Policy Statement

In adherence with FDA regulation the Perelman School of Medicine (PSOM) requires research team members, inclusive of faculty and staff, who are making a direct and significant contribution to data on clinical research protocols conducted under an Investigational New Drug (IND) to be listed as sub-investigators on the Form FDA 1572 Statement of Investigator.

History

The Form FDA 1572 (Statement of Investigator) is a statement completed and signed by the Investigator. By signing the Form FDA 1572, the Investigator attests that he/she will comply with the FDA regulations related to the conduct of the clinical investigation being conducted under the IND. Section 6 of the Form FDA 1572 requires the Investigator to list the sub-investigators participating in the conduct of the research. It is the responsibility of the Investigator to ensure that he/she includes the names of the sub-investigators engaged in the research and ensures that they are qualified and trained to perform the study related activities assigned to them.

Purpose

The purpose of this policy is to assist Principal Investigators and all other members of the PSOM research community in determining which members of the research team who perform activities on a clinical trial need to be listed on Form FDA 1572 as sub-investigators.

Who Should Know This Policy

The Principal investigator and all other members of the research team engaged in the research being conducted under an IND.

Definitions

FDA definition of a Sub-Investigator: any investigative team member who makes a direct and significant contribution to the data. Sub-investigators may include but are not limited to faculty, medical trainees, nurse practitioners, registered nurses and research coordinators. Individuals not likely to be a sub-investigator per this definition include: hospital staff, including nurses, residents or office workers who...
provide ancillary or intermediate care as part of their normal duties, research pharmacists, and individuals who have an occasional role in research, such as phlebotomists or on-call physicians.

Examples of activities that are considered to be direct and significant contribution include but are not limited to:

1. Obtaining Informed Consent
2. Subject recruitment
3. Administration of investigational product/study drug
4. Acquire/thaw/disposal of investigational product/study drug
5. Evaluation of investigational product/study drug
6. Administer cognitive evaluation testing
7. Administer study specific procedures
8. Review of subject visits in an Electronic Medical Record (EMR)
9. Perform research physical examinations
10. Evaluation of study procedures and tests
11. Evaluation of adverse and serious adverse events
12. Maintain study records

Roles and Responsibilities

The investigator must ensure that his/her staff members directly involved in the performance of research related procedures and/or the collection of data are listed on the Form FDA 1572 as sub-investigators and are adequately trained for their role.

Related Information

1. FDA Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs Frequently Asked Questions – Statement of Investigator (Form FDA 1572), May 2010
2. Code of Federal Regulations – 21 CFR 312.60
3. Guidance for Industry – ICH E6, Good Clinical Practice
4. Form FDA 1572 (7/13), OMB No. 0910-0014
5. FDA Warning Letters: Ref: 08-HFD-45-1001, Ref: 08-HFD-45-1003, Ref: 09-HFD-45-02-01, Ref: 08-HFD-45-09-01, and CBER-14-01
### Revision History

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