specific template language [3] in the ?Consent? section of the consent form.

Submit to the IRB

Submit this form to the IRB as an Other Study Document.

Give a copy, keep a copy

Review the information in the HIPAA research authorization form [16] and ask subject to sign the document. Give a signed copy to the subject and keep the original signed form in the research file. A signed copy also should be kept with the consent form in the medical record, if applicable.

When and How to Reconsent and Significant New Findings

Obtaining a signature on a consent form does not complete the consent process. Maintaining informed consent requires that you provide subjects with any new information that arises during the course of the study that may have an impact on the details of their participation or their decision about whether or not to continue participation in the study.

Important Note:

1. Except in the rare emergency situation [17], it is important to consult with or seek IRB approval before instituting any reconsenting procedures or informing current or previous subjects of significant new findings.
2. See the What, When and How to Report AEs [17] section of the Adverse Event guidance page for more details about how to report significant new findings to the subjects and to the IRB, including how the level of urgency determines how to communicate the info.

Examples of When Reconsenting Is Required

- Risk/benefit profile is changed:
    - New risks are identified
    - Increases in risks are identified
    - Decreases in expected benefit are identified
- Research procedures are added that increase risks or burdens of subject

Procedures for Reconsenting Subjects Already Enrolled in a Study

When the above changes occur, use the Consent Form Addendum

When the above changes occur, use the Consent Form Addendum [18] (UCSF template is provided on the website) and obtain signed consent when any of the changes discussed above occur. This Consent Form Addendum is a one page simple form that briefly describes what changes have been made since the subject?s last signed consent. The Consent Form Addendum is designed to facilitate the re-consent process by emphasizing the revisions. Subjects must sign the updated consent form.

Verbal notification is acceptable for minor changes

Verbal notification is acceptable for minor changes, unless the sponsor or the SFVAMC require or you as the investigator want that all subjects be notified in writing and sign a Consent Form Addendum [3] for all changes. Document in the subject?s research record after this verbal notification that you have had a consent discussion.

Minor changes are changes that decrease the subject burden or risks related to the study or have no impact on the risks/benefit profile of the study. For example, if you decrease the number of blood draws or office visits, or you make minor changes to the sample size, or you change some of the questions in the questionnaire or add a brief new questionnaire.

Reconsent is not needed in some cases

Subjects need not be reconsented at all in some cases. This would be when changes occur to the study that do not involve the consent form at all, for example, changes in investigators not listed in the consent form, or changes in procedure do not effect subjects. For example, a subject may have completed the part of the study with changes, or not be enrolled in the arm of the study that includes the changes.

Significant New Findings after Study Has Been Completed

In some cases, important new information about risks or benefits of the study drug or devices or procedures may become available after one, or some or all of the subjects have completed the study. If possible within a reasonable amount of time, previous subjects should be informed verbally or in writing of any significant findings. Some investigators will prepare a newsletter or study update to be sent to previous subjects up to two years after the study has ended.

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[1] http://irb.ucsf.edu/enrolling-individuals-cognitive-impairments-and-assessing-decisional-capacity
[2] http://irb.ucsf.edu/surrogate-consent
[3] http://irb.ucsf.edu/consent-and-assent-form-templates
[4] http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/how-consent-quick-guide.pdf
[5] http://irb.ucsf.edu/special-consent-requirements-vulnerable-populations
[6] http://irb.ucsf.edu/enrolling-subjects-who-are-legally-blind-illiterate-or-cannot-talk-or-write
[7] http://irb.ucsf.edu/consenting-non-english-speakers
[8] http://irb.ucsf.edu/verbal-electronic-or-implied-consent-waiver-signed-consent
[9] http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/decision-making-capacity-assessment-tool.docx
[10] http://irb.ucsf.edu/#discussion
[11] http://irb.ucsf.edu/#forms
[12] http://irb.ucsf.edu/#documenting
[13] http://irb.ucsf.edu/modification
[14] http://irb.ucsf.edu/experimental-subjects-bill-rights
[15] http://hrpp.ucsf.edu/sites/hrpp.ucsf.edu/files/tip-sheet-minimal-risk.pdf
[16] http://irb.ucsf.edu/hipaa
[17] http://irb.ucsf.edu/adverse-event#significant
[18] http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/consent-form-addendum.docx