

Consent Form Checklist for Using a Non-UCSF Consent Form

When relying on an external IRB and not using the UCSF consent form template, please include all of the following elements. The language below provides local context and meets California legal and University of California requirements. Please use and adapt the checklist below when modifying the consent forms, assent forms, information sheets and recruitment materials.

1	<p>The Heading: Add “University of California, San Francisco” as part of the heading in the consent form, assent form, or information sheet. Only the UCSF logo should appear on the consent form. If desired, the logo of the lead site, coordinating center, cooperative group, trial network, consortium, etc. may also appear in addition to the UCSF logo.</p>
2	<p>The Introduction: If not already listed in the heading, identify the name of the UCSF Principal Investigator and his or her department at UCSF in the introductory paragraph. For example, “Maureen Kwan, MD and her associates in the Department of Pediatrics at UCSF... [and investigator at other named site] are conducting a research study.” The UCSF IRB does not require and, in fact, discourages listing all investigators in the consent form.</p>
3	<p>Financial Interests: 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 UCSF has a financial interest, this should also be added. See Recommended Consent Form Language in UCSF HRPP Guidance.</p>
4	<p>The Procedures Section (or elsewhere as appropriate): State where the procedures for the study will take place at UCSF, as appropriate.</p>
5	<p>The Risks Section:</p> <p>[Studies that involve radiation exposure] Include radiation risk language from the UCSF consent form template.</p> <p>[Studies that involve randomization to treatment] You will be assigned to a treatment program by chance, and the treatment you receive may prove to be less effective or to have more side effects than the other study treatment(s) or other available treatments.</p>
6	<p>Studies that include the collection of specimens: [Add the following statement] Your specimens may be used for commercial use. If this happens, you will not share in any profits.</p>
7	<p>Confidentiality: [Add the following statement] A UCSF medical record will be created because of your participation in this study. Your consent form and some of your research test results will be included in this record. Therefore, your other UCSF doctors may become aware of your participation. Hospital regulations require that all health care providers treat information in medical records confidentially.</p> <p>[For studies involving HIV, tuberculosis, hepatitis B, or hepatitis C testing with participants <u>who have not already been diagnosed with those conditions</u>, and/or COVID-19 testing] California regulations require laboratories to report new cases of <i>[state the reportable diagnosis/diagnoses here]</i> to the county public health department. HIV test result reporting includes CD4+ count (or T-cell count), viral load, and viral genotype for positive results. All COVID-19 test results (positive, negative or inconclusive) must be reported. The reports include details like: your name, social security number, and other identifying information. Information about these new infections is used to track these diseases statewide and nationwide. Other than this required reporting, your results will be treated confidentially by the study staff. Personally identifying information will not be reported to other departments or agencies. For a full list of reportable conditions, go to the following link:</p> <p>https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/ReportableDiseases.pdf</p>

8	<p>Cost Language: Include one of the following options without revision or additions:</p> <p>[For studies in which the sponsor pays all costs:] The sponsor has agreed to pay for all items associated with this research study; you or your insurer will not be billed.</p> <p>For studies where subjects may be responsible for some costs:] Two types of procedures will be done during this study. Some are part of your standard medical care and others are only for research. You or your insurer will be billed for the standard medical care. You will be responsible for your co-pays, deductibles, and any other charges that your insurer will not pay. There is a possibility that your insurer may not cover all standard medical care costs if you are receiving medical services out of network. Any procedures done only for research will not be charged to you or your insurer.</p> <p>[Add the following statement, if applicable:] The sponsor will provide ‘drug x and administration of drug x’ at no cost to you.]</p>
9	<p>Treatment and Compensation for Injury: If the study poses a real or foreseeable risk of biomedical harm and the study procedures will take place at UCSF, the UCSF standard treatment and compensation for injury statement should be added to the consent form.</p> <p>Include the following standard wording: It is important that you tell your study doctor, _____ <i>[investigator's name(s)]</i>, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her at _____ <i>[telephone number]</i>.</p> <p>Treatment and Compensation for Injury: If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California or the study sponsor <i>[sponsor name]</i>, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at 415- 476-1814. [NOTE: <i>This statement must be used without changes unless (1) the Sponsor requests MMSEA 111 Language OR (2) this is a clinical trial of a COVID-19 countermeasure and the PREP Act applies OR (3) this is a VA study with a Sponsor. See the IRB website and the notes section at the end of this template for standard wording for each of these situations].</i></p> <p>For additional guidance, including MMSEA 11 or PREP Act language options, please see UCSF HRPP Guidance: Treatment and Compensation for Injury.</p>
10	<p>Contact Information: In the section that provides information about whom to contact with questions about the study, provide the local UCSF PI’s contact information.</p> <p>Important Note for Reliance Agreements: You do not necessarily need to add UCSF HRPP IRB contact information. The participant may contact the reviewing IRB for and be given UCSF information as appropriate.</p>
11	<p>Experimental Subject’s Bill of Rights: If the study poses a real or foreseeable risk of biomedical harm and takes place in California, make sure to include language such as the following: “You have been given a copy of this consent form and the Experimental Subjects 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 on the HRPP website.</p>
12	<p>HIPAA Notification: If Protected Health Information will be accessed, used, created or disclosed from UCSF medical records, use and refer to the University of California Permission to Use PHI for Research Forms. Do not incorporate HIPAA language into the consent form, and do not refer to the consent form as an “authorization 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.”</p>
13	<p>Signature Block: If the study is approved for use of the short form, the signature block must include a line for a witness’s signature but not for an interpreter’s signature.</p>