

	Principal Investigator/AI	Research Nurse	Physicians (not on protocol); NP/PA	Patient Care Coordinator
<b>Summary of Role</b>	Overall responsibility for the protocol	Protocol implementation and compliance	Clinical management of the patient	Coordination of patient scheduling and travel
<b>Medical Orders</b>	Yes	No*  *Only orders via order sets that are timepoints in the protocol; emergency orders	Yes*  *CTEP studies do not allow for NP/PA to sign investigational drug orders	No
<b>Protocol management</b>	<ul style="list-style-type: none"> <li>• Determine eligibility</li> <li>• Dose modification, DLT, MTD</li> <li>• Clinical management of patient</li> <li>• SAE report <i>final</i></li> <li>• Audit response <i>final</i></li> </ul>	<ul style="list-style-type: none"> <li>• Determine eligibility with PI</li> <li>• Ensure protocol requirements are met: Study calendar, timepoint orders, patient compliance, research samples, education</li> <li>• Data verification</li> <li>• AE capture and reporting</li> <li>• SAE report <i>draft</i></li> <li>• Audit prep</li> <li>• Audit response-<i>draft</i></li> </ul>	<ul style="list-style-type: none"> <li>• Determine eligibility with PI</li> <li>• Clinical management of patient</li> </ul>	<ul style="list-style-type: none"> <li>• Scheduling</li> <li>• Patient travel and lodging</li> <li>• Request financial assessment</li> </ul>
<b>SAE reporting</b>	Review and submit to ORSO for CCR held INDs. Other sponsors, per protocol.	Draft and submission to PI	No, if not an AI Yes, if an AI	No