Table of Contents

1. Overview

Purpose

This guidance describes the process for completing and maintaining the Statement of Investigator Form (Form FDA 1572) for clinical investigators and their personnel involved in FDA-regulated clinical research studies related to the conduct of a clinical investigation of an investigational drug or biologic per 21 CFR 312.

This process documents that the Principal Investigator (PI) understands their responsibilities and commitments as outlined in the Form FDA 1572, per 21 CRF 312, and provides the sponsor with information about investigator qualifications and the study site(s).

2. Definitions

Form FDA 1572: An agreement signed by the investigator to provide certain information to the sponsor and assure that he/she will comply with FDA regulations related to the conduct of a clinical investigation of an investigational drug or biologic.

3. General 1572 Guidelines

a) The PI or designated personnel obtains the current version of FDA Form 1572 from the FDA website (https://www.fda.gov/media/71816/download) or the sponsor.

b) Ensure the form is accurately completed electronically or on paper/wet ink that is clear and legible.

c) If additional form fields are needed, e.g., for listing multiple site or laboratory addresses, use the "Continuation Page" options on the 1572 to add entry fields.

d) No changes are made to the form after the PI signs it. If the form needs to be updated after the PI signs it, a new form should be completed and signed by the PI.

   i) Any time there is a change in the PI for the study, a new FDA Form 1572 is completed and resubmitted to all appropriate parties.

   ii) Other changes only need to be notified to the sponsor but do not require a new form. In general, keeping the 1572 up to date with current Investigator and site information is recommended.

4. Completing the 1572

a) The PI name should contain the full legal name as it appears on the investigator's birth certificate or marriage certificate. Titles and qualifications may follow the investigator's legal name (Section 1).

b) The address of the investigator should be where the investigator can be reached by mail or in person, typically the investigator's work address (Section 1).

c) All intended sites where patients will be seen, or where investigational product(s) will be shipped, including other office or clinic locations, must be listed on the 1572 (Section 3).

d) All clinical laboratory sites to be used, including central labs, local labs, imaging centers, or processing locations for protocol assays (Section 4).

e) Name and address of the Institutional Review Board (IRB) responsible for review and approval of the study(ies), e.g., WCG IRB, Drexel HRP, etc. (Section 5).

f) Names of sub-investigators assisting the investigator in the investigation's conduct (Section 6).

   i) Personnel listed should include individuals directly involved in the performance of procedures required by the protocol and collection of data.

   ii) Research coordinators contributing to critical study functions and making contributions to data, e.g., recruiting participants, collecting study data, maintaining study records, should be listed on the 1572.

   iii) Hospital staff providing ancillary care that does not provide direct or significant contribution to the data do not need to be listed.

g) List the name and sponsor's code number, if any, of the protocol(s) under the IND to be conducted by the PI (Section 7).

h) The PI must sign the 1572, agreeing to the commitments outlined in Section 9, via Part 11 compliant electronic signature or wet ink signature.

5. Filing the 1572

a) The completed 1572 is forwarded to the sponsor. The sponsor may require the original wet ink copy of the 1572.

b) A copy of the completed 1572 is maintained with the site's essential regulatory documents or in the electronic regulatory binder.

6. Responsibilities

6.1 Office for Research & Innovation Responsibilities

The Office for Research & Innovation is responsible for maintaining this guidance document, applicable tools and monitoring. For inquiries regarding this guidance, please contact the Associate Vice Provost for Research Compliance and Regulatory Affairs, as part of the Office for Research & Innovation (ORI).

6.2 Principal Investigator Responsibilities

The Principal Investigator retains overall responsibility for the study conduct, documentation, and oversight. The PI is responsible for accurately completing, signing and maintaining the FDA Form 1572. The PI must ensure the form is completed electronically or with wet ink that is clear and legible.

6.3 Study Personnel Responsibilities, as delegated by the PI

Study personnel, as delegated by the PI, are responsible for assisting the PI in ensuring compliance with this SOP and maintaining a copy of the completed Form FDA 1572 in the investigator site binder or with the essential regulatory documents. Personnel are also responsible for notifying the sponsor of any changes to the FDA Form 1572.

7. Resources

- 21 CFR, Part 312: Investigational New Drug Application
- FDA Form 1572
- FDA FORM 1572_FAQs
- FDA Form 1572_Information Guidance Sheet
- FDA Form 1572 Instructional Supplement

8. Revision and Workgroup Members

8.1 Revision

Version 001/Effective Date 1/24/2025 – Original Document: Completion of Form FDA 1572

8.2 Workgroup & Advisory Members

The Office for Research and Innovation appreciates the following individuals who served as Workgroup and Advisory Members:

Workgroup & Advisory Members	
Taish Bruton Executive Administrator College of Medicine	**Janet Matthews, MSN RN** Senior Director, Research Program Development College of Medicine
Marisa Corbett, BA, CCRC Executive Director, Research Quality Assurance Office of Research & Innovation	**Carissa Miller** Research Compliance Coordinator Office of Research & Innovation
Honora Cutler, BSN, RN Clinical Research Operations Manager College of Medicine	**Cassandra Myers, BS** Associate Vice Provost, Research Compliance and Regulatory Affairs Office of Research & Innovation
Rose Ann DiMaria-Ghalili, PhD, RN, FASPEN, FAAN, FGSA Senior Associate Dean for Research Professor College of Nursing and Health Professions	**Jacqueline Stults, MBA, BS** Research Quality Assurance/Quality Improvement Office of Research & Innovation