UCLA Research Administration
Human Research Protection Program

NCI CIRB Boilerplate Consent Language

[Updated January 3, 2022]

This is a checklist of UCLA's standard template language that should be inserted into a CIRB-approved model consent form. The NCI CIRB has set specific consent guidelines, with each section of the model consent form identified, followed by a description of what changes, if any, are permitted. Please review the NCI CIRB consent guidelines along with checklist in order to prepare the UCLA site specific consent form.

IMPORTANT NOTE: If changes are needed that are not part of this checklist, those changes must be conveyed to the CIRB for review and approval. This applies to any required changes resulting from local ancillary reviews. For example, the Medical Radiation Safety Committee (MRSC) requires the use of specific language to describe the risks of radiation procedures.

☐	**Heading:** Add "University of California, Los Angeles"
☐	**Contact for Study Questions and Injury:** Provide the local UCLA PI's contact information.
☐	**Disclosures:** Disclose financial or other conflicts of interest (whether on the part of team members or of UCLA) in a separate section before the signature block. See UCLA OHRPP Guidance. **NOTE**: All conflict of interest or financial disclosure language included in the consent must be submitted to the NCI CIRB using a Study-Specific Worksheet to be approved before it can be used with the CIRB-approved model consent document. See NCI CIRB Consent Guidelines.
☐	**Injury:** You must use UCLA's standard language when injury information is needed. See UCLA OHRPP Guidance for more details. "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. 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 billed to you or your insurer just like other medical costs, depending on a number of factors. The University does 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."
☐	**Bill of Rights:** Give the participant a copy in a language in which he or she is fluent (see here). **NOTE:** UC does not require the Bill of Rights document to be signed and does not include the Bill in the body of the consent form.
☐	**Ancillary Reviews:** If any local ancillary reviews result in changes to the consent form, you must convey those changes to the reviewing IRB. For example, the Medical Radiation Safety Committee (MRSC) or

	Radioactive Drug Research Committee may require specific changes to the consent form which describe dosimetry or specific information. **NOTE:** • All standard of care radiation risk language should NOT be added into the UCLA site specific consent form as this will not be approved by the NCI CIRB. • All research radiation risk language should be added into the UCLA site specific consent form and identified in the study specific worksheet upon submission to the NCI CIRB for final approval.