



National Institutes of Health  
National Institute of Allergy  
and Infectious Diseases  
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Date: November 1, 2024

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

**RE: Updated DAIDS Requirement: Submission of 4 SOPs upon substantial revision  
SCORE Manual Updates November 4, 2024  
New SCORE Manual Search feature**

DAIDS has revised several sections of the SCORE Manual and added a search feature as detailed below.

These changes are effective November 4, 2024, and are now available on the NIAID website. If you have any questions about these changes, please reach out to your OCSO Program Officer.

**Minor expansion to OCSO SOP review process:**

Currently, Informed Consent, Enrollment of Minors, Regulatory Inspection Readiness, and CQMP SOPs are submitted to DAIDS for initial review and approval during OCSO site activation. CQMPs are also submitted to DAIDS for subsequent substantial revisions.

Beginning December 1, 2024, DAIDS will require that any subsequent substantial revisions to these SOPs also be submitted to the OCSO PO for review and approval. Substantial revision includes any change in site procedure or policy, but would not include minor typographical, grammatical, or administrative changes.

Related information and supporting documentation will be added to the [SCORE Manual](#) in the Quality Management section and the Appendix: List of SOPs required at DAIDS CRSs.

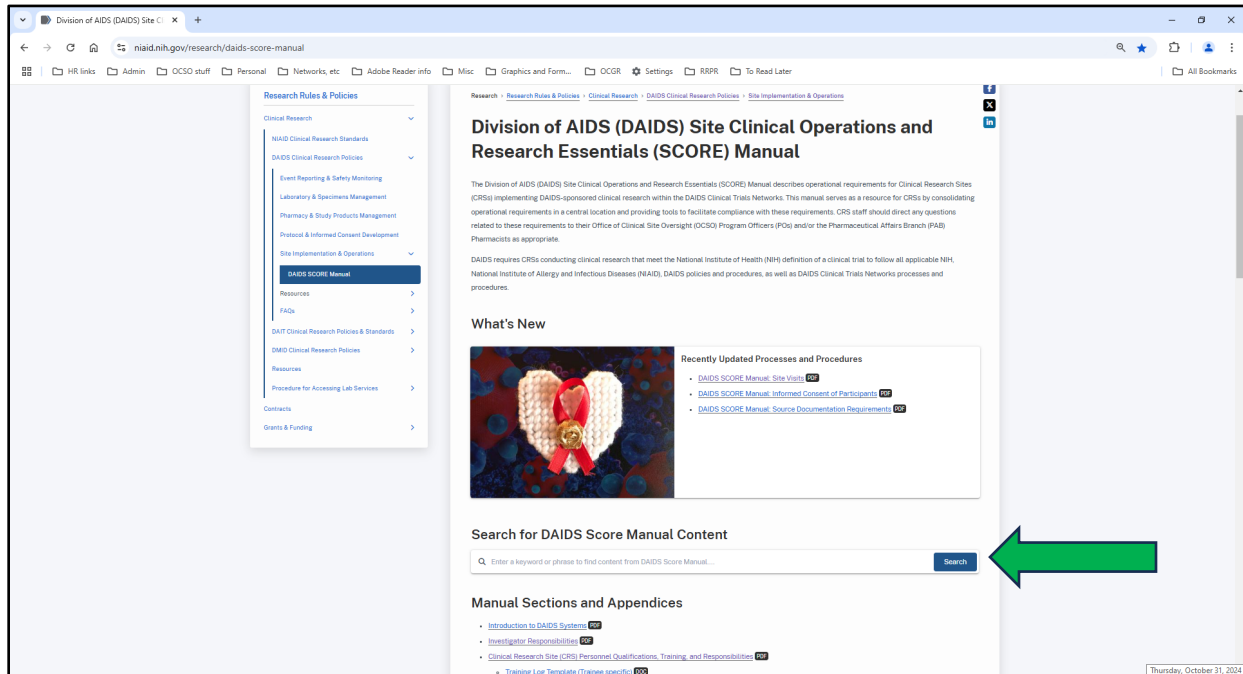
**Additional updates to the SCORE manual:**

SCORE Manual Section/ Appendix	Changes
Investigator Responsibilities V3.0	Clarified requirements for timing of eCRF sign-off by the IoR.
Appendix – Requirements for Enrolling Minors V2.0	Removed requirement for CRS to submit SOP for Enrolling Minor for IRB/EC review.
CRS Facilities Requirements V3.0	Reflects changes in types of visits DAIDS will conduct as part of Site Activation. Site Assessment Visits (SAV) will replace Site Initiation Visits (SIVs).  Reflects the addition of Additional Location (AL) content previously in the Site Activation section.

SCORE Manual Section/ Appendix	Changes
Appendix – List of SOPs required at DAIDS CRSs V4.0	<p>Notes the new requirement for 4 SOPs submitted to DAIDS to also be submitted in the future for any substantial changes.</p> <ul style="list-style-type: none"> <li>• CQMP</li> <li>• Informed Consent</li> <li>• Enrolling Minors</li> <li>• Regulatory Inspection Readiness</li> </ul> <p>Added note about submitting two SOPs to local IRB/ECs for approval.</p> <ul style="list-style-type: none"> <li>• Co-enrollment Prevention</li> <li>• Age &amp; Identity Verification</li> </ul>
Quality Management V2.0	<p>References the QA Summary Report Template now provided in excel format instead of fillable pdf. Fillable PDF version obsolete.</p> <p>Addition of new requirement to submit initial and subsequent versions of 4 SOPs to DAIDS for review and approval – Informed Consent Process, Enrolling Minors, CRS Regulatory Inspection Readiness, CQMP.</p>
Appendix Guidelines for CRS staff on Preparing the Bi-annual Quality Assurance Summary Report_V2.0	Updated to include instructions specific to the excel version of the QA Summary Report template.
Clinical Quality Management Plan: CRS QA Summary Report (excel version)	Excel version is posted on the SCORE manual site and replaces the pdf version.
Site Visits 3.0	<p>Updated the types of site visits.</p> <p>Site Assessment Visits (SAV) will replace Site Initiation Visits (SIVs).</p> <p>Updated “Quality Management Audits” section terminology and types of visits.</p> <p>Added “CRS Regulatory Inspection Readiness Visit” section.</p>
Site Activation: OBSOLETE	<p>Section has been obsolete and removed from the SCORE Manual.</p> <p>New sites will receive information from their OCSO PO on site activation requirements, while established sites will not need to review these requirements.</p> <p>Details on Additional Locations (AL) have been moved to the CRS Facilities Section.</p>
Clinical Quality Management Plan: CRS QA Summary Report (pdf version): OBSOLETE	Has been replaced by the excel version of the template.
Clinical Quality Management Plan: CRS QA Summary Report – Section 4 – additional lines (pdf version): OBSOLETE	Has been replaced by the excel version of the template.

## New SCORE Manual Search Feature:

DAIDS would also like to announce the addition of a search bar for the SCORE manual – it is located below the “What’s New” box and above the listing of sections. This new feature will specifically search and return relevant results from all sections, appendices, and FAQs in the SCORE manual. Please try it out and send any feedback to your OCSO PO.



The screenshot shows a web browser window displaying the DAIDS SCORE Manual page. The browser's address bar shows the URL [niaid.nih.gov/research/daids-score-manual](https://niaid.nih.gov/research/daids-score-manual). The page features a navigation menu on the left with categories like "Research Rules & Policies", "Clinical Research", and "Site Implementation & Operations". The main content area is titled "Division of AIDS (DAIDS) Site Clinical Operations and Research Essentials (SCORE) Manual". Below the title, there is a "What's New" section with a heart icon and a "Recently Updated Processes and Procedures" list. A search bar is located below the "What's New" section, with the text "Search for DAIDS Score Manual Content" and a search button. A green arrow points to the search button. Below the search bar is a section titled "Manual Sections and Appendices" with a list of links. The date "Thursday, October 31, 2023" is visible in the bottom right corner.