DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
National Institute of Allergy
And Infectious Diseases
Rockville, MD 20852
5601 Fishers Lane

MEMORANDUM

DATE: April 6, 2020

FROM: Manizhe Payton, Director, DAIDS Office of Clinical Site Oversight (OCSO)
Bariatu Smith, Acting Branch Chief, DAIDS Monitoring Operations Branch (MOB), OCSO

TO: **NIAID/DAIDS** HIV/AIDS Network Leadership and Operations Center Principal Investigator, Clinical Trial Units (CTU) Principal Investigators, Non-Network Clinical Trial Principal Investigators, Clinical Research Sites (CRS) Leaders, CTU Coordinators, CRS Coordinators, HIV/AIDS Network Data Management Center Directors

SUBJECT: **Suspension of On-Site Monitoring Visits Extended Through May 15, 2020 and CRS QA Summary Report due June 2020 Eliminated**

Continued Suspension of On-Site Monitoring Visits Through May 15, 2020

The Coronavirus (COVID-19) pandemic situation is rapidly evolving. Due to our concern for the safety of research participants, site staff, and monitors, the DAIDS is extending the suspension of on-site monitoring visits for an additional 4 weeks. All monitoring visits conducted by PPD at DAIDS Clinical Research Sites (CRSs) under the NIAID Clinical Site Monitoring (NCSM) and PPD contract monitoring the PHOENIx protocol (A5300B/I2003B) will be suspended through **May 15, 2020.**

To maintain regulatory compliance and integrity of clinical trials data during this period, starting during the week of April 13, 2020, we are implementing limited remote monitoring. Remote monitoring will consist of the review of key regulatory documentation and electronic Case Report Forms (eCRFs) in the database by the PPD monitors. We recognize that there are limitations to remote monitoring and not all sites may be available to engage with the monitor remotely and/or sites may not be capable of providing requested documents. Sites will have the option to decline a remote monitoring visit.

What will be covered in Remote Monitoring?

- Review of Protocol Registration and IRB approval documents
- Review of temperature logs both in the pharmacies and labs
- Review of electronic case report form data in the EDC (Electronic Data Capture) system to identify protocol deviations, SAEs

- Review of various logs: Delegation of Duties (DoD), Training, Study Product Accountability and Informed Consent Form logs

Site staff will be contacted by your PPD monitor to schedule a date and time for the remote monitoring visit. The monitor will request that you Email/Fax specific regulatory documents including previously mentioned logs in advance of the remote visit. On the scheduled visit date, the monitor will initiate a telephone call (or mutually agreed upon communication platform), which is expected to last approximately 1.5-2 hours. During the remote visit, the monitor will complete various checklists and tools that have been developed to facilitate remote monitoring and will generate a Remote Site Monitoring Report (rSMR) per usual process. The rSMR will look similar to your usual on-site visit report but will clearly designate it as a "Remote Monitoring Visit"

Please note that eCRFs reviewed in the EDC system will be re-reviewed against the corresponding source documents when on-site monitoring resumes. Any potential monitoring citation identified during remote monitoring visits may change when additional source documents are reviewed on site.

We are also gathering information on electronic systems used by sites. PPD may contact you as they survey sites regarding Electronic Medical Records (EMRs) Systems and the possibility for remote access. Kindly respond directly to PPD and provide any known information requested.

CRS Quality Assurance (QA) Summary Report

Additionally, with limited CRS operations due to the COVID-19 pandemic, you are **NOT** required to submit the CRS QA Summary Report due on June 1, 2020. Your next submission will be due on December 1, 2020. In cases where participant follow-up visits are still occurring physically or remotely, we encourage sites to continue conducting Quality Assurance and Quality Control activities of their operations to ensure the integrity, completeness and quality of data being collected.

We are grateful for your continuing efforts and dedication during these unprecedented times.