



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

Date: 21 May 2020

From: Bola Adedeji, RPh, M.S. Deputy Director, Office of Clinical Site Oversight, Division of AIDS, NIAID *BA*

To: Clinical Trial Unit (CTU) Principal Investigators (PI), Non-Network Clinical Trial PIs, and Clinical Research Site Leaders at DAIDS HIV/AIDS Clinical Research Sites (CRS)

Subject: Guidance to Clinical Research Sites: Resumption of Operations during the COVID-19 Pandemic

The purpose of this memo is to provide guidance and important considerations to assist sites as they resume clinic operations for DAIDS sponsored research. We recognize that sites are at various stages of resuming operations due to the COVID-19 pandemic. Some sites have resumed partial on-site visits, while others are still conducting research operations remotely. We also recognize that *normal* may not look exactly the same as it did before the COVID-19 pandemic and we are committed to working with sites to address challenges as they bring their sites back. Our primary concern is for the safety of participants and the staff at our clinical research sites. Our secondary goal is to preserve the scientific integrity of the research protocols.

IRB/IEC

IRB/IEC approval must be in place for protocols at all time. Prior to resumption of in-person research visits, It may be necessary to secure IRB/IEC approval if required by your local IRB/IEC. Please ensure this documentation is maintained in your regulatory file. Any lapses in IRB/EC approval of protocols should be reported to the IRB/EC as well as the OCSO PO immediately.

Institutional Requirements

Procedures to prevent the spread of COVID-19 should be consistent with state, local and institutional guidelines. The procedures may include requirements for physical distancing in settings where research participants must wait. In addition, measures to protect healthcare workers including requirements for PPE, masking, and other protective measures should be followed. Other measures instituted by your institution to protect research participants, healthcare workers, and research staff should be observed.

Protocol Team Considerations

Protocol teams have issued specific guidance to sites related to modification of protocol procedures through clarification memos or letters of amendment. Depending on the protocol and the state of reopening the trial, we anticipate that LOAs may be issued to provide further guidance about resumption of activities. All LOAs must be submitted to the IRB/EC so we can manage the actions taken during this time. Sites should consider whether they can appropriately execute the protocol as written, including conducting the evaluations as outlined in an LOA or Clarification memo. In addition, considerations should be made for appropriate shipping, receiving and management of study products as well as the collection, shipping and storage of study specimens.

Network Considerations

Networks will independently lift the pause for enrollment into their protocols as appropriate, and sites should consider any guidance issued in accordance with Network requirements. Furthermore, in light of the various COVID-19 protocols open or in development within DAIDS' Networks, DAIDS and the Network Leadership Groups will work to appropriately prioritize clinical trial activity.

Country, State and Local Restrictions

We expect sites to comply with country, state or local jurisdiction requirements for re-opening clinical research operations. Sites should consider the timing, nature and extent of such guidance and make decisions as appropriate.

SARS-CoV-2 Testing

Requirements for screening participants must comply with institutional policies. As a reminder, unless required by the protocol, SARS-CoV-2 screening is not considered a DAIDS clinical research activity.

Clinical Site Monitoring

We are planning for a gradual resumption of on-site monitoring visits. We recently communicated with sites about our plan to phase-in monitoring visits, and your PPD monitor will be reaching out to you to determine the state of operations at your site and whether a monitoring visit can be accommodated. We are greatly appreciative of sites that have facilitated remote monitoring visits.

Additional considerations:

- We recognize that there may be a surge in study visits as you phase back operations. Please ensure that study supplies and staffing needs are adequate to accommodate participant visits
- Sites should assess their capacity and the appropriate time to participate in protocols considering their resources as they determine and prioritize which protocol(s) to resume/open
- Please check the expiration date, calibration and/or appropriateness of use on all study-needed equipment, products and supplies, prior to visits, to make sure they are still valid, and replace or update as necessary
- Communication between the clinic and pharmacy is critical around resumption of study visits to ensure adequate supply of study product. We encourage sites to develop innovative strategies to promote communication in these unusual times.
- Security and access to research records must be maintained during the transition to resumption of operations
- Sites should assess the continued adequacy of the facilities in which their studies are being conducted and seek institutional and/or DAIDS/OCSO approval as necessary if the site is planning to use additional clinic locations to conduct research activities. Please refer to the 08 May 2020 "**Use of Alternate/Adjunct Venues during the COVID-19 Pandemic**" DAIDS Memo to sites
- Sites should consider generating and implementing checklists or other tools to facilitate resumption of operations and account for above issues
- DAIDS/OCSO does not intend to provide official 'approval' to sites to resume/proceed with operations. We request that sites maintain documentation of how the decision was made to proceed with operations.

We continue to be impressed by the commitment and dedication of site staff during this time, and thank you for your responsiveness and your flexibility. We sincerely appreciate the dedication of all the investigators and research staff who are working tirelessly to maintain critical research operations during these difficult times.

Please reach out to your OCSO Program Officer with any questions.