University Hospitals
Case Medical Center

Form FDA 1572: Statement of Investigator

Objectives

To understand:

- What the purpose of Form FDA 1572 is.
- The commitments the investigator agrees to by signing Form FDA 1572.
- When Form FDA 1572 is required to be completed.
- How to fill out Form FDA 1572.

What is Form FDA 1572?

- Statement signed by the investigator
- Provides information to the sponsor
- Often referred to simply as a “1572”
- Assures the investigator will comply with FDA regulations related to the conduct of a clinical investigation of an investigational drug or biologic

Why Does the Form Need to be Completed by the Investigator?

FDA 1572 has two purposes:

1. It provides the sponsor with information about the investigator's qualifications and the site that enables the sponsor to establish and document that the investigator is qualified and the site is an appropriate location to conduct the study.

2. To inform the investigator of his/her obligations and obtain the investigator's commitment to follow FDA regulations.

1572 Investigator Commitments

By signing Form FDA 1572 you agree to all of the following commitments regarding the conduct of the study:

- I agree to conduct the study(ies) in accordance with the relevant, current protocol(s) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

- I agree to personally conduct or supervise the described investigation(s).

1572 Investigator Commitments (cont)

By signing Form FDA 1572 you agree to all of the following commitments regarding the conduct of the study:

- I agree to inform any patients, or any persons used as controls, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review and approval in 21 CFR Part 56 are met.

1572 Investigator Commitments (cont)

By signing Form FDA 1572 you agree to all of the following commitments regarding the conduct of the study:

- I agree to report to the sponsor adverse experiences that occur in the course of the investigation(s) in accordance with 21 CFR 312.64.

- I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.

1572 Investigator Commitments (cont)

By signing Form FDA 1572 you agree to all of the following commitments regarding the conduct of the study:

- I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.

1572 Investigator Commitments (cont)

By signing Form FDA 1572 you agree to all of the following commitments regarding the conduct of the study:

- I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for inspection in accordance with 21 CFR 312.68.

1572 Investigator Commitments (cont)

By signing Form FDA 1572 you agree to all of the following commitments regarding the conduct of the study:

- I will ensure that an IRB that complies with the requirements of 21 CFR Part 56 will be responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

1572 Investigator Commitments (cont)

By signing Form FDA 1572 you agree to all of the following commitments regarding the conduct of the study:

- I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

When is Form FDA 1572 Required?

- Under the Federal regulations, a 1572 is required for studies of investigational drugs or biologics conducted under an Investigational New Drug (IND) application

Note: A 1572 is not required for studies not conducted under an IND and is not applicable to investigational device studies. If you are uncertain whether or not Form FDA 1572 is required for your study contact the study sponsor or the UHCMC Center for Clinical Research and Technology at 216-844-5576 for assistance.

When Must the Form be Completed and Signed by the Investigator?

- The sponsor must obtain a completed and signed 1572 before permitting an investigator to participate in a clinical investigation.

- The investigator should sign the form only after being given enough information to be informed about the study and understand the commitments described in block # 9 (Investigator Commitments). Having enough information about the study means:
  - Investigator received copies of, has read and understands, the investigator's brochure and the protocol and is familiar with the regulations governing the conduct of clinical studies.

Must Investigators Who Conduct Studies Outside of the United States Sign a 1572?

- If a foreign clinical study is conducted under an IND, then all FDA regulations (including obtaining a 1572) apply.

- If a foreign clinical study is not conducted under an IND, then a 1572 is not required.

Completing FDA Form 1572

Block 1: Name and Address of Investigator

How should an investigator's name appear on the 1572?

- Block 1 should contain the investigator's legal name

What address should be entered on the 1572?

- The investigator's official address of record should be entered in block 1

Should co-investigators be listed on the 1572?

- Co-investigators should not be listed in block 1 of the 1572. Under the regulations, each co-investigator is an investigator and must sign a separate 1572

Block 2: Curriculum Vitae (CV) / Statement of Qualifications

What is the purpose of block 2 on the 1572?

- Block 2 requires the investigator to attach a CV or other statement of qualifications showing education, training and experience that qualifies the investigator as an expert in the investigation.

Does the CV or other statement of qualifications need to be updated during a study?

- FDA regulations do not require a CV or other statement of qualification be updated during a study.

Are CVs required to be signed and dated ?

- FDA regulations do not require a CV to be signed and dated.

Block 3: Research Facilities

What address should be entered in block 3 of the 1572?

- The address(es) of the location(s) where the investigation will be conducted and where the test articles will be shipped, if different from the investigator's address of record.

What qualifies as a research facility for block 3?

- Block 3 is intended to identify facilities where study activities will be conducted and study data will be generated or collected. This includes facilities where study participants will be seen and study procedures will be performed.

If an investigator sees study participants at more than one site, should the investigator list all sites on the 1572?

- Yes, the names and addresses of each of the study sites should be listed on the 1572.

Block 4: Name and Address of Clinical Laboratory Facilities

What qualifies as a clinical laboratory?

- Block 4 is intended to identify clinical laboratories or testing facilities directly contributing to or supporting the clinical trial

Block 5: Name and Address of IRB Responsible for the Review and Approval of the Clinical Study

Does the IRB reviewing and approving the study have to be at the same location as where the research is located?

- No, the regulations permit review of research by IRBs in locations other than where the research is performed (e.g. central IRBs)

For studies approved by the UH Case Medical Center IRB following is the name and address:

IRB Administration Office
University Hospitals
Lakeside 1400
11100 Euclid Avenue
Cleveland, OH 44106
MS: LKS 7061
216-844-1529

Block 6: Names of Sub-Investigators

Who should be listed as a sub-investigator?

- Any member of the research team assisting the investigator and who makes a direct and significant contribution to the data.

Should research nurses, other nurses, residents or fellows be listed in block 6 of the 1572?

- Individuals providing ancillary or intermittent care but who do not make a direct or significant contribution to the data do not need to be listed in block 6 on the 1572.

Block 6: Names of Sub-Investigators (cont.)

Should pharmacists or research coordinators be listed in block 6 of the 1572 ?

- If the pharmacist will be compounding, labeling, monitoring and reporting test article compliance data, it would be appropriate to list the pharmacist in block 6 on the 1572

Is a statement of qualifications required for sub-investigators?

- No, the regulations require only their names be listed in block 6 on the 1572

Do individuals listed in block 6 on the 1572 have to submit information about their financial interests?

- Yes, an individual identified as an investigator or sub-investigator on the 1572 must submit financial disclosure information to the sponsor

Please contact UH Center for Clinical Research and Technology for any questions you may have about Form FDA 1572.

Center for Clinical Research and Technology

216-844-5576

Lakeside 1400, UH Case Medical Center