# Monday Morning Practice Pearls #18

## Who should be included as a sub-investigator on the FDA Form 1572?

The FDA *Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs Frequently Asked Questions – Statement of Investigator (Form FDA 1572)* addresses who can be a sub-investigator. Not all Associate Investigators (AIs) or others listed on the DOT log for a given protocol will be listed in Section #6 of the 1572.

The purpose of Section #6 is to capture information about individual members of the research team who will assist the investigator and make a direct and significant contribution to the data.

The decision to list an individual in Section #6 depends on whether they are performing significant clinical trial-related duties. In general, if an individual is directly involved in performing procedures required by the protocol and the collection of data, that individual should be listed on the 1572. The guidance specifically addresses research nurses and other staff (e.g., other nurses, fellows, pharmacists).

Note: The FDA expects that the individuals listed on the 1572 submit financial disclosure information (see question #35, https://www.fda.gov/media/78830/download).

Any 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.

ICH E3 provides additional clarity on who should be listed on the 1572, as noted below:

- Investigators.
- Any other person carrying out observations of primary or other significant efficacy variables, such as a nurse, physician's assistant, clinical psychologist, clinical pharmacist, or house staff physician. It is not necessary to include in this list a person with only an occasional role, e.g., an on-call physician who dealt with a possible adverse effect or a temporary substitute for any of the above.
- The author(s) of the report, including the responsible biostatistician(s).

## What about the 1572 form and the Delegation Log for CCR-held IND/IDE protocols?

To facilitate the implementation of CCR studies, individuals assigned with the following task/activity numbers on the Clinical Site Delegation of Authority and Staff Signature Log (DOA) should be included in the 1572: 1-5, 7-12, 14-16, 20.

| | |
|---|---|
| 1. Obtain hand-written Informed Consent | 10. Make study-related medical decisions |
| 2. Obtain electronic Informed Consent (e.g., iMed) | 11. Assess AEs and SAEs |

| | |
|---|---|
| 3. Obtain and document medical history | 12. Assess concomitant medications |
| 4. Obtain inclusion/exclusion assessment | 14. SAE form approval – delegated to a physician licensed to diagnose listed on the 1572 |
| 5. Confirm eligibility criteria met | 15. Confirm response criteria met |
| 7. Perform study product dose administration | 16. Evaluate test results, including labs, for clinical significance |
| 8. Perform physical exam | 20. Sign-off on eCRFs |
| 9. Perform significant study-specific assessments | |

Additional added tasks should be evaluated on an individual basis.