Study Completion and Study Closure		
VCU/VCU Health CLINICAL RESEARCH STANDARD OPERATING PROCEDURES		
SOP No.: CR-EN-600.3	Status: Final	Version Date: 07/22/2025 Effective Date: 08/04/2025

1. PURPOSE

This Standard Operating Procedure defines the study closure processes related to completed studies at VCU/VCU Health facilities, affiliates, and participating sites. For additional information regarding studies that are closed early or terminated early, refer to VCU/VCU Health SOP CR-EN-605 Study Suspension, Early Termination, and Early Closure.

2. REQUIREMENTS

Following the completion of the study, the study must be closed out in an orderly and systematic manner per the process outlined in this SOP.

Once a study is completed and considered closed, no further contact or interactions with the participants or the use, study, or analysis of their private identifiable information or biospecimens is permitted, and no protected health information (PHI) can be accessed either electronically or through review of medical records.

3. DEFINITIONS

Study Completion- A study is completed when enrollment on the study has been permanently closed and all active participants have completed their study visits. For studies requiring clinical trial results reporting (ClinicalTrials.gov), “primary completion date” and “study completion date” are defined as below:

Primary Completion Date - The date that the final participant was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical study concluded according to the pre-specified protocol or was terminated. In the case of clinical studies with more than one primary outcome measure with different completion dates, this term refers to the date on which data collection is completed for all of the primary outcomes.

Study Completion Date - The date the final participant was examined or received an intervention for purposes of final collection of data for the primary and secondary outcome measures and adverse events (for example, last participant’s last visit), whether the clinical study concluded according to the pre-specified protocol or was terminated.

For IRB continuing review and federal funding agency purposes, studies are not considered complete until all data analysis activities are complete.

Study Closure- A completed study is one that no longer requires IRB oversight and is closed with the IRB of record. A study is eligible for study closure with the VCU IRB (or IRB of record) when it meets all of the following criteria:

- The research is permanently closed to enrollment at the site(s) under VCU's IRB approval (VCU IRB or IRB of record); **and**
- All interactions/interventions with participants, or access to a participant's personally identifiable information, (including identifiable biological specimens) for the purpose of research data collection is complete; **and**
- All use, study, and/or analysis of identifiable private information at the research site(s) under the IRB approval is complete.

For multi-center studies closed with the VCU IRB under these conditions, PIs should respond to all queries prior to IRB closure, however, PIs may still respond to queries from the statistical center regarding previously collected data about participants who were enrolled under the VCU IRB approval (reference U.S Department of Health and Human Services Continuing Review Guidance (2010) Section D1)

4. PROCESS

A. General Study Closure activities may include, but are not limited to (Reference VCU Clinical Research resources Requirements for Study Closeout):

- For all studies:
  - Confirm all required essential records are filed in the paper or electronic ISF (includes completed case report forms, completed DOA log, etc.)
  - Confirm all reports have been submitted to the IRB and sponsor, as applicable (deviations, violations and SAEs/AEs)
    Notify IRB the study has been completed and perform IRB close-out (last item to be done)

- For studies that involve multiple sites and VCU is the sponsor (or coordinating site):
  - Confirm all sites have the required essential records in ISF (either paper or electronic)
  - Confirm VCU has all required copies of essential records in the trial master file prior to closing

- For studies that VCU holds IND/IDEs:
  - Prior to closing with the IRB, the study team must submit a withdrawal of the study or withdrawal of the IND to the FDA through a close-out report.

B. Financial Study Closure activities may include, but are not limited to:
   - Financial Disclosure Report: The investigator shall promptly update the sponsor with any relevant change in financial information for one (1) year following completion of the study (FDA 21 CFR 312.64).
   - Providing any departmental, school, or institution required reports, financial disclosure statements, or documents required for financial closure of any study with attention to the requirements of the funding source and as specified in the terms and conditions of the award, or contract.
     - The Federal awarding agency shall require recipients to submit final reports no later than ninety (90) calendar days following study closure.

C. End of Study Reporting for Investigator-Initiated Clinical Trials
   - Results of investigator-initiated clinical trials must be publicly posted on ClinicalTrials.gov within one year of the Primary Completion Date for 1) all FDA regulated Applicable Clinical Trials and 2) all NIH-funded studies initiated on or after January 18, 2017.
   - The ICH GCP E6 Guideline states the sponsor should ensure that clinical trial reports are prepared and that the structure and content meet the ICH E3 requirements. For investigator-initiated clinical trials, the principal investigator (PI) holds the responsibility for developing the end of study report as the study sponsor.
   - The end-of-study report should be archived as one set of the essential documents described in the SOP CR-CO-555 Record Retention and Archiving SOP.

5. REFERENCE

A. US Code of Federal Regulations
   - 21 CFR 312.64(c) - Investigator reports: final report
   - 21 CFR 812.150 – Reports

B. US Food and Drug Administration
   - ICH E3: Structure and Content of Clinical Study Reports

C. U.S Department of Health and Human Services
   - Continuing Review Guidance (2010) Section D1

D. Good Clinical Practice
   - ICH Harmonised Guideline Guideline For Good Clinical Practice E6(R3)
     - Section 3.17.2- Clinical Trial/Study Reports

- Appendix C- ESSENTIAL RECORDS FOR THE CONDUCT OF A CLINICAL TRIAL

E. VCU

- VCU/VCU Health Clinical Research Standard Operating Procedures
  - CR-EN-605: Study Suspension, Early Termination, and Early Closure

- Office of the Vice President for Research and Innovation
  - Sponsored Programs: Research Proposal and Awards
    - Proposal and Award Closeout
    - Post-award Activities
  - Clinical Research resources
    - Requirements for Study Closeout

- C. Kenneth and Dianne Wright Center for Clinical and Translational Research
  - ClinicalTrials.gov Program

Review/Revision History CR-EN-600		
Version No.	**Effective Date**	**Description**
CR-EN-600.3	08/04/2025	• Revised purpose to clarify scope and VCU/VCU Health site applicability • Updated definitions for study completion and closure to align with ClinicalTrials.gov, FDA, and IRB guidance • Clarified that no PHI or identifiable data/biospecimen use is permitted after study closure • Reorganized and clarified general and financial closure activities • Added procedural steps specific to VCU-held IND/IDE studies • Incorporated reference to 2010 HHS Continuing Review Guidance (Section D1) • Updated references to include ICH E6(R3), Appendix C, and internal VCU guidance • Ensured alignment with SOP CR-EN-605 and CR-CO-555

		● Improved formatting and wording for clarity and consistency ● Biennial review performed
CR-EN-600.2	06-01-2021	● Biennial review performed ● Minor formatting edits ● Reference links updated
CR-EN-600.1	08-27-2018	● Original