NSABP Foundation
Department of Regulatory Affairs

Senior Regulatory Specialist

Reports to: Director, Regulatory Affairs

The responsibility of this position is to prepare and coordinate protocol-related documents for new and existing Federal and Industry sponsored clinical trials and serve as a resource to staff and member institutions.

- Prepare documents including but not limited to drug applications, protocols, amendments, progress reports, safety report information for submission to applicable government agencies and Institutional Review Boards (IRBs) for obtaining approvals required to initiate and conduct clinical trials. Maintain protocol-related registries.

- Research regulatory issues pertaining to clinical trial protocols, consent forms, progress reports, IRB and drug approval processes to ensure adherence to regulations and guidelines.

- Serve as regulatory resource to member institutions, pharmaceutical partners and NSABP staff. Provide support to the protocol development team and sites by reviewing informed consent forms.

- Prepare instructional memoranda for investigators regarding protocol activations, amendments, notifications and closures. Develop tools and conduct training presentations to educate site staff about regulatory issues related to oncology trials.

Experience/Skills

- BA/BS degree required, advanced degree preferred
- Minimum 5 years regulatory experience within clinical research environment
- Familiarity with Federal regulations and Good Clinical Practice principles
- Sound written and verbal communications skills
- Ability to manage multiple projects and to meet tight deadlines
- Strong attention to detail with high level of accuracy