

BROOKHAVEN NATIONAL LABORATORY CLINICAL RESEARCH CENTER POLICY	CRC POLICY 1.1	PAGE 1 OF 1
	PREPARED BY: J. ROWAN	
SUBJECT: Description and Structure of the Clinical Research Center	REVIEWED BY : A. BAUMANN	
	APPROVED BY: H. BENVENISTE	
	EFFECTIVE DATE: 10/11/04	
	REVISION HISTORY: orig. 08/26/02, rev. 08/18/03, rev. 10/11/04	

1.0 AUTHORIZATION AND PURPOSE

1.1 The Clinical Research Center (CRC) is empowered by the Director of BNL under SPI 7-01.

1.2 The CRC has the responsibility to:

- Provide clinical support and oversight for studies involving human subjects.
- Provide an environment in which human research studies can be conducted in a manner compliant with Good Clinical Practices and applicable federal regulations.
- Provide a level of care commensurate with Joint Commission on Accreditation of Healthcare Organizations (JCAHO) standards.

1.3 Approved clinical research shall take place only within the CRC or its satellite facilities unless pre-approved by the CRC Manager, Medical Department Chair, and IRB.

2.0 OPERATION AND MANAGEMENT

The operation and management of the Clinical Research Center is the responsibility of the Medical Department Chair. See Laboratory Organizational Chart (Attachment A).

3.0 CRC FACILITIES:

3.1 The CRC lobby/reception area (Building 490, Area 8-40) is the central point of contact for all CRC activities. The Principal Investigator or designee shall notify the CRC Reception Desk of all study activities. (See PI Manual section 5).

3.2 A satellite facility is any BNL building or area of a building which has been identified as the location where a clinical study operating under an active IRB approved human protocol is taking place.

3.3 Satellite facilities of the CRC are identified in Attachment C of this document.

3.4 Each Satellite facility shall have a "Clinical Head". The Clinical Head shall be the physician who acts as the point of contact for the facility. The Clinical Head shall be responsible for (1) the Emergency Plan; (2) insuring the facility is operating appropriately and (3) determining that individuals working in the facility are properly authorized and trained.

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.