

**Consent Form Checklist
for Reliance on External IRBs
(November 12, 2021)**

In single IRB arrangements, the reviewing IRB (whether at UCLA or any other institution) is responsible for considering local context, including state laws and institutional requirements. This typically requires targeted changes to recruitment and consent documents so that participants have correct information.

Please use this checklist when creating the UCLA site specific consent form(s) for review by a non-UCLA IRB. Also consider whether these changes are applicable to assent forms, information sheets and recruitment materials.

<input type="checkbox"/>	Heading: Add “University of California, Los Angeles”
<input type="checkbox"/>	Contact for Study Questions and Injury: Provide the local UCLA PI’s contact information.
<input type="checkbox"/>	<p>Disclosures: Disclose financial or other conflicts of interest (whether on the part of team members or of UCLA) in the appropriate section using the following language:</p> <p>“Researcher Financial Interests in this Study – [Insert researcher’s name with financial interest] has a personal financial interest in the company sponsoring this study [insert sponsor name]. Specifically, [researcher(s) name] is receiving [identify the financial interest, e.g. salary/payment for consulting, owns stock, holds a patent, serves on the Board of Directors]. A UCLA committee has reviewed these financial interests to help prevent them from affecting the quality and reliability of this study.”</p> <p>See UCLA OHRPP Guidance.</p>
<input type="checkbox"/>	<p>HIPAA Authorization: If Protected Health Information will be accessed, used, created or disclosed from <i>UCLA medical records</i>, use and refer to the University of California Permission to Use PHI for Research Forms.</p> <p>California state law does not allow for HIPAA language in the consent form. Remove HIPAA language in the consent form and use the following statement instead: “You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.”</p> <p>NOTE: The consent form should still describe confidentiality of research data.</p>
<input type="checkbox"/>	<p>Injury (for Greater than Minimal Risk research): You must use UCLA’s standard language (unless the other institution is a UC) when injury information is needed.</p> <p>“It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study. You can tell the researcher in person or call him/her at the number(s) listed above.</p> <p>If you are injured as a result of being in this study, UCLA will provide necessary medical treatment. The costs of the treatment may be covered by the University of California or the study sponsor [sponsor name], or billed to you or your insurer just like other medical costs, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about this, you may call the UCLA Office of the Human Research Protection Program at 310-206-2040 or email mirb@research.ucla.edu.”</p> <p>See UCLA OHRPP Guidance for more details.</p>



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<input type="checkbox"/>	<p>Commercial Value (if not already disclosed): For compliance with the decision of the California Supreme Court in <i>Moore v. Regents of the University of California</i>, include the following statement. You may remove reference to specimens if the research does not collect or use specimens. You may remove reference to sharing and/or re-using specimens as appropriate to your plans:</p> <p>“Information and/or specimens collected from you for this study will become the property of the University of California or a third party designated by the University. The information/specimens may be used in this research or other research, and shared with other organizations. Under state law you will not share in any commercial value or other compensation from products developed using the information/specimens.”</p>
<input type="checkbox"/>	<p>Costs: If the study requires services or resources owned/rented/operated or provided by the UCLA Health System (e.g. clinic and/or hospital visit(s), professional medical services, clinical treatment, diagnostics, labs, medical supplies, etc.), then insert the Coverage Analysis statement appropriate to how procedures will be billed:</p> <p>If Billed All to Research: “The study will pay for the cost of supplying and administering the study drug/device, and all required study items and services as described in this consent form.”</p> <p>If Billed to a Split of Research and Insurance/Subject: “The study will pay for research-related items and/or services that are provided only because you are participating in the study. These research-related items and/or services are explained in other areas of this consent form.</p> <p>You or your health plan may be responsible to pay for all the types of items listed below:</p> <ul style="list-style-type: none"> • Items and services that would have been provided to you even if you were not in the study • Health care given during the study as part of your regular care • Items or services needed to give you study drugs or devices • Monitoring for side effects or other problems • Deductibles or co-pays for these items and/or services” <p>All Standard of Care: “There will be no additional cost to you or your health plan as a result of your participation in this study. Items and services described in this consent form would have occurred regardless of your participation in this study or, if research-related, will be provided to you at no cost.”</p> <p>NOTE: Contact coverageanalysis@mednet.ucla.edu with questions about the above.</p>
<input type="checkbox"/>	<p>Bill of Rights: Give the participant a copy in a language in which they are fluent (see here).</p> <p>NOTE: UC does not require the Bill of Rights document to be signed and does not include the Bill of Rights in the body of the consent form.</p>
<input type="checkbox"/>	<p>Ancillary Reviews: If any local ancillary reviews result in changes to the consent form, you must make those changes in the UCLA site specific consent form and convey those changes to the reviewing IRB. For example, the Medical Radiation Safety Committee (MRSC) requires the use of specific language to describe the risks of radiation procedures.</p>