

<b>BROOKHAVEN NATIONAL LABORATORY CLINICAL RESEARCH CENTER POLICY</b>	CRC POLICY 1.2.3	PAGE 1 OF 1
	PREPARED BY: J. ROWAN	
SUBJECT: CRC Secretary	REVIEWED BY: A. BAUMANN	
	APPROVED BY: H. BENVENISTE	
	EFFECTIVE DATE: 10/11/04	
	REVISION HISTORY: orig. 09/05/02, rev. 10/11/04	

## **1.0 POLICY**

It is the policy of the CRC to maintain a central administrative point of contact to compile and maintain data related to human research studies in the form of charts, databases and other methods both written and electronic. The CRC Secretary is designated as the point of contact.

## **2.0 QUALIFICATIONS**

The CRC Secretary shall have the following qualifications:

- A degree in Secretarial Science, or comparable experience, preferable with a medical or hospital administration concentration.
- Familiarity with BNL, Medical Department and CRC policies and procedures.
- Knowledge of Joint Commission on Accreditation of Healthcare Organizations (JCAHO) standards and requirements.
- Knowledge of applicable DOE, NIH and GCP regulations regarding clinical studies;
- Excellent organizational skills.
- The ability to coordinate multiple tasks and perform follow-up required completing complex tasks.

## **3.0 RESPONSIBILITIES**

3.1 The CRC Secretary shall report to the CRC Manager.

3.2 The CRC Secretary shall have the following duties and responsibilities:

- 3.2.1 Serve as Secretary to the QACSC Committee. Schedule and coordinate meetings with committee members, prepare the agenda, record and distribute the meeting minutes, and follow up on any outstanding issues.
- 3.2.2 Maintain and update all CRC Forms, as instructed by the CRC Manager. Prepare the updated CRC forms for approval by QAC&S Committee.
- 3.2.3 Maintain the Adverse Event (AE) reporting procedures and documentation and coordinate with QA Physician to complete all AE report forms and report to CRC manager and Office of Research Administration (ORA).
- 3.2.4 Maintain the subject follow-up and subject satisfactory survey program. Report to the CRC Manager, QA Physician, Principal Investigators and QAC&S Committee any incident that involves a participant's dissatisfaction.
- 3.2.5 Set up and manage file systems to input, maintain, and retrieve records and documentation relating to function in accordance with Laboratory and General Services Administration directives.
- 3.2.6 Maintain in-depth knowledge and understanding on CRC Policy and Procedures for Quality Assurance Care & Safety.
- 3.2.7 Report to the CRC Manager and QAC&S Committee of any incident that involved a breach of CRC Policy and Procedures
- 3.2.8 Maintain and update the subject accrual information on the Human Subject Database. Coordinate with research teams to ensure the completeness and accuracy of the data entry on a quarterly basis.
- 3.2.9 Give on-the-job training to new administrative personnel to facilitate their performance of required functions.
- 3.2.10 Administer the distribution of petty cash to the research participants. Remuneration, through the BNL Fiscal system, of clinical subjects, as provided by specific clinical protocols.
- 3.2.11 Serve as back up to the CRC Receptionist/Office Service Assistance for daily routine operation of the CRC, as requested by the CRC Manager.
- 3.2.12 Act as coordinator in the event of a CRC emergency.

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