



National Institutes of Health  
National Institute of Allergy  
and Infectious Diseases  
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From: Manizhe Payton, Director, Office of Clinical Site Oversight

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: *Updates to DAIDS SCORE Manual – Release #3 of 3*

As described in memo, *Informational Update: Upcoming DAIDS SCORE Manual Releases – Impact to Site*, issued on 18 June 2025, DAIDS has been working to transition all sections of the SCORE Manual to our internal document control system which requires re-releasing all sections in a new format. The final release of remaining sections is expected to be published on 15 May 2026 on the NIAID website. In addition to the transition to our internal document control system, this release also focuses on aligning the SCORE Manual with International Council for Harmonisation Good Clinical Practice (ICH GCP) E6(R3) and minor content updates. There are no significant changes to DAIDS requirements as part of these updates. A detailed summary of changes is posted on the HIV/AIDS Networking Coordination Resources Site as a supplement.

- *Introduction to DAIDS Systems*
- *Investigator Responsibilities*
- *Clinical Research Site (CRS) Personnel Qualifications, Training, and Responsibilities*
- *Guidance on Completion of DoD Log*
- *DAIDS Delegation of Duties Log*
- *Clinical Research Site (CRS) Facilities Requirements (Clinic, Laboratory, and Additional Locations)*
- *Source Records and Documentation*
- *Source Records Requirements*
- *Essential Records*
- *Recordkeeping for Essential Records*
- *Quality Management*
- *Informed Consent of Participants*
- *CRS Requirements for Enrolling Minors into DAIDS Clinical Research*
- *Screening, Enrollment/Randomization, and Unblinding of Participants*
- *Site Visits*
- *Clinical Research Site Inspection Readiness*
- *Guidance on Site Regulatory Inspection*
- *CRS Inspection Preparation Checklist*

The updated sections and appendices will be effective on 28 June 2026. We will provide an update once the revised sections and appendices are available on the NIAID website.

If you have any questions about these changes, please reach out to your [OCSO Program Officer](#).