Study Suspension, Early Termination, and Early Closure		
VCU/VCU Health CLINICAL RESEARCH STANDARD OPERATING PROCEDURES		
SOP No.: CR-EN-605.3	Status: Final	Version Date: 07/22/2025 Effective Date: 08/04/2025

1. PURPOSE

This Standard Operating Procedure defines the generally accepted processes for suspension, early termination or early closure of a research study at VCU/VCU Health facilities, affiliates, or participating sites. ***NOTE:*** For standard study completion and closure procedures, refer to VCU/VCU Health SOP CR-EN-600 Study Completion and Closure.

2. REQUIREMENTS

A research study may be closed or suspended prior to completing target enrollment for administrative or clinical reasons. Suspension, early termination, and early closure of a research study reflects a change in study-related activities. The principal investigator (PI) must promptly notify the IRB. Regardless of the reason(s) for early termination or early closure of a study, the PI and study team must follow all applicable study closure procedures.

3. DEFINITIONS

Early Closure - (Also known as premature closure) A study is considered closed early when active enrollment has been permanently discontinued prior to meeting the targeted enrollment objective, but participant follow-up, data collection, or data analysis may still continue. Early closure reflects a change in study status and must be reported to the IRB and any applicable oversight entities in accordance with institutional policies and applicable regulatory requirements. Early closure may occur when a study ends sooner than originally scheduled due to reasons including, but not limited to:

- Failure to enroll a sufficient number of participants
- Determination that the study product's efficacy is significantly better or worse than anticipated
- Identification of unanticipated safety concerns (e.g., adverse events, toxicity risks from preclinical data)

- Futility, such as a low likelihood of demonstrating a meaningful difference between study arms

- Operational futility, where the protocol can no longer meet study objectives due to issues like prolonged recruitment delays, loss of study drug, or logistical constraints

Early Termination- A study is terminated when active enrollment on the study has been permanently discontinued prior to the targeted enrollment and all participant follow up and data collection are prematurely ended. Data analysis may continue until study closure activities are complete.

Suspension - A study is considered in suspension when no further enrollment is allowed while a determination is being made regarding whether the study should be continued, undergoes required modifications to the protocol to address safety, statistical or data issues or if study enrollment should be permanently discontinued. In this state, enrollment for a study may re-open. Suspension of a study can be initiated by the IRB of record, FDA, the PI, data safety monitoring board or study sponsor.

4. PROCESS

Criteria for suspension, early termination, or early closure of a study should be determined in advance and described in the protocol. Reasons for early termination or early closure of a study could be study-wide due to poor enrollment rates, safety concerns or lack of treatment efficacy. It could also be site-specific, such as poor site enrollment or staff-related issues.

A. In the event of a study suspension, early termination, or early closure, the PI must promptly notify the IRB. Notification should include all of the following information as applicable:
   - Supporting correspondence from the sponsor regarding the suspension, early termination or early closure
   - Reason(s) for suspension, early termination, or early closure
   - Documentation of drug or device approval
   - Manuscripts
   - Reports
   - Analyses resulting from study activities
   - Proposed notification to participants
   - Any other additional items related from study activities
   - Upon receipt of notification, the associated status of the study will be updated in the applicable electronic systems.

   If the VCU IRB is not the IRB of record, the VCU IRB must also be notified of the change in study status.

B. As directed by the IRB of record, appropriate participants must be notified of a study suspension, early termination, or early closure in writing. This may also include verbal notification prior to written notification.
   - Verbal communication regarding the change in study is acceptable but must be followed by written notification. All verbal communication with the study participant must be documented appropriately in the source documents.
   - All written correspondence with participants must be approved by the IRB prior to distribution. Correspondence to participants regarding study termination or early closure should be sent by certified mail.

C. In the event of early termination, the PI must ensure that a post-termination plan describing the follow-up arrangement for concerned participants is available.
   - If the PI terminates a clinical research study without prior agreement of the sponsor, the PI should promptly inform the sponsor by providing a detailed written explanation of the early termination.
   - If the sponsor terminates a clinical research study, a sponsor's letter with the reason(s) for the early termination of the study should be obtained.
   - If the IRB terminates a clinical research study, the PI must promptly notify the sponsor by providing a detailed written explanation for the early termination.

D. Additionally, in the event of an early termination or early closure:
   - The PI should inform the VCU Office of Sponsored Programs, if the study is sponsored.
   - The date of early termination or early closure will be the date identified by the sponsor. For investigator-initiated studies, the date of early termination or early closure will be identified by the PI.

5. REFERENCES

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

B. Good Clinical Practice
   - ICH Harmonised Guideline Guideline For Good Clinical Practice E6(R3)
     - Section 2 – Investigator
       - Section 2.12 – Records and
       - Section 2.13 – Report
     - Section 3 – Sponsor
       - Section 3.17.2 – Clinical Trial/Study Reports
     - Appendix C – Essential Documents for the Conduct of a Clinical Trial

C. VCU

- VCU/VCU Health Clinical Research Standard Operating Procedures
  - CR-EN-600 Study Completion and Closure

- VCU HRPP Policies and Guidance; HRPP Toolkit
  - HRP-103-Investigator Manual

Review/Revision History CR-EN-605		
Version No.	**Effective Date**	**Description**
CR-EN-605.3	08/04/2025	● Clarified definitions of suspension, early termination, and early closure ● Added suspension initiators (e.g., IRB, FDA, PI, sponsor, DSMB) ● Specified IRB notification requirements when VCU IRB is not the IRB of record ● Clarified participant notification process, including documentation and certified mail requirement ● Expanded PI responsibilities related to post-termination plans and sponsor communication ● Aligned with ICH E6(R3) ● Aligned with HRPP Toolkit ● Updated references ● Biennial review performed ● Minor formatting edits ● Reference links updated
CR-EN-605.2	06-01-2021	● Biennial review performed ● Minor formatting edits Reference links updated
CR-EN-605.1	08-27-2018	Original