



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

MEMORANDUM

DATE: May 11, 2020

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

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

SUBJECT: **Phased Approach to Resumption of On-Site Monitoring Visits**

As you know, due to the COVID-19 pandemic, all on-site monitoring visits are suspended through May 15, 2020. Remote monitoring visits were initiated and are continuing.

We recognize that DAIDS clinical research sites are in various stages of gradual re-opening. As part of resumption of operations, DAIDS is also planning for a phased approach to resumption of on-site monitoring visits. Initially, we plan to resume on-site monitoring visits on a case by case basis. We will work closely with your site to determine whether an on-site monitoring visit can be conducted. In order for an on-site monitoring visit to be considered, all of the following criteria must be met:

- Local travel (country, state, provincial, district) and governing authority restrictions lifted?
- Site/institution policies and guidelines must allow non-essential personnel to be on site
- Availability of site personnel to physically engage the monitor and provide participant records and other essential documents

On-site monitoring visits that cannot be conducted due to restrictions above will be converted to remote monitoring visits. In cases where all of the above criteria can be met, DAIDS will work closely with you to schedule an on-site monitoring visit.

We anticipate it may be necessary to conduct additional monitoring visits to address backlogs in monitoring.

We encourage you to contact your OCSO Program Officer, OCSO MOB at ocsomob@niaid.nih.gov and your PPD monitor when your site status aligns with the criteria to resume on-site monitoring.

We appreciate your continuing efforts and dedication during these challenging times.