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| Delegation of Authority Log |
| Approval Date: 01SEP2022   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. |
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