VCU Office of the Vice President for Research and Innovation

Veeva eConsent

PURPOSE

This procedure establishes the informed consent process and documentation using the electronic platform, Veeva eConsent, in human subject research.

Electronic informed consent (eConsent) employs the use of electronic systems and processes, whether remotely or in-person, to convey information to a participant and/or document research consent.

The Food and Drug Administration (FDA) requirements for electronic records/electronic signature, informed consent, and Institutional Review Board (IRBs) are set forth in 21 CFR Parts 11, 50, and 56 respectively.

The Health and Human Services (HHS) requirements regarding the protection of human subjects are set forth in 45 CFR Part 46. The information presented to the subject, processes used for obtaining informed consent, and documentation of the eConsent must meet the requirements of these and other applicable regulations.

SCOPE

This procedure applies to all individuals and designated research staff who have the responsibility of obtaining and documenting eConsent from individuals involved in human subject research at Virginia Commonwealth University.

DEFINITIONS

eISF: electronic Investigator Site File. The computer system used to house Essential Records (including eConsents) required for the conduct of clinical research by the investigator.

eConsent: electronic Informed Consent. The use of electronic systems and processes to convey information related to clinical research as well as to obtain and document informed consent.

Informed Consent: A process by which a clinical research participant confirms their willingness to participate in a clinical research trial, after having been informed of all aspects of the trial that are relevant to their decision to participate.

IRB: Institutional Review Board. An independent body constituted of medical, scientific, and non-scientific members, whose responsibility is to ensure the

protection of the rights, safety and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trial protocol and amendments and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

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.

RESPONSIBILITIES

The PI and designated research staff are responsible to understand and follow the basic tenets and regulations regarding informed consent as outlined in CR-RE-315: Informed Consent Process and must **obtain IRB approval prior to the implementation of an electronic informed consent process**. The consent process does not change regardless of the media.

PROCEDURE

Approaching Potential Research Participants When Using eConsent

1. Potential research participants will be approached for study participation just as they would be approached in using a traditional paper-based consent.
2. Potential subjects will be provided with general information about the nature of the study and IRB approved study-specific recruitment materials may be part of this process.
3. If interested, the investigator (or designee) will explain the steps of the eConsent process. No study related procedures will be conducted prior to informed consent, including study-specific screening procedures.
4. The eConsent process can take place at the study site where both the investigator (or other authorized member of the research team) and the research participant/LAR area are at the same location (“In-Person eConsent”).
5. The eConsent process can take place remotely where the research participant reviews the consent information in the absence of the investigator (or other authorized member of the research team) (“Remote eConsent”).

Obtaining eConsent

1. The investigator (or designee) will explain the steps for the eConsent process.
2. Regardless of the media, the consent process does not change. The eConsent must contain all elements of informed consent required by HHS and/or FDA regulations.
3. No study related procedures will be conducted prior to informed consent, including study-specific screening procedures.
4. Participants and any other applicable signatories (ex: witness or legally authorized representative) will be added to SiteVault prior to performing the consent process when using Veeva eConsent.
5. eConsent will be sent to the participant in real time during the consenting process.
6. The potential research participant will have adequate time and privacy to read the informed consent on a laptop, personal computer, tablet, or mobile telephone. Follow the basic tenants and regulations regarding the informed consent process as outlined in CR-RE-315: Informed Consent Process.

The research participant may complete eConsent in-person or remotely.

1. If eConsent is conducted remotely (remote eConsent), the investigator or designee will engage with the participant in approved study methods such as telehealth platform.
2. When the participant feels educated about the clinical trial they are joining, the potential research participant's voluntary written agreement to participate will be obtained by ensuring consent is free from coercion or other undue influence.
3. The research participant will sign the electronic form, and an automated digital date and time stamp will be applied at the point-of-care or remotely. The eConsent platform meets 21 CFR Part 11 requirements.
4. Following that patient's 21 CFR Part 11-compliant eSignature, the eConsent will be automatically filed into SiteVault with a task for the delegated site staff or investigator to countersign. The investigator (or designee) will sign the electronic form using SiteVault eSignature and an automated digital date and time stamp will be applied.
5. The consent process should be documented in either Epic or a paper study note if Epic is not being utilized for that study. Documentation of the

consent process should include the method of consenting (ex: in person paper consent, in person electronic consent or remote consenting).

Re-Consent

1. Federal Regulations require that research subjects be informed of any significant new findings identified during the research which may impact the subject's willingness to continue participation. [45 CFR 46.116(c)(5); 21 CFR 50.25(b)(5); ICH E6 2.8.2] The IRB must be informed of a minor or significant protocol change, which may require re-consenting.
2. The IRB is responsible for approving or modifying the method of subject communication and must approve all consent forms and processes.
3. Follow the basic tenants and regulations regarding the informed consent process as outlined in CR-RE-315: Informed Consent Process.

Storing eConsent

1. Signed eConsents are automatically filed in the SiteVault eISF once all signatures have been obtained. When applicable, signed eConsents must also be filed in Epic in accordance with VCUHS policy titled "Research in Clinical Areas" (VCUHS credentials required).
2. The signed eConsent document will be available immediately to patients through their MyVeeva for Patients account and made accessible for the duration of the study. A copy of the completed document can also be printed directly from SiteVault.

COMPLIANCE STATEMENT

Virginia Commonwealth University allows for the use of Veeva eConsent for electronic informed consent. Veeva eConsent supports compliance with 21 CFR Part 11, EU Annex II, GDPR, and HIPAA requirements. Documentation of Veeva Vault's compliance with Validation of Computerized Systems can be accessed by contacting the Office of Vice President for Research and Innovation at Virginia Commonwealth University or through Veeva SiteVault's Validation Documents support page section. The system is validated for each change.

References

- 21 CFR 11
- FDA Guidance: Informed Consent
- FDA Guidance: Use of Electronic Informed Consent

- CR-RE-315: Informed Consent Process
- ICH GCP E6: 2.8 Informed Consent of Trial Participants

Contact

Please contact the following for questions regarding this document:

Lauren Wallace, MS, RAC-Drugs
Director of Clinical Research Regulatory Affairs/ FDA Program Officer
kanigherl@vcu.edu

Liz Kissell, MPH, CCRP
Clinical Research Monitor/ FDA Program Administrator
kisselle@vcu.edu

Revision/Change History

Date	Version	Change History
07/29/2025	1.0	Initial