



Veeva SiteVault: Use of Electronic Delegation of Authority

Purpose:

To document standard processes and procedures for the electronic assignment, management, and acknowledgement of delegated trial-related duties at Virginia Commonwealth University (VCU).

Scope:

This procedure applies to the electronic assignment, management, and acknowledgement of trial-related duties by an investigator at VCU.

Use of an electronic system to assign, manage, acknowledge, and approve trial-related duties is an approved method for VCU personnel to use when conducting clinical research. VCU personnel in the role of Principal Investigator will record delegation of trial-related duties to site staff using a validated, electronic system. Site administrative, operations, and clinical personnel will utilize a validated electronic system (SiteVault) to record, sign, and acknowledge delegated responsibilities from the Principal Investigator.

Responsibility:

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

Definitions:

DDL: Digital Delegation Log

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

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 documents¹.

Investigator: A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator. (ICH-GCP Glossary 1.34)

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.

Letter of Non-Repudiation Agreement: A letter of Non-Repudiation Agreement for digital signatures must be submitted to the FDA prior to registering as a transaction partner for the FDA

¹ ICH-GCP E6(R2), 2016. Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice. 1.23 Essential Documents



VCU Office of the Vice President for Research and Innovation

ESG². The letter must be submitted (preferably on company letterhead) and signed with a traditional handwritten signature.

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 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.³

Policy Statement

It is the policy of VCU that an electronic system will be used to record the assignment, management, acknowledgment of delegated trial-related duties and functions in the conduct of research in accordance with ICH-GCP and FDA regulations allowing use of electronic records and signatures in clinical investigations. Veeva SiteVault is the system used for electronic management of the Investigator Source File (ISF), electronic signature is validated in this system at VCU.

Compliance Statement

A letter of Non-Repudiation Agreement has been filed with the FDA for VCU on January 26, 2023 and can be found within the Office of the Vice President for Research and Innovation at VCU.

Veeva Vault has been validated by Veeva Systems in accordance with industry-standard validation guidelines and regulations (e.g. 21CFR820.75, 21CFR211.68, 21CFR11, EU Annex 11). Computer System Validation (CSV) documentation for SiteVault is available with each release.

ICH-GCP Delegation of Authority Requirements

ICH-GCP E6, R2, 4. Investigator.

4.1.5 The investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties.

4.2.4 The investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions.

ICH-GCP E6, R2, Addendum, 4.2.5-6

4.2.5 The investigator is responsible for supervising any individual or party to whom the investigator delegates trial-related duties and functions conducted at the trial site.

4.2.6 If the investigator/institution retains the services of any individual or party to perform trial-related duties and functions, the investigator/institution should ensure this individual or party is qualified to perform those trial-related duties and functions and should implement procedures to ensure the integrity of the trial-related duties and functions performed and any data generated

Procedures:

VCU uses an eISF, Veeva SiteVault, to record, document, and track delegation of trial-related tasks. Tasks are maintained electronically at the organization, site, or study level and assigned to

² FDA Electronic Submission Gateway, Appendix G: [Letters of Non-Repudiation](#)

³ [ICH-GCP E6\(R2\)](#), 2016. Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice. 1.65 Validation of Computer Systems



VCU Office of the Vice President for Research and Innovation

study team members based on requirements of the study and under oversight of the investigator. Electronic acknowledgment of trial-related duties is reviewed and acknowledged by both the delegate and the investigator in accordance with ICH-GCP and FDA regulations. Signatures, approvals, or acknowledgement of documents by VCU personnel will be collected in the system as described in the Veeva Vault User Requirement Specifications and Validation documents and in compliance with 21 CFR, Part 11. Study monitors and auditors can be given access to the original source delegation log in the eISF.

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
- [FDA Letters of Non-Repudiation Agreement](#), Appendix G
- [Veeva SiteVault Validation Documents](#)
- Title 21 CFR 312.53 – Selecting Investigators and Monitors
- Title 21 CFR 312.60 – General Responsibilities of Investigators
- Title 21 CFR 812(e) – Responsibilities of Investigators ICH GCP E6 Guidelines
- Guidance for Industry: Investigator Responsibilities –Protecting the Rights, Safety, and Welfare of Study Subjects

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	Revised broken links