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July 9, 2019

Clarification Memorandum # 1 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: eGFR/CrCl and study drug dose adjustments

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.

Protocol Version 4.0 (2.28.19) section "6.2.2 Modified Dosage Regimen" indicates that the study drug dose will be modified when participant's GFR<30 and would return to non-renal dosage once GFR>=30. The summary table in the same section, however, indicates that dose modification is based on CrCl<30 and CrCl>=30, respectively.

Although GFR and creatinine clearance (CrCl) can be used interchangeably as measurements of kidney function, the dose adjustments should be based on the estimated GFR result pended from the laboratory measurement. This clarification memo corrects the inconsistency.