UC DAVIS
OFFICE OF RESEARCH

IRB Administration
October 2, 2025

Working with the UC Davis IRB: Guidance for Sponsors, Lead Sites, and External IRBs

Compliance Statement

The University of California, Davis, in accordance with its Federalwide Assurance (FWA) with the Department of Health & Human Services, adheres to federal regulations for the protection of human research subjects. These include 45 CFR 46 ("The Common Rule"), as well as 21 CFR 50 and 21 CFR 56 for FDA-regulated products. Compliance is also guided by the principles of *The Belmont Report*, applicable state laws, and institutional policies. UC Davis has implemented a Human Research Protection Program Plan that outlines the institution's responsibilities to the research community.

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Informed Consent Requirements

UC Davis research consent documents must meet both federal and local requirements. Below are some of the most common challenges encountered with consent documents. For additional requirements, please review the UC Davis Required Consent Language Checklist. Addressing these issues before submission to the UC Davis IRB may help improve review timelines. Please note that the IRB may require additional edits.

California Experimental Subject's Bill of Rights

When research meets the State of California's definition of a medical experiment per California Health and Safety Code, Chapter 1.3. Human Experimentation 24170 - 24179.5, the California Experimental Subject's Bill of Rights must be provided to the subject before they consent to participate in the study. UC Davis IRB uses a version of the Bill of Rights that is specific to UC Davis and prefers it appears at the beginning of the consent form.

HIPAA Authorization

UC Davis does not permit HIPAA authorization language to be embedded within the consent form. Instead, researchers are required to use the separate University of California Davis Health Permission to Use Personal Health Information for Research. This document must be used without any modifications.

Note: To ensure appropriate disclosures regarding data confidentiality, it is acceptable

to include a statement indicating that authorized personnel may inspect records, including medical and research records. However, any HIPAA-related language that conflicts with the official UC Davis HIPAA authorization must be removed (e.g., language stating “this authorization expires after 50 years”).

Injury Language

Per 18-300 University Policy for Medical Treatment of Human Subjects for Injuries Resulting from Participation in Research, the University of California Office of the President (UCOP) requires standardized injury language across all UC campuses. The UC Davis injury language, as provided by UCOP, must be included as-is and cannot be edited or removed. It must be the only injury language in the consent form.

Biospecimen Language

Per UCOP Guidance Memo Standard language in Research Informed Consent Forms for Research in which biospecimens and/or information derived from biospecimens are obtained from research participants: commercial rights and research interests, the paragraph below should be included in the informed consent form for research if biospecimens and/or information derived therefrom will be collected from a research subject and used for research and/or development purposes:

Biospecimens (such as blood, tissue, or saliva) collected from you for this study and/or information obtained from your biospecimens may be used in this research or other research, and shared with other organizations. You will not share in any commercial value or profit derived from the use of your biospecimens and/or information obtained from them.”

The general examples provided in the statement "such as blood, tissue, or saliva" is not intended to be study-specific. The list may be modified, as needed. The rest of the boilerplate language may not be edited.

Medical Test Results Reportable to State of California

If the study includes medical testing for reportable conditions (e.g., HIV, tuberculosis, hepatitis) in participants who have not already been diagnosed with those conditions, the consent form must notify participants of California’s mandatory reporting requirements. See the California Department of Public Health’s list of reportable conditions for additional information.

General Data Protection Regulation (GDPR)

GDPR language should only be included in the consent form if UC Davis researchers will be interacting with and collecting data from subjects who are physically located in the EU/EEA at the time of data collection.

If the sponsor requests GDPR language solely because the sponsor is based in the EU/EEA, but UC Davis researchers are not collecting data from participants in the EU/EEA, then GDPR language should be removed from the consent form, per UCOP guidance.

Note: If the sponsor insists on including GDPR language, it must not obligate UC Davis personnel (e.g. “Contact your study doctor to exercise your rights”).

Witness Signature Line

Research consent documents should include a witness signature line to allow for ethical and legally valid informed consent in special situations. For example, a witness is necessary in the following circumstances:

- When the short form consent process is used because a full written translation of the consent form is not available in the participant’s preferred language.
- If a participant is blind, visually impaired, or illiterate, and the consent is read aloud to them.

Additional UC Davis Required Language

UC Davis’s Human Research Protection Program (HRPP) involves multiple review committees (e.g., IRB, Radiation Use Committee, Biosafety Committee, Conflict of Interest Committee, etc.) Committees outside the IRB may require specific consent language. This language will not appear in UC Davis IRB consent templates. UC Davis researchers must comply with institutional requirements as directed by these oversight committees.

Please review our Frequently Asked Questions to address other common issues.