



Monday Morning Practice Pearls #43

Who needs to be listed on the Delegation of Tasks/Signature Log?

A Delegation of Tasks/Signature Log (DOT) serves two purposes:

1. Provides documentation of the PI's delegation of certain study-related tasks.
2. Documents signatures and initials of staff who are authorized to make entries in study records so that an audit trail will be maintained.

NOTE: Since our informed consent policy requires an investigator to consent, the signature portion of the log also provides identification of who can secure informed consent and sign the investigator signature line.

DOT Logs are not addressed in the regulations and therefore are not a regulatory requirement. However, guidances support this practice:

- [FDA Guidance](#): The investigator should maintain a list of the appropriately qualified persons to whom significant trial-related duties have been delegated. This list should also describe the delegated tasks, identify the training that individuals have received that qualifies them to perform delegated tasks and identify the dates of involvement in the study.
- [ICH E6 Good Clinical Practice](#): The investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties.

The CCR's [SOP PM-6](#) "Guidelines for the Development and Maintenance of Regulatory Files/Binders" requires that a "Delegation of tasks/signature log" be maintained by the research nurse.

Okay, so who should be listed on the log?

While there is no clear guidance on what staff should be listed on the DOT or what is considered "significant trial-related duties", a good rule of thumb is to include those persons that have the following clinical responsibilities:

- Assessing study eligibility
- Obtaining informed consent/assent
- Performing study-specified procedures with the participant
- Documenting in the source documents
- Monitoring for and assessing adverse events, protocol deviations and other reportable events and
- Individual responsible for submitting and maintaining essential documents (i.e., the regulatory file)

And, who does not need to be listed on the log?

Generally, people whose role is limited to "basic science" activity to provide data for one or more study objectives (e.g., research laboratory personnel) do not need to be listed on the DOT.

In addition, individuals who perform "normal" clinical duties (e. g., day hospital or floor nurses, phlebotomists, radiology technicians, etc.) and those who do not interact with research participants or their protected health information (e. g., statisticians) do not need to be included on the DOT.

One More Thing

Keep in mind that the sponsor of the protocol may require additional people be listed on the DOT. If so, you must follow the sponsor's requirements.