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☐	**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.
4	**The Procedures Section** (or elsewhere as appropriate): State where the procedures for the study will take place at UCSF, as appropriate.
5	**Cost Language: [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. **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. [**Add the following statement, if applicable]:** The sponsor will provide 'drug x and administration of drug x' at no cost to you.]
6	**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.
7	**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.
8	**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.
9	**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. 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."