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

Each active human protocol being conducted within the CRC must identify a "Responsible Physician". The Responsible Physician shall provide overall clinical care of human subjects enlisted in the protocol in accordance with Good Clinical Practices.

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

2.1 The Principal Investigator shall be responsible for recommending a Responsible Physician (RP). (See PI Manual section 5).

2.2 The Principal Investigator, if properly qualified, may serve as RP.

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

2.4 The CRC Manager and Quality Assurance Physician shall review all research protocols submitted to the IRB and specifically review Appendix I to such application that identifies the Responsible and Participating Physician(s).

2.5 The CRC Manager's and QA Physician's approval of such protocol indicates his/her concurrence that the individual(s) named as Responsible and Participating Physician(s) have the appropriate credentials and necessary clinical privileges within the CRC to carry out the requirements of the protocol.

## **3.0 RESPONSIBILITIES OF THE RP**

The RP shall be responsible for:

- 3.1 Overall clinical care of subjects enlisted in protocol
- 3.2 Together with the PI develop all protocol specific forms and record format prior to implementation of approved protocol
- 3.3 Ensure that all Medical Records for a particular protocol are in place and are consistent with the protocol
- 3.4 Review Adverse Event Report for medial consequences
- 3.5 Ensure that the facility is medically equipped to safely carry out the research protocol and that the Crash Cart (if required) is available and that the proper medications and equipment are present.
- 3.6 Ensure that an adequate number of clinical staff are trained in Basic LS/CPR to provide coverage during clinical studies
- 3.7 Discharge of the subject after completion of the study
- 3.8 Ensure that the completed Medical Record is returned to the CRC upon completion of the study
- 3.9 Ensure that an individual is responsible for the inspection of the Crash Cart for the protocol before the first study of the day and that the staff is adequately trained to respond to an emergency using the Crash Cart.
- 3.10 Ensure that the staff are using barrier protection devices and/or other procedures necessary to control infectious disease
- 3.11 Ensure that qualified staff members are available to perform required tasks for a scheduled study
- 3.12 Assure that informed consent is properly obtained and documented.
- 3.13 Oversee the maintenance of the Clinical Program Logbook for self-assessment.

## **4.0 ACCOUNTABILITIES**

- To the PI for ensuring clinical care for subjects and compliance of that protocol.
- To the CRC Manager for ensuring proper maintenance of Medical Records.
- To the Chair of Medical Department and Laboratory Management for ensuring the performance of the aforementioned tasks.

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