

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 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.</p> <p>Actual or potential financial conflicts of interest must be submitted to and reviewed by the UCSF Conflict of Interest Advisory Committee (COIAC). If COIAC determines this study has a conflict, they will provide a consent form statement for this study.</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 provided by the Radiation Safety Committee (RSC).</p> <p>[Studies that involve randomization to treatment] You might be put into a group that receives something that is not as effective as another group. You might have more side effects than people in another group or people who don’t join this study.</p> <p>[Studies that involve collection of tissue derived from clinical specimens (i.e., “leftover tissue”)] Risk of using your tissue for research: This research study uses tissue that was taken as part of your usual care. There is a small chance that using this tissue for research will use up the tissue. If this happens, your doctors might not be able to make a clinical diagnosis or complete other tests. To help reduce the risk of this happening, a trained person will evaluate if there is enough tissue for research.</p> <p>With this process, we believe the risk of using up your tissue for research is small.</p>
6	<p>Studies that include the collection of specimens: [Add the following statement] Your specimens or information obtained from your specimens may be used for commercial use. If this happens, you will not share in any profits.</p>
7	<p>Confidentiality: [Add one the two following statements]</p> <p>[Statement 1- Use this statement if the study will access or create medical records:] If you take part in this study, there may be some loss of privacy. We will do our best to make sure information about you is kept confidential. But we cannot guarantee total privacy. Some information from your medical records may be collected and used for this study. If you do not have a UCSF medical record, one will be created for you. Your signed consent form and some of your research tests will be added to your UCSF medical record. People involved with your future care and insurance may become aware that you participated in this study. They may see information added to your medical record. Study tests and information obtained from you will be part of your research records. This information may be added to your</p>

medical record. Your personal information may be given out if required by law. Information from this study may be published or presented at scientific meetings. If it is, your name and other personal information will not be used.

[Statement 2- Use this statement if the study does not access or create medical records]: If you take part in this study, there may be some loss of privacy. We will do our best to make sure information about you is kept confidential. But we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

[For studies involving HIV, tuberculosis, hepatitis B, or hepatitis C testing with participants who have not already been diagnosed with those conditions, and/or COVID-19 testing, add this statement]

By California law, some medical test results must be shared with the county public health department. This is done so health experts can keep track of these diseases. The report we share with the health department will include information like your full name and social security number. The researchers can tell you what kinds of tests in this study will be shared.

[Include these additional 2 paragraphs if the study involves HIV testing for research purposes (including screening for study eligibility).]

Positive HIV test results will be shared with the county public health department. This applies even if it is not a new HIV diagnosis. When someone tests positive for HIV, we share this information with the San Francisco Department of Public Health:

- CD4+ count (or T-cell count)
- Viral load
- Viral genotype

If you do not live in San Francisco County, this information may also be shared with your home county health department.

8 **Cost Language:** Include one of the following options without revision or additions:

[For studies in which the sponsor pays all costs:] There is no cost to you or your insurer if you take part in this study. However, you may need to pay for items such as parking and transportation. You or your insurer will be billed for the costs of any usual medical care you receive outside of this study. You will also be responsible for any deductibles or co-payments for these usual medical care costs.

[For studies where subjects may be responsible for some costs:]

Two types of tests or procedures will be done during this study. Some are part of your usual medical care and others are only for research. Any tests or procedures done only for research will not be charged to you or your insurer. You or your insurer will be billed for the usual medical care. You will be responsible for any costs your insurance does not cover. There is a possibility that your insurer may not cover all usual medical care costs if you are receiving medical services out of network. You or your insurer may be responsible to pay for all the types of items listed below:

- 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
- Medical care you receive to diagnose or treat any medical condition(s) outside of this study
- Routine items or services needed to give you study drugs or devices
- Standard monitoring or treatment for side effects or other problems
- Deductibles or co-pays for these items or services

You may need to pay for items such as parking and transportation. If you have questions about what costs you will be responsible for, please talk with the study investigator before deciding to enroll in the study. Depending on the type of study, some of your costs could be quite high. Ask to talk to someone about cost estimates if you aren't sure how much financial risk you might have.

[For studies with no costs]: There will be no costs to you for being in this study.

9 **Treatment and Compensation for Injury:** If the study poses a real or foreseeable risk of biomedical harm and

	<p>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 to tell the Principal Investigator, <i>[insert Principal Investigator’s name]</i>, if you feel you have been injured or harmed because you took part in this study. You can tell them in person or contact them at <i>[insert telephone number]</i>.</p> <p>Treatment and Compensation for Injury: If you get hurt because of this study, the University of California will give you medical treatment that you need. You might have to pay for this treatment, or your insurance might pay for it. It depends on different things. The University or the study sponsor might pay for the medical costs instead. But usually, they don’t pay for other things besides medical care if you get hurt. If you want to know more, call the office of the Institutional Review Board at 415-476-1814.</p> <p><i>[NOTE: 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 or this consent form will be used at a SFVSHCS site, OR (4) the Sponsor chooses to remain silent, and/or the sponsor is the NIH. See the UCSF IRB’s Companion Document, section 14.1 for standard wording for each of these situations].</i></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 they are 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>Studies that include pregnancy testing of minors in California: These statements are specific to California law, so please adapt it if the study is conducted elsewhere.</p> <p>[Assent form language. Note: Include the bolded sentence only if pregnancy is an exclusion criterion, otherwise remove.] In California, information about pregnancy test results, engagement in sexual activity, and use of birth control may not be shared with parents without your permission. We will not tell your parents the pregnancy test result. If the pregnancy test is positive, you cannot be in the study and your parents may guess that you are pregnant. If you think you may be pregnant and you do not want your parents to know, you may not want to participate in this study. If you are pregnant, the study team will tell you. They will ensure you have medical follow up for the pregnancy.</p> <p>[Parent permission form language] In California, the following information may not be shared with parents without your child’s permission:</p> <ul style="list-style-type: none"> • pregnancy test results • engagement in sexual activity • use of birth control <p>Unless your child gives us permission, we will not inform you of the pregnancy test result. If your child is pregnant, the study team will ensure that your child has medical follow up for the pregnancy.</p>
14	<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>