DOM CRE Regulatory Coordinator Roles and Responsibilities

Regulatory Goal: Improve effort-tracking methods to provide a fuller picture of MOU pricing

Clinical Research Regulatory Coordinator I

1. Maintain Investigator Site File (ISF) documentation for multiple studies including consent forms, protocols, 1572s, CVs, licenses, investigator brochures, DOA and training logs, recruitment materials, safety reports, laboratory certificates, submission forms, IRB approvals, sponsor correspondence, etc
2. Prepare industry sponsored submissions to UAB-IRB for institutional sign off and submission to reviewing IRB for approval. This also includes preparation and submission of all relevant documentation to sponsor/CRO to meet study timelines
3. Submit continuing review approvals to UAB-IRB and reviewing IRB such as WCG, Advarra, etc.
4. Submit personnel amendments in IRAP to UAB-IRB
5. Prepare submission of amendment RPLs to OSP office
6. Route training and delegation of authority logs to appropriate staff and obtain signatures on all applicable study documents
7. Enter protocol-specific regulatory data into CRE study metrics tracking system (CREST)
8. Prepare for study monitoring visits and correct findings as needed
9. Maintain documents in long term storage and oversee the destruction of documents when required
10. Work with physicians and research staff to ensure they have current IRB and GCP training and current medical licensures on file
11. Responsible for uploading regulatory documents and information into OnCore and the IRAP system

Clinical Research Regulatory Coordinator II

All items listed above for Clinical Research Regulatory Coordinator I in addition to:

1. Assist with initial drafts of informed consent documents and information sheets on Investigator Initiated projects
2. Populate IRB ePortfolio for Investigator Initiated projects in IRAP and submit for IRB approval. Also assist with pre-review and determination letters from UAB-IRB on those submissions.
3. Prepare and maintain FDA applications for Investigational New Drugs (INDs) and Investigational Device Exemptions (IDEs)
4. Schedule and perform inspections and audits on various clinical trials managed by the CRE.
5. Responsible for preparation of study related material for FDA Sponsor audit with assistance from other regulatory team members (as necessary)
6. Prepare CAPAs which also may include input/review from Manager of Regulatory Relations and CRE Compliance team
7. Escalate and presents major audit findings to the Manager of Regulatory Relations and CRE Compliance team

Clinical Research Regulatory Coordinator III

All items listed above for Clinical Research Regulatory Coordinator I and II in addition to:

1. Assist with implementing Quality Assurance processes
2. Evaluates and presents Quality Assurance findings/metrics to appropriate staff members and managers
3. Works closely with the Manager of Regulatory Relations to coordinate with involved UAB departments for action plans and resolution on audit findings
4. Serves as a resource person for Clinical Research Regulatory Coordinators I and II
5. Oversees QA compliance with study protocols and ensures study guidelines are followed in accordance with Good Clinical Practices