NIH National Institute of Allergy and Infectious Diseases	Document Number: **DAIDS-OD-A-POL-00015**	Revision Number: **01**
Division of AIDS	Effective Date: **25 Apr 2025**	Page: **1** of **9**
Document Title: **Electronic Information Systems Policy**		

Table of Contents

National Institute of Allergy and Infectious Diseases	Document Number: **DAIDS-OD-A-POL-00015**	Revision Number: **01**
Division of AIDS	Effective Date: **25 Apr 2025**	Page: **2** of **9**
Document Title: **Electronic Information Systems Policy**		

1.0 PURPOSE

1.1 This policy provides guidance and recommendations to NIAID Clinical Trials Networks, contract/clinical research organizations (CROs), data management centers, clinical research sites and clinical Investigators regarding the use of electronic information systems in clinical research trials conducted by the NIAID Clinical Trials Networks.

1.2 This Policy may be used in conjunction with two tools: Appendix A: DAIDS-OD-A-GUD-00004, Requirements for using Electronic Information Systems in Clinical Research and Appendix B: DAIDS-OD-A-GUD-00005, Electronic Information System Evaluation Checklist.

- Appendix A details the elements necessary to ensure the electronic information systems used in support of this policy are in full compliance with 21 CFR Part 11 and other applicable regulatory requirements. Refer to Appendix A for more detailed information regarding the contents of this policy.

- Appendix B is an optional internal checklist which serves as a tool to help document compliance to 21 CFR Part 11.

2.0 SCOPE

2.1 This policy describes the requirements for electronic information systems used in the conduct of NIAID DAIDS Network studies conducted within the Clinical Trials Networks, unless otherwise specified in a formal agreement. Electronic information systems that fall under the scope of this policy include systems from which clinical trial data (including 3rd Party data) may be submitted to the FDA, EMA or any other regulatory authorities or systems that collect, manage, store, or generate data that can be used to reconstruct a clinical trial. The term "Electronic Information System" applies to systems that produce records in electronic form that create, modify, maintain, archive, retrieve, or transmit clinical or other data required to be maintained for, or submitted to the FDA, EMA or any other regulatory authorities. The principles in this policy are applicable when electronic records are created (1) in hardcopy and later entered into an electronic information system, (2) by direct entry by a human into an electronic information system, and (3) automatically by an electronic information system via a content management system.

2.1.1 Examples of electronic information systems for electronic records:

- TMF/eTMF
- Software versioning system
- Content management systems
- Electronic signature systems

2.1.2 Examples of Direct Data Capture systems:

- Mobile devices, Mobile platforms/applications (apps), Laptops, Tablets

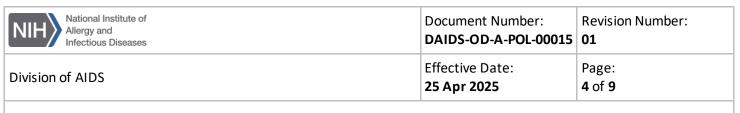| ![NIH Logo] National Institute of Allergy and Infectious Diseases	Document Number: **DAIDS-OD-A-POL-00015**	Revision Number: **01**
Division of AIDS	Effective Date: **25 Apr 2025**	Page: **3** of **9**
Document Title: **Electronic Information Systems Policy**		

Note: This refers to direct data input from mobile telephones via an application (app), as the app would be within the scope of the policy.

- Clinical outcome assessments (eCOAs), electronic participant diaries, Patient - Reported Outcomes (ePROs), Personal Digital Assistants (PDAs)

- Telecommunication applications systems (apps), used to collect data via Short Message Service (SMS), online surveys, etc.

- Electronic Health Record (EHR) systems when integrated with Electronic Data Capture (EDC) systems and when records will be included as part of a clinical trial.

- Interactive Voice/Web Response Systems (IVRS/IWRS)

- Electronic Clinical Data Management System (eCDMS)

- Electronic Informed Consents (eICs)

- Data from Laboratory Information Systems (LIMS)

- Direct digitized data, such as data from, blood pressure monitors, electrocardiogram (ECG) machines, etc.

- Central image readings (such as from Magnetic Resonance Imaging (MRI), X-ray, or other scanning systems).
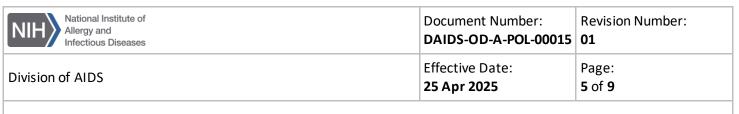
3.0 DEFINITIONS

For additional definitions, see [DAIDS glossary](#)

3.1 Acronyms:

- App(s) Application(s)
- CRO Contract/Clinical Research Organization
- CRS Clinical Research Site
- CTU Clinical Trial Unit
- DAIDS Division of AIDS
- DMC Data Management Center
- eCDMS Electronic Clinical Data Management System
- ECG Electrocardiogram
- eCOA Electronic Outcome Assessment
- eCRF Electronic Case Report Form
- EDC Electronic Data Capture
- EHR Electronic Health Records
- eIC Electronic Informed Consent
- ePRO Electronic Patient-Reported Outcome
- eTMF Electronic Trial Master File
- IoR Investigator of Record

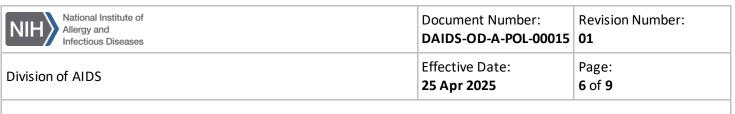| ![NIH National Institute of Allergy and Infectious Diseases]	Document Number: **DAIDS-OD-A-POL-00015**	Revision Number: **01**
Division of AIDS	Effective Date: **25 Apr 2025**	Page: **4** of **9**
Document Title: **Electronic Information Systems Policy**		

- IVRS   Interactive Voice Response System
- IWRS   Interactive Web Response System
- LC   Laboratory Center
- LIMS   Laboratory Information Management System
- LOC   Leadership and Operations Center
- MRI   Magnetic Resonance Imaging
- NIAID   National Institute of Allergy and Infectious Diseases
- OCSO   Office of Clinical Site Oversight
- PDA   Personal Digital Assistants
- PI   Principal Investigator
- PO   Program Officer
- QMP   Quality Management Personnel
- SDMC   Statistical and Data Management Center
- SMS   Short Message Service
- SOP   Standard Operating Procedure

3.2   **Audit Trail:** Documentation that allows reconstruction of the course of events. (ICH E6)

3.3   **Case Report Form (CRF):** A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject.

3.4   **Commercial Off the Shelf (COTS):** Commercially available ready-made systems that are purchased and adapted as necessary.

3.5   **Data Originators:** The original source of data. Each data element is associated with an origination type that identifies the source of its capture in the eCRF. This could be a person, a computer system, a device, or an instrument that is authorized to enter, change, or transmit data elements into the eCRF (also sometimes known as an author). (FDA) Examples of data originators include:

- Clinical investigators and delegated clinical study staff

- Participants or their legally authorized representatives

- Ancillary services representatives or other consultants such as radiologists, neurologists, etc.

- Devices such as electrocardiography (ECG) or blood pressure machines

- Electronic Health Records (EHRs)

- Automated laboratory reporting system

- IRT (Interactive Response Technology) web-based Randomization systems

3.6   **Direct Entry:** Recording data where an electronic record is the original capture of the data.

![NIH logo] National Institute of Allergy and Infectious Diseases	Document Number: **DAIDS-OD-A-POL-00015**	Revision Number: **01**
Division of AIDS	Effective Date: **25 Apr 2025**	Page: **5** of **9**
Document Title: **Electronic Information Systems Policy**		

3.7 **Electronic System:** Computer hardware, software, and associated documents (e.g., user manual) that create, modify, maintain, archive, retrieve, or transmit in digital form information related to the conduct of a clinical trial. (FDA)

3.8 **Electronic Data Capture (EDC) systems** — Electronic systems designed to collect and manage clinical trial data in an electronic format into the electronic case report form (eCRF). Data entered onto the eCRF may be derived from a variety of sources including electronic health record systems (EHRs). (DAIDS).

3.9 **Electronic Health Record (EHR):** An electronic record for healthcare providers to create, import, store, and use clinical information for patient care, according to nationally recognized interoperability standards. NOTE: The EHR has the following distinguishing features: able to be obtained from multiple sources, shareable, interoperable, accessible to authorized parties. (FDA).

3.10 **Electronic Record:** Any combination of text, graphics, data, audio, pictorial, or any other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system. (FDA).

3.11 **Electronic Source Data:** The data that are initially recorded in an electronic format. (FDA)

3.12 **Encryption:** Encoding information in a way that only authorized individuals may access it.

3.13 **In-House Software:** Software developed internally to the organization often by experts found within the company.

3.14 **Interoperability:** The ability of two or more products, technologies, or systems to exchange information and to use the information that has been exchanged without special effort on the part of the user. Fully integrated systems allow clinical investigators to enter research data directly into the EHR. (FDA)

3.15 **Purchased Software:** Software developed and sold by a third-party. Purchased software can include physical property run locally or Software as a Service.

3.16 **Risk Mitigation:** A strategy and steps taken to reduce or eliminate a risk or potential risk to data or systems integrity.

3.17 **Software as a Service (SaaS):** Software available by subscription and centrally hosted by a third-party provider; a form of cloud computing.

3.18 **Software Validation:** Confirmation by examination and provision of objective evidence that software specifications conform to user needs and intended uses, and that the requirements implemented through the software can be consistently fulfilled. (FDA)

3.19 **User Acceptance Test (UAT):** A testing protocol to verify the system performs as required.

4.0 RESPONSIBILITIES

4.1 **DAIDS/Sponsor:**

4.1.1 Program Officer:

![NIH logo] National Institute of Allergy and Infectious Diseases	Document Number: **DAIDS-OD-A-POL-00015**	Revision Number: **01**
Division of AIDS	Effective Date: **25 Apr 2025**	Page: **6** of **9**
Document Title: **Electronic Information Systems Policy**		

The *DAIDS Network Leadership Grant Program Officer (PO)* is responsible for approving the applicable network protocol documentation (as obtained from vendor/quality audits) for any electronic information system to ensure data integrity, attributability, reliability, and compliance with the applicable regulatory requirement(s).

The *DAIDS OCSO PO* is responsible for verifying that the clinical research site has written policies and processes for use of electronic information systems in the conduct of National Institute of Allergy and Infectious Diseases (NIAID) Division of AIDS (DAIDS) supported and/or sponsored clinical trials.

4.1.2   DAIDS Quality Management (QM):

As part of quality assurance, DAIDS QM are responsible for performing quality audits to ensure compliance with this policy. The audits performed by DAIDS QM are separate from routine monitoring or quality control functions.

4.1.3   DAIDS Monitoring Contractor:

The DAIDS Monitoring Contractor or designee is responsible for verifying that the data required by the protocol are complete and accurately recorded on the electronic case report forms (eCRFs) and are consistent with the source documents and that the eSignatures and electronic informed consent (eIC) if used, are thoroughly executed. The eSignatures and eIC must contain all elements required by regulations.

4.2   **The LOC PI, the LC PI, the SDMC PI, the CTU PI, the CRS Leader, and Investigator of Record (IoR) are each responsible for ensuring that the electronic information systems meet the following requirements:**

- The electronic information systems are designed to ensure data quality and integrity. These systems must have the capacity to be configured to meet protocol-specific data collection requirements to ensure completeness, accuracy, reliability and be validated for their intended use and performance.

- For in-house software, the end user validation may be carried out by either the software owner organization/entity or by the end user/entity, as appropriate.

- Any systems which are interoperable or fully integrated are validated and have appropriate controls in place to ensure data integrity and protection of human subjects.

- That written standard operating procedures (SOPs) are established and maintained for each electronic information system and ensure that there is adequate documentation that the SOPs have been followed.

- There is adequate documentation that written SOPs are established, maintained, and followed for each electronic information system.

- Verifying that electronic information systems in use are compliant with the U.S. Federal and all applicable regulations (local, national, and international).

![NIH National Institute of Allergy and Infectious Diseases]	Document Number: **DAIDS-OD-A-POL-00015**	Revision Number: **01**
Division of AIDS	Effective Date: **25 Apr 2025**	Page: **7** of **9**
Document Title: **Electronic Information Systems Policy**		

- Providing direct data access to research records and source data for authorized personnel, including DAIDS, other monitoring contractors, auditors, and regulatory inspectors as required.

- Maintaining a list of each electronic data originator and the user access to the respective electronic information system.

- Maintaining the staff system and training records for all internal staff system users and conforming to all required security and data policies when using electronic information systems under the scope of this policy.

- Ensuring that system validation procedures and controls are in place when using electronic information systems under the scope of this policy.

- Ensuring that procedures and work instructions include adequate quality control measures to maintain confidentiality, data integrity, and compliance with applicable laws, regulations, and policies.

- When applicable, ensuring eIC and eSignatures are captured as per regulations for each participant.

- Ensuring that the electronic information systems can retain records in compliance with applicable regulations and are available for inspection.

- Ensuring that the access to all electronic information systems are revoked promptly and documented upon staff departure.

- Ensuring that the DMCs are promptly notified of staffing updates with regards to access to electronic information systems.

5.0   POLICY

5.1   The electronic information systems used, when one is available that meets business requirements, should be purchased software (SaaS or run locally), designed to comply with the requirements of 21 CFR Part 11 and other regulatory authority requirements as applicable.

5.2   Each electronic information system must be validated for its intended use and purpose and conform to the requirements of Appendix A, including:

- Security

- Validation

- System Dependability

- System Features

- Training Personnel

- Standard Operating Procedures

- Interoperability and Integration of Systems

National Institute of Allergy and Infectious Diseases	Document Number: **DAIDS-OD-A-POL-00015**	Revision Number: **01**
Division of AIDS	Effective Date: **25 Apr 2025**	Page: **8** of **9**
Document Title: **Electronic Information Systems Policy**		

- Source Documentation and Record Retention

5.3 An electronic information system should be configurable for each protocol without compromising reliability, quality, and integrity of the data.

5.4 Electronic information systems which are interoperable or fully integrated must be validated and have appropriate controls in place to ensure data integrity and quality.

5.5 Electronic information system users must have the education, training, and experience necessary to perform their assigned tasks using the system for its intended purpose.

5.6 For each protocol, identify and document the software and hardware used in electronic information systems that create, modify, maintain, archive, retrieve, or transmit data. This documentation must be retained as part of the protocol essential documents.

5.7 The electronic information system will be configured to ensure that all applicable regulatory requirements for recordkeeping and record retention in clinical trials are met.

5.8 Changes to data that are stored on electronic media require an audit trail, in accordance with all applicable regulatory requirements.

5.9 Electronic Information systems and data originator devices must have adequate controls in place to ensure confidentiality, reliability, quality, and integrity of the source data as related to risk to participants. The documentation must be readily available for sponsor oversight.

5.10 A risk assessment must be performed at the system level for each electronic information system being used in the study. The assessment must evaluate the potential of the system to adversely affect human subject protection and the reliability of the study results. Security measures must be in place to prevent unauthorized access to the data and to the electronic information system.

5.11 DAIDS encourages the use of interoperable systems for NIAID (DAIDS) sponsored and/or supported clinical research.

5.12 Electronic information systems, whether interoperable or not, must have adequate controls to ensure confidentiality, integrity, and security of data.

6.0 REFERENCES

6.1 [FDA General Principles of Software Validation; Final Guidance for Industry and FDA Staff, 2002](#)

6.2 [FDA Guidance for Industry, Electronic Source Data in Clinical Investigations, 2013](#)

6.3 [Guidance for Industry: Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations Questions and Answers (fda.gov)](#)

6.4 [FDA Guidance for Industry, Electronic Records: Electronic Signatures – Scope and Application, 2003](#)

6.5 [FDA Guidance for Industry - COMPUTERIZED SYSTEMS USED IN CLINICAL TRIALS, 1999](#)

6.6   [FDA Use of Electronic Informed Consent in Clinical Investigations, Questions and Answers, 2016](#)

6.7   [FDA Guidance for Industry, Use of Electronic Health Record Data in Clinical Investigations, 2018](#)

6.8   [FDA 21 CFR Part 11 Electronic Records, Electronic Signatures, 1997](#)

6.9   [EMA Guideline on computerised systems and electronic data in clinical trials, 2023](#)

6.10   [FDA Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations Questions and Answer Guidance for Industry, 2024](#)

6.11   [ICH E6 (R3) Guideline on Good Clinical Practice (GCP)](#)

6.12   [MHRA GXP Data Integrity Guidance and Definitions; Revision 1: March 2018](#)

7.0   APPENDICES

7.1   DAIDS-OD-A-GUD-00004, Requirements for using Electronic Information Systems in Clinical Research

7.2   DAIDS-OD-A-GUD-00005, Electronic Information System Evaluation Checklist

8.0   REVISION SUMMARY

8.1   DAIDS-OD-A-POL-00015 rev 01, is DAIDS-OPC-A15-POL-00013 rev 02. This procedure has been transferred from the OPC policy number to a new OD policy document number. The appendices section and the procedure itself have been updated with the correct OD document numbers for Appendix A and B. DAIDS-OD-A-POL-00015 is the first revision of this procedure in MasterControl. The document numbering and document format have been updated to reflect current requirements. The purpose of the policy was revised, references were updated, and minor edits were made throughout the document.