DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

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March 13, 2020

TO: HIV/AIDS Network Leadership and Operations Center Principal Investigator(s), Clinical Trials Unit Principal Investigators, Clinical Research Site Leaders

FROM: Sarah Read, Deputy Director, Division of AIDS; Peter Kim, Director, DAIDS Therapeutics Research Program; Mary Marovich, Director, DAIDS Vaccines Research Program; Sheryl Zwerski, Director, DAIDS Prevention Sciences Program; Manizhe Payton, Director, DAIDS Office of Clinical Site Oversight

RE: ***Coronavirus Disease 2019 (COVID-19) and DAIDS HIV/AIDS Network Clinical Research Studies***

We are writing to provide guidance on the potential impact of the COVID-19 pandemic on DAIDS-sponsored clinical research studies. Our primary concern is the safety of research participants and the research team members at our clinical research sites. Our secondary goal is to preserve the scientific integrity of the research protocols.

In view of the rapidly evolving nature of this pandemic and the required response by public health authorities and institutions, we ask that network leadership, protocol teams, and sites maintain strong communication channels with each other and with DAIDS to facilitate optimal, and where reasonable, standardized approaches to common issues related to protocol implementation.

DAIDS understands that the COVID-19 pandemic is impacting various regions and locations in different ways and we are cognizant of the need for local decisions and actions to ensure the safety of the community. To facilitate an expeditious response to the evolving pandemic, DAIDS will do our best to account for and accommodate the requirements and guidance(s) issued by local public health authorities and institutions. Furthermore, we will expedite the review of clarification memos (CMs), letters of amendment (LOAs), and protocol amendments needed to address the impact of the COVID-19 pandemic on the implementation of protocols.

Additionally, the ability of DAIDS contract resources such as site, pharmacy and lab monitoring and support may be limited due to travel restrictions, safety considerations and other related issues. DAIDS will keep relevant parties informed of such limitations and work with the network leadership, sites and labs to develop alternative strategies to ensure the quality of our clinical trials.

The guidance below is based on our current understanding of the pandemic and may change as the epidemiology of the pandemic evolves and new information becomes available.

March 13, 2020

Network Leadership

- Network leadership groups should develop communication plans to ensure that site investigators, protocol teams, and DAIDS are properly notified as issues and changes to the conduct of studies are required and implemented.
- Consideration should be given to delaying the opening of new protocols at this time. Factors such as participant safety, site staff safety, and availability of site and lab personnel and resources should be considered before a decision is made to open a study.
- DAIDS reserves the right to delay the opening of a protocol as needed to ensure the safety of all involved, to maintain the integrity of the trial, and as dictated by the availability of contractual resources to effectively oversee the protocol.
- Networks should document decisions, actions and directives to stakeholders appropriately
- Networks are encouraged to share this guidance with protocol teams and other relevant individuals within their Network as appropriate.

Protocol Teams

- Based on any current disruptions and the potential for future disruptions to study implementation at sites and labs, protocol teams should consider developing contingency plans; these plans may or may not result in changes to the protocol and/or operations. Consideration should be given to the specific aims of the protocol, protocol interventions, participant population and other contextual factors. These changes may include but are not limited to mode of visit, visit schedules, visit window, investigational study product dispensation procedures, laboratory and other testing schedules. For example, visit windows may be broadened, visits may be performed virtually or not at all to enable greater flexibility for sites and as required by local institutions.
- Contingency plans for wide scale disruption of study visits should be considered and developed in conjunction with the DAIDS protocol Medical Officer.
- Communication to site investigators should be made, as appropriate, regarding any special considerations (e.g. key safety labs) that need to be addressed if and when research visits need to be delayed or canceled. Safety should be prioritized.
- The possibility and impact of temporarily stopping new enrollments into the protocol should be considered.
- Protocol teams should consider the appropriate vehicle for making changes to the protocol as needed including the use of protocol amendments, LOAs, and clarification memos following the previously defined DAIDS guidance.
- Importantly, all decisions should be clearly documented.

Site Staff

- We acknowledge that institutions may have developed guidance for their organizations to ensure that the environment is as safe as possible when participants come in for a research visit. As such, sites should comply with any guidance provided by their local institutions, IRB/EC and/or local health departments. When conflict exists between local directives, DAIDS policies/guidance(s), or protocol requirements, sites should comply with the requirement that is the most protective towards research participants and site staff.
- Site staff should notify the protocol team as well as the OCSO Program Officer (PO) as soon as possible when local policies or participant safety requirements prevent them from implementing protocol requirements. Documentation and notification of protocol deviations should occur in accordance with protocol requirements.
- Protocol modifications issued by DAIDS to eliminate immediate risks to participant safety (i.e. protocol CMs, LOAs, and amendments) may be implemented immediately and concurrently with submission for IRB/EC approval unless otherwise stipulated by the local IRB/EC. Sites should follow the protocol registration policy for notifying the Protocol Registration Office of IRB/EC approvals.
- Sites may consider implementing processes to prevent or properly prepare for in-person research visits by participants who may have COVID-19. Examples include communicating with participants prior to the research visit to triage for signs/symptoms of COVID-19.
- The site pharmacist or investigator should communicate with the DAIDS protocol pharmacist if changes to the process for dispensation of investigational study product are needed to ensure participant/staff safety or accommodate institutional requirements.
- Sites should consider whether they have the resources to continue enrolling new participants for any given protocol and prior to opening a new protocol.
- Sites should contact their DAIDS OCSO PO if institutional restrictions may impact the ability of DAIDS clinical research monitors to conduct monitoring visits at the sites. In these cases, OCSO POs will work closely with the site to strengthen quality management procedures or implement other oversight measures during this time.
- It is recognized that lab personnel and resources may have to be diverted to service the diagnostic needs of the current pandemic. Sites should communicate to network leadership, protocol teams, and the DAIDS OCSO Program Officer if their capacity for protocol specific testing is limited.
- Site staff are encouraged to share this guidance with relevant individuals within their sites, pharmacies and labs as appropriate.

DAIDS recognizes and is grateful for the dedication of all the investigators and research staff who are working tirelessly to maintain critical research operations during these difficult times. This is a rapidly evolving situation, and we are committed to clear and timely communication. We will update you with further guidance as it is received. Please contact your DAIDS representative in the Scientific Research Programs with any questions about this guidance.