***Instructions for researchers:*** *The purpose of this form is to provide information about how study risks might be different for the individual being enrolled under a ‘Protocol Enrollment Exception.’ This includes any potential risks not described in the main consent form, as well as already-described risks that may be more severe and/or likely for this individual.*

*This specific addendum is only to be used in the case of a Protocol Enrollment Exception. Protocol Enrollment Exceptions must be submitted on the Protocol Enrollment Exception Request Form in iRIS prior to enrolling a person who does not qualify for the study****.***

***Delete all highlighted instructions before submitting this addendum to the IRB.***

**UNIVERSITY OF CALIFORNIA, SAN FRANCISCO**

**Protocol Enrollment Exception – Additional Risk Information**

### STUDY TITLE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

### PRINCIPAL INVESTIGATOR: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

**The purpose of this form is to tell you about additional risk information that is not described in the main informed consent form for this study.**

**ADDITIONAL RISK INFORMATION**

*Describe any additional/more severe/more likely risks in lay language.*

**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 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *(insert name)* 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