UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

BERKELEY □ DAVIS □ IRVINE □ LOS ANGELES □ RIVERSIDE □ SAN DIEGO □ SAN FRANCISCO
SANTA CRUZ

SANTA BARBARA □

HIVTR-CCR5

RODNEY ROGERS
Project Manager HIVTR-CCR5
550 PARNASSUS AVE., M-884
SAN FRANCISCO, CA 94143-0780

PHONE (415) 514-6454
FAX (415) 353-2233

December 16, 2021

Clarification Memorandum # 4 to HIVTR-CCR5 Protocol Version 4.0 (2.28.19)

To: HIVTR-CCR5 Principal Investigators
HIVTR-CCR5 Study Coordinators

From: Rodney Rogers, Project Manager, UCSF

Protocol Title: Impact of CCR5 Blockade in HIV+ Kidney Transplant Recipients

Protocol ID# DAIDS-ES 20730

Principal Investigator: Peter Stock, MD, PhD

RE: Secondary Clinical Endpoints measuring HIV Persistence

This clarification memo does not result in a change in the protocol informed consent document. The Division of AIDS does not require you to forward it to your IRB; however, as always, you must follow your IRB's policies and procedures. If IRB review of clarification memos is required at your site, please submit this document for review. Each site should file a copy of this clarification memo with the protocol for reference. The protocol clarifications contained in this memo should be implemented immediately. These updates will be included in the next version of the protocol if it is amended at a future date.

The HIVTR-CCR5 protocol secondary clinical endpoint measuring HIV persistence utilizes a three-assay approach:

a) HIV reactivation (frequency of CD4+ T cells producing HIV multiply spliced RNAs upon TCR stimulation)
b) HIV DNA and RNA in peripheral blood CD4+ T cells
c) Plasma HIV RNA levels (single copy assay)

HIV reactivation (frequency of CD4+ T cells producing HIV multiply spliced RNAs upon TCR stimulation) measured by the Tilda assay will not be performed for this protocol. The data that comes from this assay is now considered to be highly variable and is no longer performed at UCSF.

The protocol will continue to measure HIV persistence utilizing HIV DNA and RNA in peripheral blood CD4+ T cells and plasma HIV RNA levels (single copy assay)