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CLARIFICATION MEMO

DATE: May 31, 2023

TO: ACTG CTU Principal Investigators, CRS Leaders, and CTU/CRS Coordinators

FROM: A5379 Protocol Team

SUBJECT: Clarification Memo #1 for Protocol A5379 Version 3.0

This clarification memo (CM) 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 institutional review board (IRB); however, 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 CM with the protocol for reference.

The protocol clarification contained in this memo should be implemented immediately.

The reason for this CM is to clarify that there is no study protocol deviation eCRF and to correct a typo.

The following are clarifications (noted in bold or strikethrough) to Protocol A5379, Version 3.0, 13Dec2022, titled, "B-ENHANCEMENT OF HBV VACCINATION IN PERSONS LIVING WITH HIV (BEe-HIVe): Evaluation of HEPLISAV-B." These clarifications will be included in the next version of the A5379 protocol if it is amended at a future date.

1. In section 12.4, the sentence about study protocol deviation eCRF is deleted, as there is no study protocol deviation eCRF.

   12.4 Reporting Protocol Deviations

   The site principal investigator and staff are responsible for identifying and reporting deviations. If protocol deviations are identified, corrective actions are to be developed by the site and implemented promptly. Protocol deviations must be reported to the IRB/EC per their guidelines.

   ~~Refer to the MOPS for the definition of protocol deviation and instructions for completing the study protocol deviation eCRF.~~

2. The date in the header of the protocol Version 3.0 is meant to be 13Dec2022.