

	<p style="text-align: center;">Delegation of Authority Site Instructions for Documenting Study Staff Role on Delegation of Authority Document</p>
TITLE	DEFINITION
Principal Investigator	The person responsible for the conduct of the study at Creighton University.
Investigator	A trained individual member of the study team designated and supervised by the Creighton Principal Investigator to perform critical trial-related procedures and/or to make important trial-related decisions as outlined in the Delegation of Authority Log.
Study Coordinator (SC)	A trained individual member of the study team designated and supervised by the Creighton Principal Investigator to perform critical trial-related procedures and/or to make important trial-related decisions as outlined in the Delegation of Authority Log.
Research Pharmacist	A trained individual member of the study team, designated and supervised by the Creighton Principal Investigator to perform critical study drug receipt, storage, preparation, dispensation, and drug accountability paperwork as outlined in the Delegation of Authority Log.
Staff administering study drug	A trained individual member of the study team designated and supervised by the Creighton Principal Investigator to perform critical trial-related study drug administration as outlined in the Delegation of Authority Log.
Staff performing study-required procedures	A trained individual member of the clinical trial team designated and supervised by the Principal Investigator at Creighton to carry out trial-related duties. Individuals who conduct protocol-specified procedures that are not defined by the investigator or the protocol as a standard of care procedure or assessment should be noted on the Delegation of Authority Log. If the assessment or procedure is critical to the outcome the study or is a component of the objective of the study, the staff members should also be noted as an investigator on the 1572 (e.g., rater on a mental health study, technician performing protocol-specified specimen handling and processing)

Please note: In addition the Principal Investigator and Investigators, Study Coordinators, Research Pharmacists, and Staff members administering study drug are required to be listed as investigators on the 1572. Other study team members who are providing assessments or procedures that are critical to the outcome of meeting the objectives for the study should be evaluated on case-by-case basis for inclusion as investigator on the 1572.