

 National Institute of Allergy and Infectious Diseases	Document Number: DAIDS-OCS-A28-MAN-00009	Revision Number: 01
Division of AIDS	Effective Date: 09 Nov 2025	Page: 1 of 4
Document Title: SCORE Manual: Electronic Systems		

Division of AIDS (DAIDS) Site Clinical Operations and Research Essentials (SCORE) Manual: Electronic Systems

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ELECTRONIC SYSTEMS

DAIDS has an [Electronic Information Systems](#) (EIS) policy that describes the requirements for electronic systems used in the conduct of DAIDS clinical trials and applies to:

- DAIDS Clinical Trials Networks
- Contract Research Organizations (CROs).
- Data Management Centers (DMCs).
- Staff for Clinical Trial Units (CTUs) and Clinical Research Sites (CRSs).
- Principal Investigators/Investigators of Record (PIs/IoRs).

Electronic systems that fall under the scope of this policy include systems from which clinical trial data may be submitted to the United States (U.S.) Food and Drug Administration, European Medicines Agency, or any other regulatory authorities.

Refer to DAIDS EIS policy and appendix, [Requirements for Using Electronic Information Systems in Clinical Research](#), for complete details of DAIDS' requirements. The policy includes an [Electronic Information System Evaluation Checklist](#), which serves as a tool for the user as well as for DAIDS staff to assess compliance with 21 Code of Federal Regulation (CFR) Part 11. The appendix addresses how data quality elements can be satisfied where electronic systems are being used to create, modify, maintain, archive, retrieve, or transmit research study data. [Frequently Asked Questions \(FAQ\)](#) exist to address commonplace policy-related issues and/or technical questions.

REFERENCES

1. [U.S. Code of Federal Regulations, Title 21, Parts 11 and 312](#)
2. [International Council for Harmonisation Good Clinical Practice \(ICH E6\)](#)
3. [DAIDS-OD-A-POL-00015, DAIDS Electronic Information Systems \(EIS\) policy](#)
4. [DAIDS Requirements for Using Electronic Information Systems in Clinical Research](#)
5. [DAIDS Electronic Information System Evaluation Checklist](#)
6. [DAIDS Electronic Information Systems \(EIS\) policy – Frequently Asked Questions](#)
7. [U.S. Food and Drug Administration \(FDA\) Draft Guidance for Industry, Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11- Questions and Answers, October 2024](#)
8. [FDA Guidance for Industry - COMPUTERIZED SYSTEMS USED IN CLINICAL TRIALS, 1999](#)
9. [FDA General Principles of Software Validation; Final Guidance for Industry and FDA Staff, 2002](#)
10. [FDA Guidance for Industry, Electronic Source Data in Clinical Investigations, 2013](#)
11. [FDA Guidance for Industry, Electronic Records: Electronic Signatures – Scope and Application, 2003](#)
12. [FDA Use of Electronic Informed Consent in Clinical Investigations, Questions and Answers, 2016](#)

REVISION SUMMARY

Revision/ Version	Summary of Changes
V1.0	Original Version and became effective on 1/19/2021.
01	DAIDS-OCS-A28-MAN-00009 rev 01 is the first revision of this manual in the MasterControl system. The document numbering and format have been updated to meet current requirements.