Sponsor-Investigator IND/IDE Applications

VCU/VCU Health CLINICAL RESEARCH STANDARD OPERATING PROCEDURES

SOP No.: CR-RE-350.3	Status: Final	Version Date: 09/02/2025 Effective Date: 09/15/2025

1. PURPOSE

This Standard Operating Procedure provides guidelines for Investigational New Drug (IND) and/or Investigational Device Exemption (IDE) requirements for sponsor investigator research projects at VCU/VCU Health.

2. REQUIREMENTS

It is the policy of VCU/VCU Health that all research involving investigational agents (drug, biologic, or device) be reviewed and approved for use in compliance with all federal, state, and institutional regulations and policies. Approval may require review by the Food and Drug Administration (FDA) in the form of an IND or an IDE application.

3. DEFINITIONS

Food and Drug Administration (FDA) - The United States regulatory authority that is responsible for protecting the public health by ensuring the safety, efficacy and the security of human and veterinary drugs, biological products, medical devices, the nation's food supply, cosmetics and products that emit radiation. The FDA also provides accurate, science based health information to the public.

Investigational Device Exemption (IDE) – A request that allows an investigational device to be used in a clinical study in order to collect safety and effectiveness data.

Investigational New Drug (IND) – A request from a clinical study sponsor to obtain authorization from the FDA to administer an investigational drug or biological product to humans.

Investigator - An individual who actually conducts a clinical investigation (ex: under whose immediate direction the drug is administered or dispensed to a participant). In the event, the investigation is conducted by a team of individuals, the investigator is the responsible leader of the team (ex: principal investigator on record with the IRB). Any other individual member of the investigator's team is known as a "sub-investigator."

Sponsor - A person who takes responsibility for and initiates a clinical investigation. The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization. The sponsor does not actually conduct the investigation unless the sponsor is a sponsor-investigator. A person other than an individual that uses one or more of its own employees to conduct an investigation that it has initiated is a sponsor, not a sponsor-investigator, and the employees are investigators.

Sponsor-investigator - An individual who both initiates and conducts an investigation, and under whose immediate direction the investigational product is administered or dispensed. This term does not include any person other than an individual. A sponsor-investigator complies with all the applicable FDA regulations obligations of both a sponsor and an investigator (21 CFR 312 or 21 CFR 812).

4. PROCESS

A. The VCU Office of the Vice President for Research and Innovation (OVPRI)'s FDA program offers guidance in determining whether an IND/IDE is required and provides assistance with submitting to the FDA for the lifespan of an IND/IDE and how to comply with all applicable FDA regulations.

B. To receive assistance from the FDA program, reach out to the FDA program at the contacts provided on OVPRI's Regulatory Affairs webpage.

C. The following applicable VCU policies and program manual should be followed:

- VCU Policy – Reporting Sponsor-Investigator Investigational New Drug Applications (IND) or Investigational Device Exemptions (IDE)
- VCU FDA program manual

5. REFERENCES

A. Code of Federal Regulations
- 21 CFR 312 – Investigational New Drug Application
- 21 CFR 812 – Investigational Device Exemption

B. Good Clinical Practice
- ICH E6 (R3): Harmonized Tripartite Guideline for GCP

C. VCU

- VCU Faculty-Held IND/IDE Resource Website
- VCU Policy – Reporting Sponsor-Investigator Investigational New Drug Applications (IND) or Investigational Device Exemptions (IDE)

Review/Revision History CR-RE-350		
Version No.	**Effective Date**	**Description**
CR-RE-350.3	09/15/2025	● Revised to clarify IND/IDE definitions and roles of sponsor, investigator, and sponsor-investigator ● Added description of OVPRI FDA program support and related policy references ● Reformatted for clarity and consistency across sections ● Aligned with ICH E6(R3) ● Aligned with HRPP Toolkit ● Biennial review performed ● Minor formatting edits ● Definitions updated ● References and reference links updated
CR-RE-350.2a	07-01-2020	● Links updated
CR-RE-350.2	07-01-2020	● Biennial review performed ● Minor formatting edits ● Definitions updated ● References and reference links updated
CR-RE-350.1	02-03-2018	● Original