

## Consent Form Checklist for Collaborative Research (Making UCLA Required Revisions to the Consent Form when Relying on Another IRB)

The UCLA IRBs are willing to rely on other specified IRBs [in limited circumstances](#). The reliance on another IRB means that the UCLA IRB will accept the review of the science, procedures and methods as well as the consent documents of the reviewing IRB. However, minor changes will likely be required to the recruitment and consent documents so that the participant will have the needed local context to be truly informed about the study.

Please review and use checklist below when modifying the consent forms. Adapt these changes *as appropriate* for the assent forms, information sheets and recruitment materials.

<input type="checkbox"/>	<b>The Heading:</b> Add “University of California, Los Angeles” as part of the heading in the consent form, assent form, or information sheet.
<input type="checkbox"/>	<b>The Introduction:</b> Identify the name of the UCLA Principal Investigator and his or her department at UCLA in the introductory paragraph. For example, “Maureen Kwan, MD and her associates in the Department of Pediatrics at UCLA and ... [investigator at other named site] are conducting a research study.” The UCLA IRB does not require, and, in fact, discourages listing <i>all</i> investigators in the consent form.
<input type="checkbox"/>	<b>The Procedures Section</b> (or elsewhere as appropriate): State where the procedures for the study will take place at UCLA, if appropriate.
<input type="checkbox"/>	<b>Contact Information:</b> In the section that provides information about whom to contact with questions about the study, provide the local UCLA PI’s contact information. <b>Important Note:</b> You do not necessarily need to add UCLA OHRPP IRB contact information. The participant may contact the reviewing IRB and be given UCLA information as appropriate.
<input type="checkbox"/>	<b>Financial Interests:</b> If any members of the research team have a financial or other conflict of interest, this information should be added in the appropriate section of the consent form. If UCLA has a financial interest, this should also be added. See <a href="#">Recommended Consent Form Language</a> in UCLA OHRPP Guidance.
<input type="checkbox"/>	<b>HIPAA Notification:</b> If Protected Health Information as defined by <a href="#">HIPAA</a> will be accessed, used, created or disclosed from <b>UCLA medical records</b> , use and refer to the <a href="#">University of California Permission to Use PHI for Research Forms</a> which is posted on the UCLA OHRPP website. Do not incorporate HIPAA language into the consent form. Rather, use the following statement in the consent section at the end: “You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.”
<input type="checkbox"/>	<b>Treatment and Compensation for Injury:</b> If the study poses a real or foreseeable risk of biomedical harm <i>and</i> the study procedures will take place at UCLA, the UCLA standard treatment and compensation for injury statement should be added to the consent form. See UCLA OHRPP Guidance: <a href="#">Treatment and Compensation for Injury</a> . <b>Important Note:</b> If the study is being reviewed by another UC, then because all the UCs have the same policy, that statement does not need to be changed.

<input type="checkbox"/>	<p><b>Cost Language:</b> 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 one of the following Coverage Analysis statements must be included in the Cost section of the consent form:</p> <p><input type="checkbox"/> <b>Research Only:</b> 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><b>OR</b></p> <p><input type="checkbox"/> <b>Mixed Cost:</b> 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. 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"><li>• Items and services that would have been provided to you even if you were not in the study</li><li>• Health care given during the study as part of your regular care</li><li>• Items or services needed to give you study drugs or devices</li><li>• Monitoring for side effects or other problems</li><li>• Deductibles or co-pays for these items and/or services</li></ul> <p><b>OR</b></p> <p><input type="checkbox"/> <b>All Standard of Care:</b> 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><b>NOTE:</b> Please direct any questions related to Coverage Analysis to the Clinical Trials Administration Office at <a href="mailto:coverageanalysis@mednet.ucla.edu">coverageanalysis@mednet.ucla.edu</a>.</p>
<input type="checkbox"/>	<p><b>Research Participants Bill of Rights:</b> If the study poses a real or foreseeable risk of biomedical harm and takes place in California, make sure the consent form includes language such as the following: “You have been given a copy of this consent form and the Research Participant’s Bill of Rights to keep.” And ensure that the participant is given a copy in a language in which he or she is fluent. Copies in English and several translations are available <a href="#">here</a>.</p>