Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs, Frequently Asked Questions

Statement of Investigator (Form FDA 1572) May 2010 Procedural

This guidance describes how to complete the Statement of Investigator form (Form FDA 1572). It includes a list of 38 Frequently Asked Questions encountered when completing the form. The following Summary provides highlights of Key Points found in the May 2010 Procedural. For an expansion on any of these points, and for points not highlighted here, please refer to the original document. Numbers below correspond with the numbered questions in the document.

2. Why does this form need to be completed by an investigator?

   • To 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
   • To inform the investigator of his/her obligations and obtain the investigator’s commitment to follow pertinent FDA regulations.

3. When must this form be completed and signed by an investigator?

   Whenever a sponsor selects a new investigator to participate in a clinical investigation that is being conducted under an investigational new drug application (IND), the sponsor must obtain a completed and signed 1572.

4. Must the investigator be a physician?

   No, however, if the clinical investigator is a non-physician, a qualified physician should be listed as a subinvestigator for the trial and should be responsible for all trial-related medical decisions.

5. What are the minimum qualifications of an investigator?

   Sponsors must select investigators who are qualified by training and experience as appropriate experts to investigate the drug. Regulations do not specify minimum requirements or qualifications required by an investigator.

21. Should co-investigators be listed on the 1572 in Section #1? Is it acceptable to have more than one investigator at a single site?

   It is acceptable to have more than one investigator at a single site, however, as commonly used, the term co-investigator indicates an individual fully responsible for fulfilling all of the obligations of an investigator as described in 21 CFR 312.60. If this is the case, each co-investigator must sign a separate 1572.

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

   No.

24. Are CVs required to be signed and dated?

   No.
27. If an investigator sees study subjects at more than one site, should the investigator list all sites on the 1572?

   Yes.

32. Should research nurses, other nurses, residents, fellows, office staff, or other hospital staff be listed in Section #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. Additionally, specific names of rotational staff who might perform specified protocol procedures or collect clinical data do not have to be listed in Section #6, rather, the names of rotational individuals and the procedures they are expected to perform should be included in the clinical study records.

33. Should pharmacists or research coordinators be listed in Section #6?

   This is a matter of judgment dependent upon the contribution the individual makes to the study. If the individual makes a direct and significant contribution to the data for a particular study, then they would be listed in Section #6. According to this criteria, Research Coordinators should usually be listed in Section #6.

34. Is a statement of qualifications required for subinvestigators?

   No.

35. Do individuals who are listed in Section #6 on the 1572 have to submit information about their financial interests?

   Yes. A person listed as an investigator or subinvestigator who is directly involved in the treatment or evaluation of research subjects must submit financial disclosure information to the sponsor. For the purposes of financial disclosure, the term investigator also includes the spouse and each dependent child of the investigator and subinvestigator.