
	Office of Sponsor and Regulatory Oversight	Document #: FI01-406-S01
	Form FDA 1572 Instructions	Revision #: 6
		Effective Date: 10JUL2023

1. General Information and Instructions


- 1.1. This form instruction is to assist clinical investigators in completing Form FDA 1572 Statement of Investigator. Under FDA regulations, a 1572 is only required for studies of investigational drugs and biologics conducted under an IND. It is not required for studies that are not done under an IND and is not applicable to investigational device studies.
- 1.2. Form FDA 1572 has two purposes: 1) to provide the sponsor with information about the Principal Investigator's qualifications and the clinical site that will enable the sponsor to establish and document that the investigator is qualified and the site is an appropriate location at which to conduct the clinical investigation, and 2) to inform the investigator of his/her obligations and obtain the investigator's commitment to follow pertinent FDA regulations.
- 1.3. Form FDA 1572 may be downloaded from <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM074728.pdf>. See Appendix A for a copy of the Form. Only the current release of the form will be accepted by OSRO; expired versions of Form FDA 1572 are unacceptable.
- 1.4. A new 1572 is required when any one of the following conditions apply: 1.) an investigator is participating in a new protocol which is added to an active IND; 2.) the Principal Investigator of an ongoing study changes, 3.) a change of location in which the study is being conducted, or 4.) when a new study team member who will make a direct and significant contribution to the study data is added to the Task Delegation Log.
- 1.5. For further information, consult the [FDA Information Sheet](#) Guidance for Sponsors, Clinical Investigators, and IRBs: Frequently Asked Questions – Statement of Investigator (Form FDA 1572) published in May 2010.

2. Completing Form FDA 1572


- 2.1. Note: The field numbers provided in the following steps correspond to the numbered boxes on Form FDA 1572.
- 2.2. Field 1: NAME AND ADDRESS OF INVESTIGATOR
 - 2.2.1. The investigator's full legal name (e.g., name on the investigator's birth certificate or marriage certificate) must be used.
 - 2.2.2. The work address where the investigator can be reached by mail or in person should be entered. An administrative room number within a building must be included.
- 2.3. Field 2: EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION
 - 2.3.1. A curriculum vitae (CV) or other statement of qualifications, showing the education, training and experience that qualifies the investigator as an expert in the clinical investigation of the drug/biologic for the use under investigation will be provided for each investigator and sub-investigator.

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- 2.3.2. OSRO expects the CV to be current within the last 4 years and to include the investigator’s or sub-investigator signature and date.
- 2.3.3. Check the box corresponding to the provided document.
- 2.4. Field 3: NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED
 - 2.4.1. The name(s) and address(es) of the location(s) where the investigation will be conducted and to where the test articles will be shipped, if different from the investigator's address of record, should be entered.
 - 2.4.2. The full business address must be used. An administrative room number within a building must be included.
- 2.5. Field 4: NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY
 - 2.5.1. The name(s) and address(es) of the clinical laboratories or testing facilities that conduct tests that are both directed by the clinical study protocol and contribute to the primary or secondary objectives thus directly contributing to or supporting the clinical study (for example, diagnostic labs performing blood work, imaging centers, cardiology labs, etc.) are identified. This may include analytical labs that provide pharmacokinetic analysis, and laboratories supplying efficacy data for clinical investigations conducted under an IND.
 - 2.5.2. The full business address must be used. An administrative room number within a building must be included.
- 2.6. Field 5: NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW AND APPROVAL OF THE STUDY(IES)
 - 2.6.1. The name and full business address must be provided, including office/room number.
- 2.7. Field 6: NAMES OF SUB-INVESTIGATORS
 - 2.7.1. Sub-investigators are individuals who are part of the investigative team led by the principal investigator. They assist the investigator and make a direct and significant contribution to the data, i.e., make substantial contributions to the conception, design of the study, and execution of the study including, but not limited to, obtaining informed consent from protocol participants, the acquisition of data, or to the analysis and interpretation of data.
 - 2.7.2. There are no “co-principal investigators (Co-PIs).” If an investigator is considered to be a “co-principal investigator,” the Co-PI will need to provide his/her own Form FDA 1572.
 - 2.7.3. The decision to list an individual depends on his/her level of responsibility (i.e., whether he/she is performing significant clinical investigation-related duties). In general, if an individual is directly involved in the performance of procedures required by the protocol, and the collection of data, that person should be listed on Form FDA 1572.
 - 2.7.4. Hospital staff, including nurses, residents, or fellows and office staff who provide ancillary or intermittent care but who do not make a direct and significant contribution to the clinical data, should not be listed.

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- 2.7.5. A research coordinator who recruits subjects, collects and evaluates study data, and maintains study records should usually be listed.
- 2.7.6. Note: Individuals listed in this field must submit financial disclosure information to the sponsor.
- 2.7.7. If there are no sub-investigators, then enter “None.”
- 2.8. Field 7: NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR THE STUDY(IES) TO BE CONDUCTED BY THE INVESTIGATOR
 - 2.8.1. List the full protocol title and protocol number (if available) for the study under the IND that will be conducted by the investigator signing Form FDA 1572.
- 2.9. Field 8: PROVIDE THE FOLLOWING CLINICAL PROTOCOL INFORMATION
 - 2.9.1. Select one of the following that best describes the study phase and provide the requested document.
 - 2.9.1.1. For Phase 1 investigations, a general outline of the planned investigation including the estimated duration of the study and the maximum number of subjects that will be involved.
 - 2.9.1.2. For Phase 2 or 3 investigations, an outline of the study protocol including an approximation of the number of subjects to be treated with the drug and the number to be employed as controls, if any; the clinical uses to be investigated; characteristics of subjects by age, sex, and condition; the kind of clinical observations and laboratory tests to be conducted; the estimated duration of the study; and copies or a description of case report forms to be used.
 - 2.9.1.2.1. The protocol or a detailed description is required.
- 2.10. Field 9: COMMITMENTS
 - 2.10.1. By signing the form, the investigator is committing to the following conditions.
 - 2.10.1.1. To conduct the study(ies) in accordance with the relevant, current protocol(s) and to only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.
 - 2.10.1.2. To personally conduct or supervise the described investigation(s).
 - 2.10.1.2.1. To inform any patients, or any persons used as controls, that the drugs are being used for investigational purposes and 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.
 - 2.10.1.3. To report to the sponsor adverse experiences that occur in the course of the investigation(s) in accordance with 21 CFR 312.64. To read and understand the information in the investigator’s brochure, including the potential risks and side effects of the drug.

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- 2.10.1.4. 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.
- 2.10.1.5. 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.
- 2.10.1.6. To 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. To promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. To not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.
- 2.10.1.7. To comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

2.11. Fields 10 - 11 INVESTIGATOR SIGNATURE AND DATE

- 2.11.1. The investigator signs and dates the form. The date format is mm/dd/yyyy. An electronic certified signature should be used.
- 2.11.2. The investigator’s signature on the form constitutes the investigator’s affirmation that s/he is qualified to conduct the clinical investigation and constitutes the investigator’s written commitment to abide by FDA regulations in the conduct of the clinical investigation.



3. Appendix A. Form FDA 1572 Statement of Investigator, version 3/22.

<p>DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION</p> <p>STATEMENT OF INVESTIGATOR <i>(TITLE 21, CODE OF FEDERAL REGULATIONS (CFR) PART 312)</i> (See instructions on reverse side.)</p>		<p>Form Approved: OMB No. 0910-0014 Expiration Date: March 31, 2025 See <i>OMB Statement on Reverse</i>.</p> <p>NOTE: No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator, Form FDA 1572 (21 CFR 312.53(c)).</p>	
1. NAME AND ADDRESS OF INVESTIGATOR			
Name of Clinical Investigator			
Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code
2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS PROVIDED (<i>Select one of the following.</i>)			
<input type="checkbox"/> Curriculum Vitae		<input type="checkbox"/> Other Statement of Qualifications	
3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED			CONTINUATION PAGE for Item 3
Name of Medical School, Hospital, or Other Research Facility			
Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code
4. NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY			CONTINUATION PAGE for Item 4
Name of Clinical Laboratory Facility			
Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code
5. NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW AND APPROVAL OF THE STUDY(IES)			CONTINUATION PAGE for Item 5
Name of IRB			
Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code
6. NAMES OF SUBINVESTIGATORS (<i>If not applicable, enter "None"</i>)			
			CONTINUATION PAGE – for Item 6
7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR THE STUDY(IES) TO BE CONDUCTED BY THE INVESTIGATOR			



8. PROVIDE THE FOLLOWING CLINICAL PROTOCOL INFORMATION. (Select one of the following.)

- For Phase 1 investigations, a general outline of the planned investigation including the estimated duration of the study and the maximum number of subjects that will be involved.
- For Phase 2 or 3 investigations, an outline of the study protocol including an approximation of the number of subjects to be treated with the drug and the number to be employed as controls, if any; the clinical uses to be investigated; characteristics of subjects by age, sex, and condition; the kind of clinical observations and laboratory tests to be conducted; the estimated duration of the study; and copies or a description of case report forms to be used.

9. COMMITMENTS

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).

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.

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.

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.

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.

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.

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

**INSTRUCTIONS FOR COMPLETING FORM FDA 1572
STATEMENT OF INVESTIGATOR**

1. Complete all sections. Provide a separate page if additional space is needed.
2. Provide curriculum vitae or other statement of qualifications as described in Section 2.
3. Provide protocol outline as described in Section 8.
4. Sign and date below.
5. FORWARD THE COMPLETED FORM AND OTHER DOCUMENTS BEING PROVIDED TO THE SPONSOR. The sponsor will incorporate this information along with other technical data into an Investigational New Drug Application (IND). INVESTIGATORS SHOULD NOT SEND THIS FORM DIRECTLY TO THE FOOD AND DRUG ADMINISTRATION.

10. DATE (mm/dd/yyyy)

11. SIGNATURE OF INVESTIGATOR

Sign

(WARNING: A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001.)

The information below applies only to requirements of the Paperwork Reduction Act of 1995.

The burden time for this collection of information is estimated to average 100 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to the address to the right:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DO NOT SEND YOUR COMPLETED FORM TO THIS PRA STAFF EMAIL ADDRESS.