



GUIDANCE

UW Procedures for Listing Sub-Investigators on Form FDA 1572

Research teams and sponsors can vary considerably in who they consider to be Sub-Investigators for purposes of completing Food and Drug Administration Form FDA 1572, Statement of the Investigator (1572). Sponsors may also request inclusion of specific research team members on the 1572, which deviates from local practice. Given this variability, the need for consistency, and the significant obligations associated with being listed as a Sub-Investigator, this guidance was established to support research teams in identifying only the necessary individuals to include as sub-investigators on Form 1572. This guidance may also be used in responding to sponsor requests for updates to the form.

Overview

The FDA definition of sub-investigator includes any individual member of the research team who assists the investigator and makes a direct and significant contribution to the data. In determining if a contribution by a research team member is direct and significant a key consideration is whether the team member is performing significant investigation-related duties independently. The UW considers only activities performed independently, without direct oversight, verification, or co-signing by the investigator, to involve a direct and significant contribution. Therefore, only individuals who perform significant investigation-related duties independently should be listed on Form 1572, with all other research team members managed through the Delegation of Authority process.

Individuals Expected by the UW to be Listed as Sub-Investigators

- 1) Appropriately licensed research team members responsible for signing orders for investigational product administration.
- 2) Appropriately licensed research team members responsible for making independent determinations related to the trial that could directly impact trial activities (e.g., Adverse Event relatedness determinations, final eligibility sign-off).
- 3) Research team members who perform activities independently and which only the Investigator or someone with equivalent licensure or training are required to perform.
- 4) Research team members specified in the protocol who, based on their qualifications or expertise, provide a specific protocol related function independently (e.g., internist required to perform all study physical exams).

Individuals Not Expected to be Listed as Sub-Investigators

- 1) Research coordinators and other members of the research team, such as hospital staff, that perform activities that fall within the scope of their standard job descriptions. While coordinators and other staff may be involved in many day-to-day activities of the research, including activities requiring training specific to the study, these activities must all be monitored and verified by the investigator/sub-investigators so are not considered independent.
- 2) Pharmacists, unless stipulated by the Investigator for a particular trial.

Unless otherwise required by the written contract, this guidance should be followed.