

## Quick Guide: How to Consent, Assess Comprehension, and Document Informed Consent for Clinical Research

<b>Preparing for Consent Discussion</b>	
<b>Approved Consent</b>	<ul style="list-style-type: none"> <li>Use the most current IRB-approved version of the consent form. This is available within iRIS.</li> <li><b>No changes</b> may be made to the consent form once approved; that is, there may be no cross outs, strike throughs, or additional wording added.</li> </ul>
<b>Timing</b>	<ul style="list-style-type: none"> <li>Informed consent from the subject (or the legally authorized representative or the parent) must be obtained <b>prior to initiating any research procedures</b>, including screening, unless the IRB has granted a waiver to do otherwise.</li> <li>Plan to <b>allow plenty of time</b> for questions and a thorough discussion.</li> </ul>
<b>Privacy</b>	Conduct the process in a manner and location that ensures participant privacy.
<b>Qualified Person</b>	<ul style="list-style-type: none"> <li>The investigator obtaining consent must be qualified and appropriately trained to explain the research and assess participant comprehension.</li> <li>The person must be listed in the IRB application as key personnel, though person need not be listed in consent form.</li> </ul>
<b>Give Consent Form</b>	<ul style="list-style-type: none"> <li>Give prospective subject a copy of the consent form.</li> <li>Do not read the consent form verbatim but do verbally describe the information below during the consent discussion.</li> <li>Or, if the potential subject prefers, he or she may read the information beforehand.</li> </ul>

<b>Most Critical Topics to Cover During Consent Discussion</b>	
<b>Purpose</b>	<b>Why are you the researcher</b> doing this study? (What do you hope to find out?) <b>Why is the subject</b> being asked to participate? Use language the subject is comfortable with. Avoid scientific terms and jargon unless appropriate for the subject.
<b>Procedures</b>	<b>What, when, where and how?</b> What is involved in doing the research? When, where and how often will study visits or hospital stays take place? What will occur at the visits? Emphasize the experimental aspects. Describe randomization process if relevant. Use charts for complicated procedures and schedules.
<b>Alternatives</b>	<b>What other options</b> are available for care of the subject? Emphasize voluntariness of research.
<b>Risks</b>	<b>What</b> are commonly reported risks? What are any serious or unknown risks? How will risks be minimized? Discuss any other burdens or inconveniences (e.g., large time commitment, costs, inconvenience of travel to different sites).
<b>Benefits</b>	<b>What</b> are the potential benefits to subjects? To society? Be objective – most studies are more likely to benefit future patients instead of current study subjects.
<b>Questions</b>	<b>Whom</b> to contact for more information? With concerns? If injured?

<b>Other Topics to Cover in Consent Discussion</b>	
<b>Confidentiality</b>	<b>How</b> will the subject's private information be kept secure? Will specimens be stored for future research? Will private info be shared with an outside party? Release of PHI should also be explained.
<b>Financial Issues</b>	<b>What costs</b> will the subject/insurance need to cover? Will study cover any costs? Will the subject be paid? When and how will payments be made?
<b>Withdrawal from Study</b>	<b>How</b> can the subject stop participating in the study? Will special provisions need to be made to withdraw a subject's participation safely?
<b>Ongoing Consent</b>	<b>How</b> will the subject be informed of any changes in the study or significant new findings that may affect his or her willingness to continue participation?

## Quick Guide: How to Consent...for Clinical Research (continued)

<b>Tips for Ensuring Comprehension</b>	
<b>Guides and Checklists</b>	Highlight important information from consent form to help guide discussion. Use a checklist to help guide or track discussion if that is helpful to you.
<b>Interactive Conversation</b>	Ask potential subject to repeat or paraphrase understanding of different points of discussion. Ask open-ended questions or non-directive (i.e., questions that begin with who, what, when, how or please describe). Encourage questions. Specifically ask if subject agrees to participate.

Conduct Consent Discussion → Give Experimental Subjects Bill of Rights → Sign Consent Form → Sign HIPAA Form → Give copies of Consent Form and HIPAA Authorization → Ongoing Consent

<b>Documenting Consent and Other Required Forms</b>	
<b>Experimental Subject's Bill of Rights</b>	<ul style="list-style-type: none"> <li>• Either before or at end of consent form discussion, give the subject a copy of Experimental Subjects Bill of Rights in a language in which he or she is fluent.</li> <li>• Review information.</li> <li>• IRB does <i>not</i> require signature (though UCSF Cancer Center does).</li> </ul>
<b>Required Signatures</b>	<ul style="list-style-type: none"> <li>• Once an individual agrees (or legally authorized representative [LAR] or parent agrees on subject's behalf) to participate in study, subject (or LAR or parents) should sign and date consent form.</li> <li>• The individual obtaining consent should also sign and date the consent form.</li> <li>• Witness signatures are required in only very rare cases. See Obtaining and Documenting Consent guidance.</li> </ul>
<b>HIPAA Form</b>	<ul style="list-style-type: none"> <li>• Give copy of UCSF Subject Authorization for Release of PHI for Research (HIPAA Form).</li> <li>• Review form and answer questions.</li> <li>• Subject should sign the form.</li> </ul>
<b>Copies to Subjects and Records</b>	<ul style="list-style-type: none"> <li>• Give subject a copy of 1) the signed consent form, 2) the signed HIPAA form and 3) a copy of the Experimental Subjects Bill of Rights.</li> <li>• Keep a copy 1) the signed consent form and 2) the signed HIPAA form in research medical records, and medical records if appropriate.</li> </ul>
<b>Notes in Records</b>	<p>Note in patient records, and medical records if appropriate,</p> <ul style="list-style-type: none"> <li>• when consent process took place and who consented, and</li> <li>• that consent form, HIPAA form and Bill of Rights were given to subject.</li> </ul>

\*See "[Quick Guide for Consenting Non-English Speakers](#)" on IRB website when consenting non-English speaking subjects."