***SAMPLE INFORMED CONSENT FORM ADDENDUM***

*Instructions for researchers* ***(delete prior to submitting to the IRB for review and approval)***

* *Participants have a right to know about new information or changes in the study that may affect their health or their willingness to continue in the study*
* *The ICF addendum is for participants already enrolled in the study*
* *If the study is still enrolling, the study’s main ICF must be revised to include the new information*
* *New participants will be presented with the revised main ICF; already-enrolled participants will be presented with the ICF addendum. Some sponsors require that already-enrolled participants sign the revised main ICF, which is acceptable as long as the new information is carefully discussed with the participants.*
* *Describe new information or changes in the study in lay language and explain how the information is relevant to participants.*
* *Keep the ICF addendum short (1-2 pages) so the new information stands out. Use 12 point font.*
* *Allow time for discussion with the participants and allow time for questions.*
* *Statements in italics are instructions or examples, and should not be included in the actual ICF addendum. Remember that IRB review and approval is required before the ICF addendum is presented to participants.*
* *The PI does not need IRB approval to verbally notify participants of new information such as risks. Verbal notification should be documented in the research records. Even if verbal notification occurs, the participants must still be presented with the revised main ICF or ICF addendum. Remember that the informed consent process is an ongoing process that doesn’t end with the signing of an ICF.*

**UNIVERSITY OF CALIFORNIA, SAN FRANCISCO**

**Informed Consent Form Addendum**

### STUDY TITLE:

### PRINCIPAL INVESTIGATOR:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**The purpose of this form is to tell you about new and important information we have learned since you joined this research study. The original consent form you signed is still valid except for the changes described here.**

**NEW INFORMATION**

*Example 1: Heart attack is identified as a new rare but serious study risk:*

***New risk identified: Heart Attack (rare but serious)***

*The possible risk of heart attack has been added for participants receiving Drug XYZ-123. In this study, you are receiving Drug XYZ-123.*

*Example 2: Adding an additional X-ray procedure*

***Change in study procedures: Adding an additional chest X-ray***

*At the beginning of the study, you had an X-ray of your chest to check for XYZ. The study doctor has added another chest X-ray at the 6-month mark of study participation. The study doctor believes that the additional chest X-ray is important because XYZ. [Note to researchers: In this example, the UCSF Radiation Safety Committee (RSC) would first need to review and approve the additional X-ray procedure and radiation. Based on RSC’s review, the radiation risk language might need to be revised. In the ICF addendum, provide the finalized radiation risk language. If the study is still enrolling, be sure to add the finalized radiation risk language to the main ICF as well.]*

**PARTICIPATION IN RESEARCH IS VOLUNTARY**

You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

**Who can answer my questions?**

You can contact the research team at \_\_\_\_\_\_\_\_\_\_\_ (*insert phone number*) with any questions or concerns about the information provided in this form.

**The above information has been explained to me and all of my questions have been answered. By signing this form I indicate that I have received this new information and plan to continue to participate in this research study.** If I have any additional questions I can always contact members of the research team. If I have questions about my rights as a research participant, I can call the UCSF Institutional Review Board at (415) 476-1814. A copy of this document will be given to me.

Date Participant's Signature for Consent

Date Person Obtaining Consent

[STOP! Only include the following signature line if you may consent non-English speaking subjects using the [short form consent method](http://hrpp.ucsf.edu/consenting-non-english-speakers) AND this request has been addressed in the IRB application.]

Date Witness – Only required if the participant is a non-English speaker

[STOP! Do not use the following signature lines unless third party consent is being requested and has been addressed in detail in the IRB application.]

AND/OR:

Date Legally Authorized Representative

\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date Person Obtaining Consent

OR:

*The person being considered for this study is unable to consent for themself because they are a minor. By signing below, you are giving your permission for your child to be included in this study.*

Date Parent or Legal Guardian