**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

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

**5601 Fishers Lane**

Date: September 8, 2021

From: Manizhe Payton, Director, Office of Clinical Site Oversight
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TO: NIAID/DAIDS HIV/AIDS Network Leadership, Operations Center Principal Investigator(s), Clinical Trial Unit (CTU) Principal Investigators, Clinical Research Site (CRS) Leaders, CTU Coordinators, CRS Coordinators, Data Management Center Directors

**RE: New DAIDS Requirement for Clinical Research Sites: Co-Enrollment Prevention SOP**

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In the fourth quarter of 2021, DAIDS will be introducing a new requirement related to co-enrollment prevention, which is closely related to the age and identity verification process requirement implemented in January 2021.

Co-enrollment is defined as enrollment of a participant in more than one clinical trial or in the same clinical trial at multiple locations. Specifically, the term refers to co-enrollment that is prohibited by protocol eligibility criteria. Where prohibited, co-enrollment can cause harm to the participant and can adversely impact the integrity of study data. DAIDS clinical research sites (CRSs) have experienced a number of prohibited co-enrollments over the past grant cycle, and this requirement will improve participant safety and study data integrity.

The requirement will apply to all CRSs participating in DAIDS-sponsored research within the DAIDS Clinical Trial Networks. Each CRS must develop, implement, and maintain a robust procedure that describes how the CRS will identify and prevent co-enrollment in DAIDS clinical trials and other non-DAIDS clinical trials to the extent possible. SOPs can stand alone or this content can be included in other related site SOPs at the site's discretion. Co-enrollment prevention SOPs should be in place no later than January 1, 2022. The following additional information and resources for sites will be added to the SCORE Manual in the Screening, Enrollment/Randomization, and Unblinding section.

1. Expansion of the Co-enrollment Prevention section on pages 5-7

2. Addition of 3 new appendices and frequently asked questions (FAQs):
    - CRS Guidance for Developing a Co-Enrollment SOP - Describes content that sites should consider adding to their SOPs, and provides guidance on assessing the risk of co-enrollment.
    - Template for Co-Enrollment Prevention SOP –Provides content already formatted for sites to easily use when creating their SOP, even if they use an institutional template. This template is optional and made available as a resource to assist sites with creating their SOP. Sites are not required to use this template.

- Template Letter to the IRB/EC – Provides background and rationale for why DAIDS is requesting the SOP be submitted for review/approval by the IRB/EC or other institutional body. This template is optional and made available as a resource to assist sites with communicating with their IRB/EC. Sites are not required to use this template letter.
- Co-Enrollment Prevention FAQs

In addition, the following change will be made to the Quality Management section of the SCORE Manual:

1. Revision of the Appendix: List of SOPs required at DAIDS CRSs to include Co-enrollment Prevention SOP.

The DAIDS team has worked with the HIV/AIDS Network leadership and stakeholders to inform our approach to this new requirement.

We anticipate the new and updated documents will be available in the SCORE Manual on the NIAID website on Monday, September 20th. A webinar on the Co-enrollment Prevention requirements will be held on Tuesday September 28th. Individuals must sign up in advance – the sign-up information is included in the notification email from HANC that contains this memo. This webinar will be recorded and posted on the HANC website for those who cannot attend.

We recognize the tremendous efforts our sites have made to comply with DAIDS requirements through the transition to the new grant cycle, and the many priorities being managed during the COVID-19 pandemic. We also realize the impact of adding a new requirement at this time is not insignificant, but we are willing to be flexible and work with sites to help put this requirement in place. We believe it will strengthen the integrity of our clinical trials and our responsibility for ensuring participant safety. If you have any questions about these changes, please reach out to your OCSO Program Officer.