



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

## MEMORANDUM

DATE: March 19, 2020

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

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

SUBJECT: **Coronavirus Disease 2019 (COVID-19) Guidance: Suspension of On-Site Monitoring Visits Conducted by PPD at DAIDS Clinical Research Sites**

Due to the COVID-19 pandemic and our concern for the safety of participants, site staff, and monitors, DAIDS is suspending all on-site monitoring visits globally for 4 weeks. We have explored alternative options for conducting remote monitoring, however due to specific system requirements coupled with limited site staff availability, this option was not feasible. Therefore, all monitoring visits conducted by PPD at DAIDS clinical research sites will be suspended beginning March 19, 2020 and this suspension will continue through April 17, 2020.

This suspension applies to all monitoring visits conducted under the NIAID Clinical Site Monitoring Contract and include monitoring visits for the PHOENIX protocol (A5300B/I2003B).

We recognize that routine research operations at sites are also changing to comply with COVID-19 precautions. In cases where participant follow-up visits are still occurring physically or remotely, we encourage sites to strengthen Quality Assurance and Quality Control (QA/QC) measures during this time when monitoring visits are suspended.

We will be closely monitoring the evolving COVID-19 situation, protocol activities and clinical site research operations and evaluate lifting the pause or modification to this directive in April.

We extend a very special appreciation to the site staff and community partners for your continuing efforts and dedication as we move through these challenges in the upcoming months and beyond.