Delegation Log Considerations

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While the principle of a Delegation of Authority (DOA) Log is relatively straightforward, operationalizing DOA completion & upkeep across multiple studies can be challenging. The following are some considerations and suggestions that may be helpful for your study team.

Profile Pages

Some teams with a high number of studies implement a profile page for each study member. These profile pages may be completed by role (e.g., PI, Sub-I, CRC, Data Assistant, etc.) and outline the tasks that are delegated to each person in that role. They also have signatures, hand-writing, and number samples from each individual.

In addition to the profile pages, a master delegation log is created for individual studies where only the person's name and role are entered. The PI may sign off on this log only once and then again only if there is a change. The PI's signature is not required next to each individual, as with traditional DOAs. This streamlines the process by only needing to complete tasks delegated once instead of on a study-by-study basis. If additional tasks are required that have not been listed, the forms can be updated to add these tasks.

Secondary Clinical Personnel

Another consideration depending on the size of your institution is who should be added to the delegation logs. Federal guidelines require that those individuals having significant contributions and impact on the study and outcomes be listed, but those completing tasks falling under their standard clinical practice do not need to be.

Radiologists are good examples. If you are working on a study that requires research participants to have a yearly CT scan and you are working at a large institution with hundreds of radiologists that read scans as part of their daily workload, it would be difficult to add all of them on delegation logs and maintain proper protocol training documentation. In this case, because the radiologists are reading the research scans as a part of their normal role, they would not need to be added to the DOA Log. However, if radiologists or radiology technicians must complete study-specific training in order to perform protocol-specified scans, the person in charge of training and performing the study-specific scan should be on the DOA Log.

However, if you work at a smaller institution where you regularly interact with fewer people, it is usually easier to add all of them to the DOA Log and keep track of training in the traditional way.

Pharmacy Staff

Like the Radiology example, your institution's pharmacy may have lots of technicians that handle all different investigational products. In situations like this, you can appoint one or two main managers or heads of departments to be responsible for training and oversight of duties for each study. In this case, only the manager would be listed on the DOA Log.

Digital Platforms

As research organizations move away from paper in favor of electronic platforms, DOAs and Profile Pages may be created in your clinical trials management system (or eRegulatory platform). In addition to clearer audit documentation, investigators can log in at any clinic and view who is authorized to perform study tasks like informed consent, imaging interpretation, etc. Consult with your manager and sponsor representative to determine your department's standard operating procedure when it comes to the DOA in electronic platforms.