Participant Status and Change of Status		
VCU/VCU Health CLINICAL RESEARCH STANDARD OPERATING PROCEDURES		
SOP No.: CR-CO-545.4	Status: Final	Version Date: 04/09/2026 Effective Date: 04/17/2027

1. PURPOSE

This Standard Operating Procedure defines participant status through the entirety of a research project and establishes the standards and procedures for changing a participant's status throughout their participation.

2. REQUIREMENTS

A research participant's status may change during the conduct of a research project for a variety of reasons. These may include completion of study treatment, investigator removal of a participant from a study, or voluntary withdrawal of consent to continue participation in a project. Criteria for removing research participants from a research project are outlined in the study protocol. Any change in participant status should be thoroughly and promptly documented in the participant's research record and in VCU's Clinical Research Management System.

3. DEFINITIONS

Consented- Participant has signed the Informed Consent Form (ICF). The eMR Research Participant Indicator in the patient chart becomes active.

Withdrawn- Participant has signed the ICF and has withdrawn consent prior to randomization.

Not eligible- Participant has signed the ICF but was deemed ineligible. This status is the equivalent of a "Screen Failure."

Eligible- Participant has signed the ICF and is confirmed eligible to participate in the study.

On study- Participant has signed the ICF, is eligible, and has been registered or randomized to a treatment/intervention. Note: No participant who is ineligible (screen failure) should have a status of "On Study."

On treatment- Participant has signed the ICF, is eligible, is on study, and has started treatment/intervention. Note: If the study does not involve a treatment/intervention, do not enter an "On Treatment" date.

Off treatment- Participant has completed or stopped the study treatment/intervention.
Note: All participants should have a status of "On Follow-Up" or "Off Study" after the "Off Treatment" status.

On follow-up- The Participant has completed or stopped the study treatment/intervention and is being monitored in the follow-up period of the study.

Off study- Participant has completed or stopped both the study treatment/intervention and follow-up. They will no longer be followed or have study-related visits.

Expired- Participant has died while on study.
Note: Enter the date of death in both the "Off Study Date" and the "Expired Date" fields.

4. PROCESS

Upon project enrollment, the status of a research participant should be managed as follows:

A. Research participants who sign consent and are enrolled in a research project must be entered into OnCore with the appropriate status within 24 hours of enrollment. Their status should also be documented in their patient chart and the study enrollment log, as applicable.

B. A participant may be removed from a study at any time. The research protocol should detail removal criteria, which may include, but is not limited to:
   - Compromising of participant's safety
   - The participant is non-compliant
   - The study is closed by the sponsor, the IRB, or other regulatory authorities
   - Administrative reasons
   - The best interest of the participant

   The investigator should always inform the participant of the reason for removal. Documentation of the removal, including the date of removal and rationale, should be entered into the participant's research record. The IRB should be notified of the removal at the time of continuing review. If the reason for removal is related to an unanticipated problem involving risks to participants or others, prompt reporting would be required according to the policies of the IRB of record.

C. Any change in a participant's study status must be promptly documented in OnCore and the participant's study file.

D. If a participant withdraws consent at any time, documentation of the participant's withdrawal should be filed in the participant's research record according to the sponsor's guidelines set forth in the informed consent form. The IRB should be notified of the withdrawal at the time of continuing review. If the reason for withdrawal is related to an unanticipated problem involving risks to participants or others, prompt reporting would be required according to the policies of the IRB of record.
Note: participants may decide to withdraw from certain components of the protocol such as withdrawing from images, specimens, etc. It's important to clarify withdrawal with the subject and document the withdrawal accordingly if participants withdraw from participation in the study after receiving treatment.

E. If a participant withdraws consent, all data collected prior to the date of withdrawal remains within the study database and can be included in data analysis.

F. If a participant withdraws consent and later recants their withdrawal, the participant must sign a new consent form and HIPAA authorization to continue participating in the project.

G. Delegated research personnel must notify the PI as soon as possible, preferably within 1 business day, of any participant withdrawal or important update regarding the withdrawal.

H. A participant is identified as 'lost-to-follow-up' (LTFU) according to the sponsor-provided definition. If the sponsor does not provide guidance, the participant is considered LTFU if all of the following criteria are met:
   - The last contact date for a participant has exceeded two (2) consecutive years.
   - Since the last contact date, documentation of at least three (3) attempts to contact the participant, which may include telephone, electronic message, and/or an IRB-approved certified letter to the last known address.

I. It is recommended that a death search be performed, such as an obituary search but this is not required to assign a participant a status of LTFU.

J. If a participant is determined to be lost to follow-up, a thorough explanation of the contact attempts should be documented (i.e., the certified letter receipt should be filed in the participant's research record with a copy of the

IRB approved letter sent), and the participant's status should be changed/confirmed in OnCore.

5. REFERENCES

A. US Code of Federal Regulations
- 45 CFR 46 – Protection of Human Subjects

B. US Food and Drug Administration
- Information Sheets for IRBs, Clinical Investigators, and Sponsors

C. US Office for Human Research Protections
- OHRP Guidance on Withdrawal of Subjects from Research

D. VCU/VCU Health Standard Operating Procedures
- CR-AD-120 – Clinical Research Management System

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

F. VCU Health Policy
- Research in Clinical Areas

G. VCU
- VCU OnCore Participant Management Manual

Review/Revision History CR-CO-545

Version No.	Effective Date	Description
CR-CO-545.4	04/15/2026	• Revised lost-to-follow-up criteria to remove the mandatory SSDI search
CR-CO-545.3	08/04/2025	• Clarified the time frame delegated research personnel must notify the PI of any participant withdrawal • Clarified contact attempt documentation examples • Streamlined lost to follow-up documentation; clarified placement of certified letter and added IRB approval reference. • Revised to specify IRB notification timing and added guidance on unanticipated problem reporting. • Updated all definitions • Aligned with ICH E6(R3) • Aligned with HRPP toolkit • Updated references • Biennial review performed • Minor formatting edits

		● Reference links updated
CR-CO-545.2	06-01-2021	● Biennial review performed ● Minor formatting edits ● Reference links updated
CR-CO-545.1	06-01-2018	● Original