DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

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

To: **CTU PIs and CRS Leaders at DAIDS HIV/AIDS Clinical Research Sites**

Subject: **Use of Alternate/Adjunct Venues during the COVID-19 Pandemic**

The purpose of this memo is to provide guidance to sites on the elements of an alternate/adjunct venue requiring site consideration. The extremely infectious nature of the SARS-CoV-2 has forced many of our sites to modify the way in which their clinical research site operations are conducted. Modifications may include the use of alternate/adjunct venues in an effort to reduce the risk of transmitting the virus.

What is a Venue?

A venue is considered an extension of a DAIDS-approved clinical research site which is co-located at the same address as the clinical research site. Sites have the flexibility to use outside spaces, tents, garages or other appropriate *venues* when interacting with participants during the COVID-19 pandemic. Use of these venues must be consistent with protocol requirements and comply with institutional policies, national, state, and other local guidance, and relevant approvals must be secured, if required.

DAIDS Involvement in Venues

Sites should extend the same precautions and protections as they typically would, when interacting with participants at venues. Sites must consider the following in their use of these venues:

- Participant safety and confidentiality
- Research staff safety
- Study product integrity including cold-chain management and chain of custody
- Specimen handling and integrity including chain of custody
- Data confidentiality and integrity including security and chain of custody for participant records

DAIDS approval is **not necessary** for the use of these types of venues within and around the CRS premises. However, sites must document how these venues are being used in their study records.

What is NOT Considered a Venue?

If the CRS plans to use additional locations at an address that differs from their DAIDS-approved CRS, then, this is not considered a venue. These would be considered additional locations for which DAIDS prior approval must be obtained, and these additional locations must be documented on the FDA Form 1572 or Investigator of Record Agreement Form. *Recruiting* participants from these additional locations without conducting any study procedures does not constitute the use of an additional location.

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. We recognize flexibility is necessary and are committed to working with you to facilitate research activities at your site during this pandemic. 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.

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