Form FDA 1572		
VCU/VCU Health CLINICAL RESEARCH STANDARD OPERATING PROCEDURES		
SOP No.: CR-ST-220.3	Status: Final	Version Date: 11/22/2024 Effective Date: 01/15/2025

1. PURPOSE

The purpose of this SOP is to provide guidance on the completion, maintenance, and identification of key study personnel on the FDA Form 1572.

2. REQUIREMENTS

A Form FDA 1572 is required to provide the sponsor with information about the Principal Investigator's (PI) qualifications and the clinical site, which will enable the sponsor to establish that the PI is qualified and the site is an appropriate location to conduct the study. The form also informs the PI of their obligations and documents the PI's commitment to following FDA regulations. The PI's signature on the form documents their affirmation of qualification to conduct the clinical study and their affirmation to abide by FDA regulations. A false statement made per the 1572 is considered a criminal offense under 18 U.S.C. 1001 and can lead to the disqualification of the investigator.

Form FDA 1572 is only required for studies of investigational drugs and biologics conducted under an Investigational New Drug Application per 21 CFR 312.53(c).

This policy does not apply to investigator-specific Form FDA 1572 required for National Cancer Institute-sponsored studies.

3. DEFINITIONS

Form FDA 1572

A 1572 is an FDA form that is an agreement signed by the investigator to provide certain information to the sponsor and assure they will comply with FDA regulations related to the conduct of a clinical investigation of an investigational drug or biologic.

Principal Investigator

The Principal Investigator (PI) is the individual with overall responsibility for the scientific and technical, financial, and regulatory direction and success of a project. The PI ensures that a project is carried out in compliance with federal regulations and the terms, conditions, and policies of the sponsor, VCU, and VCU Health. The PI may delegate some duties to key research personnel; however, the ultimate responsibility for the management of the project rests with the PI.

Sponsor-Investigator

An individual VCU faculty member (not a company) who both initiates and conducts an investigation and complies with all the obligations of both a sponsor and an investigator.

Sub-investigator

A sub-investigator is an individual member of a research team, other than the Principal Investigator that plays a significant role in the design and conduct of a research project and is generally delegated significant duties as part of a research team, including, but not limited to, conducting informed consent, study procedures, and evaluation of participants' medical and clinical status.

Investigational New Drug (IND)

An IND is a request from a clinical sponsor to obtain authorization from the FDA to administer an investigational drug or biologic product to humans.

4. PROCESS

All projects requiring a Form FDA 1572 should adhere to the following:

A. The most current version of the Form FDA 1572 (located on the FDA web page) must always be used.

B. Only individual(s) who meet the following criteria should be identified as the responsible investigator in section 1 on the Form FDA 1572:
   - The PI who is listed on the IRB application for the VCU site

C. The investigator is not required to be a physician. In this case, a qualified physician must be listed as a sub-investigator. The physician sub-investigator will be responsible for trial-related medical decisions.

D. Should a study have Co-Principal Investigators, each investigator must complete and sign a separate Form FDA 1572.

E. The PI should identify the individuals to be listed in section 6 of the Form FDA 1572. Per FDA Guidance, individuals who are involved in research activities that go beyond routine clinical care by making significant contributions to study data, conducting study procedures, and fulfilling the key objectives of the study should be listed on the 1572. These may include, but are not limited to, coordinators, radiologists, surgeons, pathologists, fellows, nurse practitioners, physician assistants, and oncology nurses. Hospital staff such as pharmacists, pharmacy technicians, infusion nurses, and inpatient nurses, who provide ancillary care but do not make a direct and significant contribution

to the study data, are not generally identified on the Form FDA 1572. The sponsor typically decides what role(s) should be included.

F. Form FDA 1572 is updated when information on the form changes such as a change of Principal Investigator(s) or individuals listed in section 6 of the Form FDA 1572.

G. A new Form FDA 1572 is not required when the Office of Management and Budget (OMB) expiration date is reached. However, a new form should be used the next time an update is required.

H. For sponsored studies, a copy of the signed Form FDA 1572 (per sponsor requirements) is forwarded to the sponsor with the original/copy always maintained in the regulatory binder. For Sponsor-Investigator studies (also called Investigator Initiated studies), the original Form FDA 1572 is maintained at VCU, even if a study is funded externally.

5. REFERENCES

A. Code of Federal Regulations
- 21 CFR 50 - Protection of Human Subjects
- 21 CFR 56 - Institutional Review Boards
- 21 CFR 312 - Investigational New Drug Application

B. FDA
- Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs Form FDA 1572 Instructions

C. United States Code
- 18 U.S.C. 1001 - Statements or Entries

D. VCU
- VCU HRPP Policies and Guidance
- VCU Regulatory Affairs Program

Review/Revision History CR-ST-220		
Version No.	**Effective Date**	**Description**
CR-ST-220.3	**01/15/2025**	● Minor formatting edits ● Updates FORM 1572 requirements explanation ● Updates FORM 1572 definition ● Updated IND definition ● Clarified who meets the criteria to be identified as a responsible investigator ● Reference links updated ● Updates FORM 1572 requirements explanation
CR-ST-220.2a	06-01-2020	● Links updated
CR-ST-220.2	06-01-2020	● Biennial review performed ● Minor formatting edits ● Reference links updated
CR-ST-220.1	08-27-2017	● Original