

R2A2 CLINICAL RESEARCH CENTER (CRC) MANAGER

Role

- To provide line management for the operation of the CRC.

Responsibilities

- Oversee day to day operation of the Clinical Research Center to insure human subject safety and Investigator/Staff compliance with existing policies and regulations.
- Implement procedures for the preparation and maintenance of medical records using protocol specific forms generated by the PI/RP
- Implement procedures for the scheduling and transportation of subjects and registering subjects upon arrival at BNL
- Maintain a program for monitoring infection control at all BNL sites where clinical research is conducted
- Maintain a program for preventive maintenance of all equipment used in clinical research that is not a component of the research facility itself
- Implement procedures for the operation of the CRC Pharmacy including a controlled substance monitoring program
- Establish and implement a program to assess subject satisfaction
- Review JCAHO requirements annually and make recommendations to Medical Department Chair for compliance
- Maintain and revise CRC policy and procedural guidelines and present such to the Medical Department Chair for review and approval.
- Participate as a member of the CRC Quality Assurance, Care and Safety Committee.
- Advise Clinical Investigators of regulations and/or requirements of proposed and approved clinical studies.
- Conduct the CRC medical records monitoring program
- Develop, organize and schedule staff training on clinical research issues and topics.
- Coordinate and/or participate in various audits and surveys on BNL's clinical research programs
- Coordinate the triennial JCAHO accreditation survey.

Accountabilities

- To the Chair of the Medical Department and Laboratory management for performance of the above tasks.
- To the subjects and CRC staff, to create an environment wherein subjects' rights and individual safety are the primary focus.
- To the Medical Department Chair to inform him/her of issues of non-compliance with CRC operating policy and procedure.
- To the PI's, to advise them regarding applicable Federal regulations and BNL policies.

Authorities

- Allocate CRC resources as appropriate.
- Stop or interrupt a clinical study upon evidence of a hazard to the safety and/or rights of a human subject.
- Implement procedures consistent with Federal guidelines and BNL CRC Policies to promote the safety and rights of human subjects participating in clinical protocols.

