



Veeva SiteVault: Use of an Electronic Investigator Site File

Purpose:

To establish standard processes and procedures for the use of the electronic Investigator Site File (eISF) for the conduct of research at Virginia Commonwealth University.

To describe the methods to create, modify, maintain, or transmit essential documents in an electronic system for the conduct of research.

Scope:

This procedure applies to activities and essential documents required for the conduct of research at VCU.

Users of this system will be the investigator and investigator delegates, including site administrative and operations personnel.

External users (monitors, inspectors) with responsibility for reviewing research documents will be granted direct access to the eISF system by VCU.

This procedure does not apply to research or clinical information captured in another system such as an electronic health record, Institutional Review Board (IRB) or review committee system, or clinical trial management system.

This procedure does not apply to federal or state regulatory activities captured in another system such as financial conflict of interest (FCOI) reporting as required by the National Science Foundation (NSF) and the Public Health Service (PHS)¹.

Responsibility:

VCU personnel will be responsible for both performing and complying with this procedure and assuring the appropriate personnel are trained on this procedure.

Definitions:

Certified Copy: A copy (irrespective of the type of media used) of the original record that has been verified (i.e., by a dated signature or by generation through a validated process) to have the same information, including data that describe the context, content, and structure, as the original².

Direct Access: Permission to examine, analyze, verify, and reproduce any records and reports that are important to evaluation of a clinical trial. Any party (e.g., domestic and foreign regulatory authorities, sponsor's monitors and auditors) with direct access should take all reasonable precautions within the constraints of the applicable regulatory requirement(s) to maintain the confidentiality of subjects' identities and sponsor's proprietary information.

eISF: electronic Investigator Site File. The computer system used to house Essential Documents required for the conduct of clinical research by the investigator.

¹ 42 CFR § 50.605. Management and reporting of financial conflicts of interest.

² Integrated Addendum to ICH EC(ER) Guideline for Good Clinical Practice E6(R2). 1.63 Certified Copy.



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Essential Documents: Those documents which individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor and monitor with the standards of Good Clinical Practice and with all applicable regulatory requirements. Often referred to as regulatory documents³.

External Users: Users of the eISF who are not employees of VCU but are granted direct access to the eISF in order to fulfill their responsibilities as outlined by regulatory authorities, contracts, and HIPAA waivers in the capacity of sponsor or inspector.

FCOI: Financial Conflict of Interest

HIPAA Privacy Rule: Provides federal protections for personal health information held by covered entities and gives patients an array of rights with respect to that information. At the same time, the Privacy Rule is balanced so that it permits the disclosure of personal health information needed for patient care and other important purposes (such as research).^{4, 5}

IRB: Institutional Review Board

ISF: Investigator Site File. The investigator site file includes all Essential Documents which individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced by the investigator. These documents serve to demonstrate the compliance of the investigator with the standards of Good Clinical Practice and with all applicable regulatory requirements. The ISF does not include the full scope of Trial Master File documents which apply to the sponsor role in research.

NSF: National Science Foundation

PHS: Public Health Service

PHI/PII: Protected Health Information/ Personally Identifiable Information

Profile Documents: Documents for people or organizations which are study agnostic or can be used across multiple studies. Examples: Medical License, IRB Roster, Lab Normal Ranges.

Source Data: All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies).⁶

Source Documents: Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and medico-technical departments involved in the clinical trial).⁷

Validation of Computer Systems: A process of establishing and documenting that the specified requirements of a computerized system can be consistently fulfilled from design until

³ ICH-GCP E6(R2), 2016. Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice. 1.23 Essential Documents

⁴ HHS.gov, 1996. Health Insurance Portability and Accountability Act of 1996

⁵ HHS.gov, 1996. HIPAA for Professionals

⁶ ICH-GCP E6(R2), 2016. Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice. 1.51 Source Data

⁷ ICH-GCP E6(R2), 2016. Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice. 1.52 Source Documents



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decommissioning of the system or transition to a new system. The approach to validation should be based on a risk assessment that takes into consideration the intended use of the system and the potential of the system to affect human subject protection and reliability of trial results.⁸

Policy Statement

It is the policy of VCU that documents and data required for the conduct of research will be held in the eISF to streamline regulatory processes, facilitate remote access to regulatory documents for site personnel and external users, and promote quality and visibility in research regulatory operations.

The eISF system enables the investigator to create, modify, maintain, or transmit essential documents to permit the evaluation and conduct of trials, providing identification, version history, search and retrieval for essential documents.

Compliance Statement

VCU uses Veeva SiteVault for the eISF. Veeva SiteVault supports compliance with 21 CFR Part 11 and HIPAA requirements. Documentation of Veeva Vault's compliance with Validation of Computerized Systems can be accessed at the Office of the Vice President for Research and Innovation at VCU or through Veeva SiteVault's Validation Documents support page section. The system is validated for each change.

Procedures:

Use of the electronic Investigator Site File

Veeva SiteVault is the system of record for data and documents for regulatory conduct of research including creation, modification, maintenance, or transmission of essential documents and data.

This eISF system provides internal and external safeguards of limited access, audit trails, date/timestamps, access privileges, and security controls on essential documents in accordance with regulations governing use of electronic systems in research.

Study Set Up and Maintenance

Studies will be created and maintained in the eISF by designated regulatory personnel of VCU.

Document Collection and Processing

- Research documents will be uploaded or created in the system by users based on training and permissions referenced in the User Requirement Specifications and VCU user provisioning and training policies and procedures.
- Document versions will be managed in the eISF in accordance with the system User Requirement Specification and validation documents.
- Research documents will be viewable based on validated permissions of the system by site staff, investigators, and external users such as monitors, sponsors and inspectors.

⁸ ICH-GCP E6(R2), 2016. Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice. 1.65 Validation of Computer Systems



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- Study documents will be viewable in the eISF's electronic binder structure to support quality and completeness reviews.
- Users will complete tasks and receive notifications for actions on documents in the system.

Profile Documents – People and Organizations

Data and associated documents for site personnel, organizations (site, labs, sponsors, IRBs, CROs) will be stored and maintained in the eISF as the system of record for VCU.

Electronic Signatures and Acknowledgements

Signatures, approvals, or acknowledgement of documents by investigators and site personnel will be collected in the system as described in the User Requirement Specifications and Validation documents and in compliance with 21 CFR, part 11 and in accordance with VCU's policy on electronic signatures.

User Provisioning

Users are created, activated, and inactivated by site personnel with responsibility for user provisioning. Audit trails for all user actions are available to designated site personnel.

Inactivation of users will immediately remove their access from the system as described in the Validation documents.

Training

After completing training, site personnel and external users (sponsors/monitors/inspectors) will be given access to the system by the site. Once a user has system access, they may then be assigned to the documents and studies relevant to their role.

Designated site personnel will be responsible for inactivating user accounts when a person leaves the organization or no longer needs access to assigned studies or documents.

Inactivating an account immediately restricts user access to the system.

Certified Copy

Refer to VCU's policy on Certified copy in the eISF.

Essential documents which are originated or finalized outside of the eISF system may be certified as an exact copy in the eISF system, thus allowing for the destruction of the paper version. This applies to regulatory and essential documents. For source documents and data, refer to [SITE NAME] policy on source document and data capture.

Redacted documents are not considered certified copies per ICH-CGP or FDA definitions. FDA does not have a specific term used to describe the redacted copies for source documents.⁹

PHI/PII in the eISF

⁹ ICH-GCP E6(R2), 2016. Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice 4.9 Reports and Records.



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Refer to VCU's policy on PHI/PII in electronic systems.

References

- [ICH E6 \(R2\)](#): Harmonized Tripartite Guideline for Good Clinical Practice
- [FDA E6\(R2\)](#) Good Clinical Practice: Integrated Addendum to ICH E6(R1)
- [FDA Guidance for Industry](#): Computerized Systems Used in Clinical Investigations, 2007
- [FDA Guidance for Industry](#): Electronic Source Data in Clinical Investigations, 2013
- [FDA Part 11](#), Electronic Records; Electronic Signatures - Scope and Application, 2003
- [CFR Title 21](#), Part II
- FDA Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11 – [Questions and Answers](#), 2023
- [Veeva SiteVault Validation Documents](#)

Contact

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Revision/Change History

Date	Version	Change History
02/22/2023	1.0	Initial
03/29/2023	2.0	Added contact information
12/11/2023	3.0	Fixed broken links