Monday Morning Practice Pearls #43

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

A Delegation of Tasks Log (DOT) provides documentation of the PI's delegation of certain study-related tasks. 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.

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 responsibilities:

- Assessing study eligibility
- Obtaining informed consent/assent ** Per NIH Policy 301, must also be listed in PROTECT to obtain consent **
    - If staff is only obtaining screening consent, that must be listed as a separate activity on the log.
- Performing study-specified procedures with the participant
- Documenting in the source documents
- Monitoring for and assessing adverse events, protocol deviations and other reportable events.
- For FDA regulated studies, all sub-investigators on the 1572 must be listed on the log.

Other protocol responsibilities that would be listed on the log:

- Individuals responsible for submitting and maintaining essential documents (i.e., the regulatory file)
- Staff entering data into study database (e.g., data managers)
- If an IND protocol, responsible pharmacist
- Collaborators who are listed as AIs and who interact directly with study participants and/or their personally identifiable information)

Note: If the protocol specifies how a procedure/activity is performed that is not routine, then the staff person is performing a research described procedure (not routine clinical care) and must be on the log to perform that activity.

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., fellows that are not listed as AIs, day hospital or floor nurses, phlebotomists, radiology staff, pathology staff, surgeons performing routine biopsies, 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. However, remember that if any of these individuals are listed as an AI on the protocol, they need to be on the delegation log.

Patient care coordinators do not need to be listed on the delegation log because they do not perform research specific tasks beyond the scope of their position.

One More Thing for FDA-regulated Studies

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

Related CCR SOPs

SOP PM-1 *PI Delegation of Tasks for Research*

SOP PM-6 *Guidelines for the Development and Maintenance of Regulatory Files/Binders*