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: 5 December 2025

From: Manizhe Payton, Director, Office of Clinical Site Oversight

MANIZHE E. PAYTON -S

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Date: 2025.12.05 08:49:37 -05'00'

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: ***DAIDS SCORE Manual Updates Released on 9 November 2025***

We are writing to let you know that DAIDS revised the following sections of the SCORE Manual to align with internal formatting requirements.

- ***Delegation of Duties Log***
- ***Pharmacy Requirements***
- ***Electronic Systems***
- ***Laboratory Requirements***
- ***List of SOPs Required at CRSs***
- ***DAIDS Protocol Registration & IRB/EC Communications***
- ***Protocol Compliance***
- ***Premature Termination or Suspension of a Clinical Trial***

The updated sections and appendices are now available on the NIAID website and took effect on 9 November 2025. Our intent was only to modify the format of the documents and not change their content in any manner. Unfortunately, the extended government shutdown created unintended downstream impacts that affected the timing and quality of this release. Specifically:

- Planned communications to sites notifying them of these changes could not be executed.

- We were later informed that errors appeared in the following sections which were posted to the NIAID external facing website on 9 October 2025:
    - ***Delegation of Duties Log***
    - ***List of SOPs Required at CRSs***
    - ***Premature Termination or Suspension of a Clinical Trial***

Now that normal operations are resuming, we are actively addressing these issues. Corrections will be published to the SCORE Manual site as soon as possible.

In the interim, we are providing the following guidance to support your ongoing work:

Delegation of Duties (DoD) Log

The DoD Log is intended as a template; sites may adapt it to meet protocol-specific and site-specific needs. Until the corrected version is posted, sites may reinstate the following original text in the **Significant Study-Related Duties table** on page 3 of 18:

5. Enters/Manages Data
6. Manage Regulatory Documents/Submissions
7. Perform significant study specific assessments*

The updated log includes version control in the header to help sites track future changes. If your site makes modifications, please add your own version date to distinguish it from the currently posted SCORE Manual version.

List of SOPs Required at CRSs

- Sites are <u>not</u> required to re-establish any previously required SOPs.
- Sites should continue to submit any substantial revisions made to the four (4) SOPs requiring OCSO review and approval:
    - *Informed Consent/Assent Process and Documentation*
    - *Process for Enrolling Children and Adolescents into DAIDS Clinical Research*
    - *Clinical Quality Management Plan (CQMP)*
    - *CRS Regulatory Inspection Preparation*
- Sites must submit and maintain documentation of IRB review and/or acknowledgement for the following SOPs:
    - *Clinical Research Site (CRS) Process to Verify Participant Age and Identity*
    - *CRS Process to Identify and Prevent Co-Enrollment*

Premature Termination or Suspension of a Clinical Trial

- Sites should be aware that HIV/AIDS Networks have the authority to initiate suspension of clinical research activities at sites when quality performance issues are identified that may significantly impact patient safety and data integrity.

We sincerely apologize for any confusion caused by the release of these SCORE Manual sections and appreciate your patience and partnership as we work to correct the affected materials. We will keep you informed about upcoming revisions and welcome any feedback that helps ensure the SCORE Manual remains a clear, valuable, and accessible resource for our research partners.

Please reach out to your Program Officer with any questions about the SCORE Manual.