


Enrollment in Ancillary Studies		
 VCU/VCU Health CLINICAL RESEARCH STANDARD OPERATING PROCEDURES		
SOP No.: CR-CO-535.3	Status: Final	Version Date: 07/22/2025 Effective Date: 08/04/2025

1. PURPOSE

This Standard Operating Procedure defines the processes for establishing ancillary studies and enrolling research participants in ancillary studies. This SOP applies to all clinical research studies conducted at VCU/VCU Health facilities, affiliates, and participating sites.

2. REQUIREMENTS

All relevant clinical research regulations, policies, guidelines, and standard operating procedures (SOPs) apply to ancillary studies.

The principal investigator (PI) proposing an ancillary study must ensure that sufficient methods are in place to protect the confidentiality and safety of study participants. The ancillary study PI or designee must inform potential participants that participation in the ancillary study is voluntary and not a condition of participation in the primary study, unless otherwise required by an Institutional Review Board (IRB)-approved protocol. During the entire lifecycle of the ancillary study, the ancillary study PI must coordinate with the primary study sponsor, investigators, and study team to ensure that their interests and the integrity of the primary study are protected.

3. DEFINITIONS

Primary Study- A primary study is the main clinical research study in which participants are enrolled (also referred to as a parent study).

Substudy- A study, regarded to be within the work scope of the primary study. Substudies are part of the overall clinical trial framework and are designed to complement the main study's goals.

Ancillary Study- An ancillary study is an adjunctive or supplemental study to a primary study. An ancillary study may or may not be a clinical trial, regardless of the clinical trial status of the primary trial. An ancillary study's goals may be outside the primary study's goals.

4. PROCESS

The PI of an ancillary study:

- A. Must consult with the PI of the primary study prior to submission of an associated ancillary study for IRB consideration.
- B. Must ensure the sponsor(s) of the primary study have been notified, if applicable.
- C. Must establish mechanisms and/or procedures for enrollment in ancillary studies in coordination with the primary study PI.
- D. Must maintain documentation of all correspondence with the primary study PI and sponsor in the ancillary study regulatory binder, if applicable.
- E. The PI of the ancillary study may also be the PI of the primary study. When serving as the PI for both studies, the PI or designee should maintain separate regulatory binders for each study and must coordinate all communication, conduct, and documentation relevant to both studies.

5. REFERENCES N/A

Review/Revision History CR-CO-535		
Version No.	Effective Date	Description
CR-CO-535.3	08/04/2025	<ul style="list-style-type: none"> ● Clarified definitions of primary study, ancillary study, and substudy for consistency with NIH and clinical trial guidance ● Updated language to reflect VCU/VCU Health naming conventions ● Clarified participant rights regarding voluntary participation in ancillary studies ● Expanded requirements for sponsor and PI coordination and documentation ● Biennial review performed ● Minor formatting edits ● Reference links updated
CR-CO-535.2	06-01-2021	<ul style="list-style-type: none"> ● Biennial review performed ● Minor formatting edits ● Reference links updated
CR-CO-535.1	07-27-2018	<ul style="list-style-type: none"> ● Original