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| <b>BROOKHAVEN NATIONAL LABORATORY<br/>CLINICAL RESEARCH CENTER POLICY</b><br><br>SUBJECT: Responsible Physician – Duties and Responsibilities | CRC POLICY 4.1   | PAGE 1 OF 1 |
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### **1.0 POLICY**

Each active protocol being conducted at the CRC must identify a “Responsible Physician” (RP). The RP shall provide overall clinical care of human subjects enlisted in the protocol in accordance with Good Clinical Practices. The RP shall be credentialed as a clinical physician in the CRC.

### **2.0 DESIGNATION OF A RESPONSIBLE PHYSICIAN**

2.1 The Principal Investigator shall be responsible for recommending an RP.

2.2 The PI, if properly qualified, may serve as the RP.

2.3 At a minimum, either the PI or RP must be a BNL employee unless an exception is approved by the IRB.

### **3.0 RESPONSIBILITIES OF THE RP**

The RP shall be responsible for:

3.1 Overall clinical care of subjects enlisted in a protocol.

3.2 Together with the PI, develop protocol specific forms and record format prior to implementation of the approved protocol.

3.3 Ensuring that all Subject Records are in place are consistent with the protocol.

3.4 Ensuring that the facility is medically equipped to safely carry out the research protocol and that the *crash cart* (if required) is available and that proper medications and equipment are present. The RP may authorize the self-administration of stock over-the-counter pain medication for the relief of minor discomfort (i.e., headache) caused by a research protocol. This will be documented in the subject chart.

3.5 Discharge of the subject after completion of the study.

3.6 Assuring that informed consent is properly obtained and documented.

### **4.0 ACCOUNTABILITIES**

4.1 To the PI for ensuring the clinical care for subjects and compliance with the protocol.

4.2 To the CRC Manager for ensuring proper handling and update of the Subject Records.

4.3 To the Chair of the Medical Department and BNL Management for ensuring the proper clinical performance of the 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.