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| <b>BROOKHAVEN NATIONAL LABORATORY<br/>CLINICAL RESEARCH CENTER POLICY</b> | CRC POLICY 6.2                               | PAGE 1 OF 1 |
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| SUBJECT: CRC Safety   | REVIEWED BY: W. GUNTHER                      |             |
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### **1.0 POLICY:**

The Clinical Research Center, under the supervision of the CRC manager, shall conduct its operations in a manner which creates a safe and hazard-free environment for the clinical subjects and the CRC staff while providing the highest level of medical care.

### **2.0 SAFETY MANAGEMENT PLAN:**

To promote safety and reduce the risk of human injury, the following procedures exist;

2.1 Stop Work Orders: All staff have been empowered with the ability to issue a "Stop Work Order" if they discover a situation which displays imminent danger or hazard.

2.2 Experimental Safety Reviews (ESRs): BNL regulations provide that all research experiments, including clinical research shall be implemented under an approved ESR. The ESR provides for a peer review of the procedures to be performed, the appropriateness of the equipment used and the capabilities and training of the staff assigned to promote a safe research environment. The ESRs are reviewed on an annual basis.

2.3 Quality Assurance, Care and Safety Committee (QACSC) has been established to monitor CRC operations and activities.

2.4 Maintenance and Review of Clinical Logbooks: All clinical programs are required by Section 4.5 of this Manual to maintain a logbook which details activity associated with carrying out clinical research. These logbooks are subject to review by the CRC Manager and serve as a risk-assessment mechanism for identifying issues or incidents that may impact safety.

2.5 Review of all Adverse Event Reports: All AE reports are reviewed by the Quality Assurance Physician, CRC Manager, the Quality Assurance, Care and Safety Committee (QAC&SC) and the IRB in order to insure proper and complete resolution and to determine whether the protocol should be amended or discontinued to minimize the probability of future adverse events. (See CRC Policy 4.6 and IRB Manual).

2.6 The CRC Manager shall be responsible for ensuring that the Safety Management Plan is implemented in the CRC by performing an assessment of the relevant portions of the plan on an annual basis. The annual self-assessment shall be presented to the Quality Assurance and Care Committee.

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.