Information and guidance sheet for the completion of the Statement of Investigator Form. (Form FDA 1572).

Purpose

- The Statement of Investigator, Form FDA 1572, is an agreement, signed by the Principal Investigator (PI), to provide certain information to the Sponsor about the Principal Investigator's qualifications and the clinical site.
- To support verification by the Sponsor that the Principal Investigator is qualified and the site is an appropriate location at which to conduct the clinical investigation.
- To inform the Principal Investigator of his/her obligations and obtain the commitment to follow pertinent FDA regulations related to the conduct of a clinical investigation of an investigational drug or biologic.

Important notes

- All information presented in this guidance is as a supplement to the FDA guidance titled **"Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs Frequently Asked Questions – Statement of Investigator (Form FDA 1572) May 2010".** It is recommended to read the information sheet alongside this information and guidance sheet.
- The current version of the form and instructions can be located at:
    - http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm

  This is the link to access all FDA forms. Once you have accessed the link, scroll down to the "1572" noted in the forms column to ensure use of the most current form and instruction sheet. In the instance when the FDA's Office of Management and Budget (OMB) has not posted an updated Form FDA 1572 and the expired version is the only one available on the website, it is acceptable to use the expired form.

When should the Form FDA 1572 be completed and signed by the Principal Investigator?

- When a study is being conducted under an Investigational new drug application (IND).
- When an investigator is participating in a new protocol that has been added to the IND.
- When a new investigator is added to the study (21 CFR 312.53(c)).
- It must be completed and signed before an investigator can participate in a clinical investigation.
- When the investigator is informed about the clinical investigation and understands the commitments stated in section #9 of the Form FDA 1572.

Should I complete the Form FDA 1572 if the study is not under an IND?

- A Form FDA 1572 is only required for studies of investigational drugs and biologics conducted under an IND and so studies that are not done under an IND or if they are investigational device studies,(these are conducted under and IDE), do not require a Form FDA 1572 to be completed and signed.

Changes and corrections to the information on the Form FDA 1572.

- If there are changes to information contained on a signed and dated Form FDA 1572 that has already been submitted to the sponsor, the Form FDA 1572 does not have to be revised nor a new form completed by the Principal Investigator.All changes however should be documented by the Investigator and the Sponsor notified so that the IND can be updated.
- All entries on the form must be legible and complete (typed or handwritten) and completed in English.Hand written corrections to the Form FDA 1572 may be made by the Investigator by crossing out incorrect information with a single line, signing and dating the error.Corrections to typographical errors using correction fluid (e.g. “White Out”) and/or correction tape are not allowed.

Should I complete the Form FDA 1572 if the study is outside of the United states?

- If the study being conducted outside of the United States is under an IND then all FDA requirements, including the requirement to complete and sign Form FDA 1572, must be met.
- In some instances local laws or regulations prohibit the signing of an FDA Form 1572.Under this circumstance the FDA would expect those sites to operate as non-IND sites and there would be no requirement for a Form FDA 1572 to be completed and signed.Please follow the instructions given by the study Sponsor.

Completion of the Form FDA 1572.

- All sections of the Form FDA 1572 must be completed.
- If using a paper copy of the form, rather than an electronic form, the Form FDA 1572 ideally should be printed as a single, double sided sheet. If this is not possible then all pages should be securely attached together so that there is assurance that the complete form was read, understood, completed and signed by the Investigator.
- If additional space is needed for a specific section, continuation pages should be used. If a paper copy of the form is used then all additional sheets should be securely attached to the form.
- Section #8 refers only to phase I, 2 and 3 investigations. If the study is phase 4 but has the characteristics of a study described under 21 CFR 312.21, then the Investigator does not need to mark either of the boxes in Section #8, but should identify in Section #7 that the study is a phase 4 study.
- Each co-investigator is fully responsible for fulfilling all of the obligations of an Investigator as identified in 21 CFR 312.60 and therefore must complete and sign a separate Form FDA 1572.
- Each sub-investigator must be listed in section #6. A sub-investigator is classed as an individual who is part of the team lead by the Principal Investigator.
- Hospital staff, nurses, residents and office staff who provide ancillary or intermittent care but who do not make a direct/significant contribution to clinical data do not need to be listed individually.

END OF INFORMATION AND GUIDANCE SHEET