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HIVTR-CCR5

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Clarification Memorandum # 3 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: Reporting out of window evaluations on the electronic case report forms (eCRFs)

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.

We recognize that due to the impact of COVID-19 on in-person study visits, some protocol assessments are performed out of the protocol defined visit window. If the assessment is collected for the primary and secondary endpoint evaluations, we would like to capture the results on the eCRFs. Although these are still protocol deviations (reportable in the Emmes IDES and the source records), these assessments are key to the protocol endpoint analysis.

This clarification memo provides sites with a range for these assessments to assist with case report form completion and statistical analysis.

REMINDER: <u>All</u> assessments outside of the <u>"Protocol Visit Window"</u> (which have never changed) are still protocol deviations and must be reported in the Emmes IDES along with the reason it was performed out of window (i.e. if COVID-19 related). There has been **<u>no change to the Protocol Visit Windows</u>** and no change to the protocol.

This clarification memo only provides a defined maximum out-of-range limit for reporting on

the case report forms. Once the maximum upper range is exceeded, the assessment should be reported as "Missed" in the Emmes IDES Forms Grid (instead of a deviation for out-of-range) by submitting a missing value request for the missed assessment, and should be adequately documented in the research record/source documents. A Protocol Deviation form for the missed assessment should also be entered into the Emmes IDES.

Study Assessment	Protocol Visit Window	Maximum Upper Range allowed
6 months kidney biopsy	-14 days/+46 days	+90 days from the visit target date (max 44 days out of window)
Iohexol study at week 52	-14 Days/+91 Days	+120 days from the visit target date (max 29 days out of window)
Cystatin C/eGFR Year 1	-14 Days/+91 Days	+120 days from the visit target date (max 29 days out of window)
Cystatin C/eGFR Year 2	-14 Days/+91 Days	+120 days from the visit target date (max 29 days out of window)
Cystatin C/eGFR Year 3	-14 Days/+91 Days	+120 days from the visit target date (max 29 days out of window)
Mechanistic Samples Year 1	-14 Days/+91 Days	+120 days from the visit target date (max 29 days out of window)
Mechanistic Samples Year 2	-14 Days/+91 Days	+120 days from the visit target date (max 29 days out of window)