VCU Office of the Vice President for Research and Innovation

Veeva EDC: User Account Management

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1. Purpose

This procedure describes the process of requesting and managing user accounts and user security at Virginia Commonwealth University for Veeva EDC. Access to Veeva EDC is based on an individual's need to view, add, change or delete data or content. Access is based upon a business need, an administrative need or special circumstances that warrant such access. This procedure outlines actions relating to requesting, establishing, issuing and suspending user accounts.

2. Scope

This policy applies to activities 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. All accounts created for VCU personnel will be created using the university's single sign-on (SSO) system which utilizes dual factor authentication.

External users (external site study teams and inspectors) with responsibility for data entry or conducting inspections will be granted access to the EDC system by VCU.

3. Responsibility

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

4. Definitions

Application: Veeva EDC

EDC system: Electronic data capture system. The computer system used to house research data collected for the conduct of clinical research by the investigator. Veeva's EDC is made up of multiple environments. The production environment is the "site" side of the system where data entry occurs. The other environments within the system are considered the "sponsor" side of the system where building the study and testing of the study build is performed.

External users: Users of the EDC who are not employees of Virginia Commonwealth University but are granted direct access to the EDC in order to fulfil their responsibilities as outlined by regulatory authorities and contracts in the capacity of participating site or inspector.

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.

5. Compliance statement

Veeva EDC supports compliance with 21 CFR Part 11. Documentation of Veeva's EDC compliance with validation of computerized systems can be accessed at the Office of the Vice President for Research and Innovation or through Veeva's EDC Validation Documents support page section. The system is validated for each change.

6. Procedures

6.1. Account provisioning to system

- VCU User accounts:
  - Complete system training via RedCap
  - You will receive an email notification from Veeva when an account has been created by OVPRI IT.
    - Each user will utilize the following username format: username@vcu.edu
  - Log into Veeva EDC and confirm appropriate access
  - Report inaccurate or inappropriate access to erahelp@vcu.edu immediately
  - Ensure passwords are not shared
- External user accounts:
  - Accounts will be created by the study team utilizing VeevaID within the production environment
    - Individuals who already have a VeevaID should provide their ID to the team provisioning access.
    - Individuals who don't already have a VeevaID will be prompted to make one when their account is created in the EDC system
  - Study team provisioning accounts should ensure the individual is trained and on the delegation of authority log prior to granting access to the EDC

6.2. Account provisioning to studies

- Veeva EDC has standard roles that an individual can be assigned on a study-by-study basis. Individuals can be assigned multiple roles in the system in a single study. In addition to the standard roles, the following additional roles are available in VCU's Veeva EDC:

    - Restricted CDMS CRC: Same responsibilities as CDMC Clinical Research Coordinator role plus restricted data access permission
- Access to studies will be managed by the individual on the study team who is assigned the CDMS User Administrator role for each study.
- Upon initial study shell creation, OVPRI will provision one CDMS User Administrator role who will then become responsible for granting access to the individual study to other team members
- Individuals provisioning study team access on a study should ensure that the individuals are trained on the study prior to provisioning access
- Study access provisioning should occur in the EDC environment(s) where access is needed
    - Example: Users only performing data entry or signing casebooks (such as a principal investigator) only need to have access to the study in the production environment
- Steps to adding user to study:
    - VCU staff or external users previously/currently on other studies in the system:
        - Tools> System tools > Users
        - Dropdown next to “+ New User” > Add “existing user”
        - Enter username
        - Click “edit”
        - Click “add studies” and select applicable study(ies)
        - Click on new study and select role for individual (and assign appropriate site and country access for those performing data entry or signing casebooks) for the appropriate environment (development, test, or production)
        - Hover over the gear icon and click “+ New Role+” to repeat if individual is being granted multiple roles
    - New external staff needing to be added to a study:
        - Tools> System tools > Users
        - Dropdown next to “+ New User” >Add “VeevaID user”
        - Enter VeevaID
        - Click “edit”
        - Click “add studies” and select applicable study(ies)
        - Click on new study and select role for individual (and assign appropriate site and country access for those performing data entry or signing casebooks) for the appropriate environment (development, test, or production)
        - Hover over the gear icon and click “+ New Role+” to repeat if individual is being granted multiple roles

7. References

- Veeva ID
- Standard Clinical Data Study Roles
- Managing Study User Accounts & Role Assignment

8. Contact

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9. Document History

Version	Effective Date	Brief Description of Change
1.0	8/27/25	Initial Version