UCSF **Human Research Protection Program**

Consent Form Checklist for Using a Non-UCSF Consent Form

The UCSF IRBs are willing to rely on other specified IRBs in limited circumstances. They are also willing to consider accepting and reviewing consent forms when not written in the UCSF format in certain circumstances in which the form has been or will be approved by another duly constituted IRB.

Provided the consent form meets the federal criteria for IRB approval of a consent form, the minor changes below provide local context and meet California legal and University of California requirements. Please use and adapt the checklist below when modifying the consent forms, assent forms and information sheets and recruitment materials.

☐ 1	**The Heading:** Add "University of California, San Francisco" as part of the heading in the consent form, assent form, or information sheet.
☐ 2	**The Introduction:** 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 discourages listing all investigators in the consent form.
☐ 3	**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.
☐ 4	**The Procedures Section** (or elsewhere as appropriate): State where the procedures for the study will take place at UCSF, as appropriate.
☐ 5	**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. See UCSF HRPP Guidance: Treatment and Compensation for Injury. ***Important Note for studies being reviewed by another UC:*** Because all the UCs have the same policy, that statement does not need to changed.
☐ 6	**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. ***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.
☐ 7	**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.
☐ 8	**HIPAA Notification:** If Protected Health Information as defined by HIPAA 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 which is posted on the UCSF HRPP 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."