VCU Office of the Vice President for Research and Innovation

# Veeva EDC: Study Closeout and Archival

## Table of Contents


*1. Purpose* ..... *2*

*2. Audience* ..... *2*

*3. Scope* ..... *2*

*4. Definitions* ..... *2*

*5. Responsibilities* ..... *2*

*6. Procedures* ..... *3*

**6.1. Close out procedures** ..... **3**

*7. Contact* ..... *3*

*8. References* ..... *4*

*9. Document History* ..... *4*

## 1. Purpose

The objective of this policy is to describe the process for verifying completeness and archiving the EDC for a specific study.

## 2. Audience

This policy applies to all VCU staff involved in managing the Veeva EDC system for a specific study.

## 3. Scope

This policy applies to all clinical studies where data is electronically captured and maintained in the Veeva EDC. It does not apply to studies that are using an EDC system outside of the Veeva EDC.

## 4. Definitions

*EDC:* Electronic data capture

*Lock (of data):* In Veeva EDC, you can lock data that you need to preserve. Locking data prevents any changes or any actions from occurring on the form or event until the form or event is unlocked. When an item is data locked, it is in a read-only state. The audit trail remains accessible.

## 5. Responsibilities

| Role | Responsibilities |
|---|---|
| VCU OVPRI (OVPRI reserves the right to delegate compliance of this policy to departments) | Implement and ensure compliance to this policy.<br><br>Revise this policy when required by regulatory requirements or VCU organizational circumstances.<br><br>Create user accounts that both permit and limit access as stated in this policy. |
| Study team member who is reviewing data for accuracy and completeness | Verify the EDC is ready for archive.<br><br>Assume the role of Archivist:<br>● Initiate and oversee the archival |

| | |
|---|---|
| | process<br>● Preserve the data, information and audit trails from unauthorized changes |

## 6. Procedures

6.1. Close out procedures

At the end of the study, all data must be locked prior to close out of the study in order to generate study closeout PDFs of the data.

In order to generate study closeout PDFs:

- Prior to generating study closeout PDFs, the data must be signed by the principal investigator at the site prior to the subject/site/study being locked.
- After signatures are completed, the site must be locked. This will prevent the site from adding, modifying or deleting any additional data. Once a site is locked, closeout PDFs can be generated for that site. This can be repeated for all sites involved in the study.
- The site has the ability to review, download and accept/reject the closeout PDFs. Each site should download a copy of their PDFs and file in their investigator site file.

Once all sites have been locked and closeout PDFs have been generated:

- The study can be locked and the study becomes read only.
- A copy of all closeout PDFs should be filed in the trial master file for the study. This can also be generated by the data management member of the study team.
- Once study is closed and all PDFs have been generated and accepted, move study to archived state. It is also recommended to turn off all active recurring jobs and disable user access to the study.

## 7. Contact

Please contact either of the following for questions regarding this document:

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

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

## 8. References

- ICH Good clinical practice E6(R3)
- 21 CFR 312.57 and 21 CFR 312.62(b)
- 21 CFR 812.140
- Generating study closeout PDFs for sites

## 9. Document History

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