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| **GENERAL INSTRUCTIONS** – delete this box from the completed form. Red text represents instructions to you – to be deleted from the final version.**NOTE: This form is designed to be a starting point on the Delegation of Authority Log (DoA Log). Update it as necessary for your specific study. The DoA can be formatted or designed in any manner, study teams can use this as a starting point or only a guide for the content.** * Regulations require that the Principal Investigator personally conduct and adequately supervise the clinical study. This log serves to identify any responsibility that has been delegated by the PI to study team members. Each individual should be qualified by education, training and experience (and state licensure where relevant) to perform their respective task(s). It is required that delegated responsibilities are discussed with all staff and investigators to confirm understanding of their role and responsibilities.
* Generally, a DoA log serves to document both delegated responsibilities and handwriting and signature samples. This template is designed to capture both. If no handwritten document will exist as part of the study record (including consents, source documents, or case report forms), this template can be updated to remove all signature boxes. Special care should be taken to ensure that absolutely no handwritten document by a study team member is ever generated if signature boxes are removed. It is highly recommended that signature boxes are kept on this form as a precaution against unforeseen future events or situations requiring handwritten documentation.
* The PI should initial and date when an individual starts on the study as that is their documentation that the individual is trained and qualified to perform the tasks they are delegated. It is not required that a PI sign when an individual leaves a study and this log does not provide a space to do so. Study teams can update this log to include that if required for specific study needs.
* This log must be updated when any of the following occur:
	+ New staff are added – delegation must be dated and completed prior to any work by the staff member on the study.
	+ Existing staff are delegated new or additional tasks – delegation must be updated and completed prior to this new task being completed. Documentation of when this task is assigned must be part of this DoA log or capture elsewhere as part of study records.
	+ Existing staff are no longer working on the study – this must be dated and completed after work has stopped by this staff member. It is expected that this is completed in a timely manner. No timeline for completing this exists in the regulatory guidance but study teams should consult with sponsors or Lead Teams if there is a deadline.
* For all staff performing a role or responsibility that requires credentialing or licensure, please provide that information with name. Example: MD, DO, NP, RN, PharmD, RPh, etc.
* The Tasks Appendix should be used to document all available tasks on the study.
* There may be additional study responsibilities or tasks that could be assigned to a team member that are not listed in the study-specific tasks list. These may be hand-written in the box labeled "Other Study Responsibilities".
* The [SOP on Delegation of Authority and Responsibilities](https://www.bumc.bu.edu/ohra/required-training/institutional-standard-operating-procedures-sops/) should be consulted as needed.
* Additional pages should be printed or rows added as required for study needs.
* Page numbers do not automatically update as it is unknown how many pages will be necessary for the entire study. The page information in the footer should be added when the study is over and no new staff will be added.
* Delete the CRRO template version date and add in the study-specific version date of this document.
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| *Signature* |
| *Role* |
| *\* Must include all licensure, degrees, credentials, and certifications that an individual holds.* |

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| **Principal Investigator Confirmation – *Only to be Completed at Study Closure*** |
| *I confirm that all listed staff were trained and delegated appropriately. All information on this document is correct.*  |
| Printed Name | Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Signature |

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| Appendix: Tasks and Responsibilities Code |
| Code + Responsibility | Description |
|  | Consent | Conduct informed consent discussion.  |
|  | Consent – LIP\* | Licensed Independent Practitioner conducting informed consent discussion. See [HRPP Policy 8.1.3.7](https://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#8.1.3.7) for more details. This person must discuss the purpose, risks, benefits, and alternatives with study candidate.  |
|  | Confirms Eligibility\* | Reviews all inclusion and exclusion criteria and confirms participant is eligible for study. |
|  | Physical Evaluation\* | Performs physical exam or assessment as needed. |
|  | Neurological Evaluation\* | Performs neurological exam or assessment as needed. |
|  | Makes study-related medical decisions\* | Completes per-protocol procedures related to clinical decision making.  |
|  | Collects Medical History | Reviews and documents medical history including current and historical medication.  |
|  | Review Vital Signs and Laboratory Results for Clinical Significance\* | Performs per-protocol review of specific safety outcomes. |
|  | Administers Questionnaires | Provides paper copy of questionnaire/survey to participant or completes interview.  |
|  | Study Drug Order\* | Licensed and authorized per state and local policy to order study drug.  |
|  | Study Drug Preparation and Management\* | Prepares study drug based on study procedure. Provides study drug to study team contact for giving to participant. Performs all dispensation or destruction procedures per local policy or protocol. Must be licensed pharmacist or pharmacy technician working under the supervision of a licensed pharmacist.  |
|  | Study Drug Dispense to Participant\* | Provides study drug to participant per defined study procedures . Must be medical clinician or nurse of at least RN level and will rely on local policy.  |
|  | Study Drug Instruction\* | Provides instruction and information on study drug to participant. Must be medical clinician or nurse of at least RN level and will rely on local policy.  |
|  | Case Report Form Completion | Completes data entry, including medical record abstraction. May be on paper CRFs or within electronic data system.  |
|  | Data Query Resolution | Reviews all discrepant data and makes changes as required.  |
|  | Adverse Event Assessment\* | Reviews all adverse events for expectedness, attribution, and grading for required toxicity safety and reporting.  |
|  | Safety Reporting | Manages safety reporting to authorities as per protocol. Includes adverse events and protocol deviations. Could include FDA, Lead Team, Sponsor, or other authority.  |
|  | Regulatory | Manages IRB reporting, regulatory documents and binder, and any other required regulatory reporting or submissions. |
|  | Biospecimen Sample Collection | Collects sample directly from participant or from clinical collection site.  |
|  | Biospecimen Sample Processing | Completes all protocol-required processing including placing in short-term or long-term refrigerator/freezer storage sites.  |
|  | Biospecimen Sample Shipping | Directly ships or manages shipping for research biospecimen laboratory samples. May require specific certifications or training if shipping hazardous or regulated materials.  |
| *\* Requires state licensures.*  |