

BROOKHAVEN NATIONAL LABORATORY CLINICAL RESEARCH CENTER POLICY SUBJECT: CRC Manager	CRC POLICY 1.2.2	PAGE 1 OF 1
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1.0 POLICY

The Medical Department Chairperson as part of his/her responsibility to the BNL Director to provide clinical support and oversight for studies involving human subjects, will appoint, a CRC Manager to provide line management for the operation of the CRC.

2.0 BACKGROUND/QUALIFICATIONS

The CRC Manager position shall have the following qualifications:

- Minimum of a bachelor degree or appropriate experience in a related field.
- Knowledge of BNL and Medical Department contractual and financial policies and procedures.
- Knowledge of Department of Energy, National Institutes of Health, BNL and Medical Department policies and procedures regarding human subject protection in clinical research.
- An understanding of Joint Commission on Accreditation of Healthcare Organization (JCAHO) for Ambulatory Care Facilities policies and required procedures.

3.0 REPORTING STRUCTURE

3.1 The CRC Manager reports directly to the Medical Department Chairperson

3.2 The performance of the CRC Manager shall be reviewed annually by the Medical Department Chairperson.

4.0 RESPONSIBILITIES (R2A2 ATTACHMENT E of this document)

- 4.1 Maintain and promulgate the policies and procedures governing the conduct of clinical (human subject) research at BNL.
- 4.2 Monitor the documents (Investigator files, Medical records, Case Report Forms) associated with clinical protocols to determine compliance with applicable regulations and IRB approved protocols.
- 4.3 Supervise the activities of the administrative support staff of the CRC.
- 4.4 Serve as a member of the QAC&SC, Credentialing, and POPP committees
- 4.5 Implement Adverse Event reporting procedures.
- 4.6 Oversee transportation of subjects and subject satisfaction.
- 4.7 Monitor infection control and preventative maintenance programs.
- 4.8 Oversee CRC Pharmacy operation.
- 4.9 Oversee Clinical Staff training.
- 4.10 Maintain currency with Federal Guidelines, JCAHO Requirements and Laboratory Policies.
- 4.11 Coordinate all CRC inspections, reviews and surveys.

The only official copy of this file is the one online on the Medical Department website under "Clinical Research Center Policy Manual." Before using a printed copy, verify that it is the most current version by checking the document effective date on the website.