



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

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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: ***Final Publication DAIDS SCORE Manual – Release #3 of 3***

The final revised sections integrating the SCORE Manual into DAIDS internal document control system are now available on the NIAID website. This release incorporates minor content changes and ICH GCH E6 (R3) updates. Please take time to orient site staff and update site-specific processes as needed. As a reminder a detailed summary of changes is available on the HANC website. The updated sections and appendices will be effective on 28 June 2026.

- ***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***

If you have any questions about these changes, please reach out to your OCSO Program Officer.