



National Institutes of Health
National Institute of Allergy
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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: ***Minor Updates to DAIDS SCORE Manual Sections: Investigator Responsibilities, Essential Documents, Essential Documents Recordkeeping Appendix, CRS Facility Requirements, Site Activation Process, Source Documentation Requirements Appendix and Record Retention Flowchart***

DAIDS has made the following updates to the Site Clinical Operations and Research Essentials (SCORE) Manual.

1. To ensure alignment with current DAIDS policy, regulations, and ICH E6 (R2), revisions have been made to the **Investigator Responsibilities** (page 5), **Essential Documents** (page 5) and **Essential Documents Recordkeeping Appendix** (page 1) sections to describe the requirement for Investigators to maintain a complete set of signed and dated eCRFs for each study for which they are the Investigator of Record.
2. Additional revisions were made to the **Essential Documents** section to include revision of the definition of a clinical research record (page 5).
3. Revisions to the **CRS Facility Requirements** section (page 5) include revised language to distinguish required vs. recommended attributes for a record storage facility.
4. Minor revisions to the **CRS Facility Requirements** (page 6, 7) and **Site Activation Process** (page 4) sections to clarify the definition of an Additional Location and to describe the process for requesting the use of an Additional Location from DAIDS/OCSO.
5. Minor revisions to the **Source Document Requirements Appendix** (Page 6) to clarify how certified copies can be made when multiple pages are being copied as part of a packet.
6. Revisions to the **Record Retention Flowchart Appendix** to ensure alignment with requirements of the Code of Federal Regulations and ICH GCP.

These updates to the SCORE Manual are effective as of 16MAY2022 and the revised sections are now posted to the [NIAID website](#). If you have any questions about these changes, please reach out to your OCSO Program Officer.