

## Delegation of Authority Log

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1. Delegation of Authority Logs (DOA) at our site will be completed through Clinical Research IO (CRIO). The Sponsor DOA version will be used as a template for creating the DOA within CRIO.
2. If applicable or if designated by Sponsor UNBLINDED activities may be designated by inserting a "U" in front of the task number or letter. For example, if the task on the Sponsor version is "09. IP Preparation" will be designated as assigned to unblinded personnel as "U09. IP Preparation." Or, if desired by Sponsor, a separate duty noting staff is unblinded will be added.
3. PRIOR to completing the Delegation of Authority Log a discussion will occur (during a staff meeting if possible but at minimum between Regulatory Specialist and Site Director) to decide who will be entered onto the DOA Log.
4. IN ALL EVENTS a person listed on FDA Form 1572 in Box 6 will be included on the DOA Log and will have GCP training, current license and CV available but MAY not, in all cases, have protocol training. *See Business Continuity Plan Policy for more information for cases where a Sub-I may not have current training and when/how they will receive this training should their services be needed.*
5. In the event that a primary endpoint is dependent on the study procedure (i.e. imaging), the lead staff/contractor performing the study procedure will be listed on the DOA unless otherwise specified by the protocol. The lead staff/contractor will be responsible for training and documenting training of all other staff performing the procedure.
6. In the event that the procedure is NOT a primary endpoint for the study, the staff and/or contractor performing the procedure will not be listed on the DOA.

### **Best Practices**

- Add all duties in bulk. Most likely, you will be entering in the duty codes and descriptions exactly as they appear from the sponsor. However, you are free, per regulatory guidelines, to utilize your own duty code system and/or further customize the duties.
- When delegating duties to individuals, utilize the "copy" feature to minimize duplicate work. For instance, coordinator duty profiles are often the same, so you may simply copy another coordinator's profile for other coordinators. Once you copy, you can make further modifications customized to that individual.
- Utilize the "duty" view to see how many people are delegated to each duty. This allows you to ensure appropriate redundancy in staffing.
- Utilize the Common Folder system for documents such as GCP training, CV, or medical licenses. Utilize the Training Tracker for documents specific to the study, such as protocol training, EDC training, IP administration training, etc.
- When a new training requirement is issued for the same duty – for example, a new version of EDC is issued – treat that as an additional training requirement and link it to the same duty as the original. This way, you have parallel tracking systems.

<b>DOA Process</b>	
Owner	Step
1. Regulatory Specialist	Define the duty codes and descriptions. Copy the duty codes and descriptions verbatim, as received from the sponsor, and add additional duty codes as the PI sees fit.
2. Regulatory Specialist	Add duties to each individual user on the study. Utilize the “copy” feature to save time and ensure synchronization. After copying, make appropriate customizations to that individual.
3. Regulatory Specialist	Update your Regulatory Binder with the latest blank form.
4. Regulatory Specialist	Notify users of their need to e-sign the duty assignments.
5 PI and all Study Staff on Delegation Log	Review duty assignments. Reject any duty assignments you disagree with and state the reason why. Sign off on remaining assignments.
6. Regulatory Specialist	Create training requirements specific to the study. For each training requirement, identify whether it’s required for all study staff personnel, or tied to one or more duties.
7. Regulatory Specialist	After training requirements are complete, identify any individual requirements that are stored offline or exempt. Link any training requirements to documents already uploaded in the system. This minimizes the number of outstanding requirements.
8. PI and all Study Staff on Delegation Log	Review dashboard to identify outstanding training requirements. When you receive your training certification, email it to the Regulatory Specialist.
9. Regulatory Specialist	Review the training certification, confirm its accuracy, upload into the appropriate Training folder for the study, then link to the outstanding requirement.
10. Regulatory Specialist	On an ongoing basis, review outstanding DOA approvals and training requirements and follow up with personnel as appropriate.