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## **INSTRUCTIONS FOR FILLING OUT FORM FDA 1572 – STATEMENT OF INVESTIGATOR**

*(The field numbers below correspond to the numbered boxes on the Form FDA 1572)*

### **Field 1: NAME OF AND ADDRESS OF INVESTIGATOR**

Provide the clinical investigator's full legal name (e.g., name on the investigator's birth certificate or marriage certificate). Titles, degrees, and/or professional qualifications may follow the investigator's legal name, if desired. The address is where the investigator can be reached by mail or in person. Usually this corresponds to the investigator's work or business address.

Field 1 should only list one clinical investigator. The term co-investigator is not defined in FDA regulations. As commonly used, the term is meant to indicate that each co-investigator is fully responsible for fulfilling all of the obligations of an investigator as identified in 21 CFR 312.60. Thus under 21 CFR 312.3(b), each co-investigator is an investigator, and as such must sign a separate Form FDA 1572.

### **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**

The investigator is required to attach either 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.

### **Field 3: NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED**

Provide the address(es) of the location(s) where the investigation will be conducted and clinical data will be generated or collected and to where the test articles will be shipped.

Field 3 is intended to identify facilities where study activities will be conducted and clinical data will be generated or collected. This includes facilities where subjects will be seen and study procedures will be performed, e.g., locations such as health care facilities where the test articles will be administered, or where physical exams will be performed. Facilities where other important clinical investigation functions are performed may also be identified. For example, a research laboratory where the test article is prepared, a special storage facility where the test article will be kept, or a location where tissue specimens are collected should be in this section.

If an investigator sees study subjects at more than one site, the name and address of each of the study sites should be identified in Field 3. However, if the protocol specifies that the investigative product can be administered at a subject's home (for example, the protocol allows for daily injections to be administered by a registered nurse in the subject's home), the subjects' home addresses do not have to be listed on the Form FDA 1572. Study records should reflect that the test article was administered at subjects' homes per the protocol.

Use the Continuation Page if additional space is needed.

### **Field 4: NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY**

Identify clinical laboratories or testing facilities directly contributing to or supporting the clinical study (for example, diagnostic labs performing blood work, imaging centers, cardiology labs, etc.). This may include analytical labs that provide pharmacokinetic analysis, and laboratories supplying efficacy data for clinical investigations conducted under an Investigational New Drug Application (IND).

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If a laboratory is sending samples to satellite or other contract labs for additional testing, it is only necessary to list the primary laboratory, provided that laboratory can trace the samples to each of the satellite and/or contract labs where the tests were performed.

Use the Continuation Page if additional space is needed.

**Field 5: NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW AND APPROVAL OF THE STUDY(IES)**

Use the Continuation Page if additional space is needed.

**Field 6: NAMES OF SUBINVESTIGATORS**

21 CFR 312.3(b) states: "In the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team. 'Subinvestigator' includes any other individual member of that team." 21 CFR 312.53(c)(1)(viii) requires the investigator to provide "a list of the names of the subinvestigators (e.g., research fellows, residents) who will be assisting the investigator in the conduct of the investigation(s)."

The purpose of Field 6 is to capture information about individuals who, as part of an investigative team, will assist the investigator and make a direct and significant contribution to the data. The decision to list an individual in Field 6 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 the Form FDA 1572. For example, if the protocol notes that each subject needs to visit a specified internist who will perform a full physical to qualify subjects for the clinical investigation, that internist should be listed in Field 6.

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, do not need to be listed individually.

Use the Continuation Page if additional space is needed.

**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**

List the names and code numbers (if any) of all the protocols under the IND that will be conducted by the investigator signing the Form FDA 1572. A code number is an identifying number assigned by the sponsor.

**Field 8: PROVIDE THE FOLLOWING CLINICAL PROTOCOL INFORMATION**

Note: Only one box may be selected.

For a combined Phase 1/2 investigation, check only the second box.

For a Phase 4 post marketing clinical trial, check only the second box, and state in Field 7 that the study is a Phase 4 study.

**Field 9: COMMITMENTS**

Field 9 contains important commitments that the investigator agrees to by signing the form. The investigator should sign the form only after being given enough information to be informed about the clinical investigation and to understand the commitments described in Field 9. Having enough information about the study typically means that the investigator has received copies of, has read, and understands the protocol and investigator's brochure (if required), and is familiar with the regulations governing the conduct of clinical studies.

**Field 10: DATE**

Enter the date that the form is signed by the investigator.

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**Field 11: SIGNATURE OF INVESTIGATOR**

The investigator identified in Field 1 must sign the form.

The investigator's signature on this form constitutes the investigator's affirmation that he or she 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 investigations.

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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.

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**Frequently Asked Questions – Statement of Investigator (Form FDA 1572)**

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FDA has published an *Information Sheet for Guidance for Sponsors, Clinical Investigators, and IRBs Frequently Asked Questions – Statement of Investigator (Form FDA 1572)* May 2010 that is intended to assist sponsors, clinical investigators, and institutional review boards involved in clinical investigations of investigational drugs and biologics conducted under 21 CFR Part 312 (Investigational New Drug Applications or IND regulations). Please refer to this guidance for further information on how to complete the Statement of Investigator Form FDA 1572 and to review FDA's responses to the most frequently asked questions about Form FDA 1572.