

BROOKHAVEN NATIONAL LABORATORY CLINICAL RESEARCH CENTER POLICY	CRC POLICY 2.3	PAGE 1 OF 1
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SUBJECT: Initiating an IRB-Approved Protocol	REVIEWED BY: A. BAUMANN	
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1.0 POLICY

The BNL Clinical Research Center (CRC) shall only support research projects involving human subjects if a valid IRB number exists and is on file with the CRC Secretary. See the IRB Manual for Human Studies Research Submission Process.

2.0 ORA NOTIFICATION REGARDING A NEW PROTOCOL:

- 2.1 On a monthly basis, following the IRB meeting, the ORA will provide written notification to the CRC Main Desk (Secretary) regarding any additions, terminations or amendments to the active IRB protocol listing.
- 2.2 The CRC Secretary shall obtain a copy of the IRB-approved protocol application and related consent form(s) from the ORA.

3.0 RESPONSIBILITIES OF THE CRC SECRETARY:

The CRC Secretary with assistance from the Medical/Hospital Services Assistant shall:

- 3.1 Update the active IRB files and Informed Consent files maintained at the CRC Desk based on the information received from the ORA.
- 3.2 Remove IRB files and related consent forms from the CRC Desk for any studies terminated.
- 3.3 Post a copy of the IRB-ACTIVE listing, provided by the ORA, at the CRC Desk. This document provides a summary description of all active IRB numbers, Principal Investigator, IRB and ORA approval dates, names of Responsible and participating Physicians and applicable Consent Forms.

4.0 RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR: (see PI Manual 5.0)

- 4.1 The PI shall have all documents associated with the IRB approved protocol reviewed and approved by the CRA. Upon this approval the CRA will notify the CRC Manager who will then send a memo to the PI that the study is cleared to begin.
- 4.2 The PI shall insure that the Responsible Physician prepares Standing Orders as necessary and submits such Standing Orders to the CRC Secretary. Standing Orders provides detailed instructions regarding all clinical steps associated with the research protocol including, but not limited to:
 - (1) procedures (i.e. questionnaires, blood or urine screenings, etc);
 - (2) pharmaceutical administration instructions, as applicable.
- 4.3 The PI should contact the CRC Main Desk and discuss the new protocol with the CRC Secretary to clarify issues concerning (1) volunteer fee reimbursement, (2) subject scheduling, (3) transportation requirements, (4) meal requirements, (5) greeting instructions, (6) lab test and (7) any other research coordination issues.
- 4.4 The PI is responsible for maintaining Case Report Forms in accordance with Good Clinical Practice (GCP) standards.

5.0 COMMENCEMENT OF CLINICAL (IRB) PROTOCOL:

Research outlined under an IRB-approved protocol shall begin only after all of the above responsibilities and those responsibilities listed in the PI Manual have been carried out. The CRC Main Desk should not create a chart or otherwise assist with coordination of a research subject unless that subject is being scheduled under an IRB-approved protocol.

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.