BROOKHAVEN NATIONAL LABORATORY CLINICAL RESEARCH CENTER POLICY	CRC POLICY 2.1	PAGE 1 OF 1
	PREPARED BY: W. GUNTHER	
	REVIEWED BY: F. HENN	
SUBJECT: Policy Regarding Clinical Research	APPROVED BY: G-J. WANG	
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1.0 BACKGROUND

BNL abides by the Department of Health and Human Services (DHHS) 45 CFR 46, a document which sets forth regulations regarding research involving human subjects. The SBMS "Human Subjects Research" Subject Area delineates these requirements.

The Office of Human Subjects Research Administration (ORA) has the responsibility to provide an environment in which human research studies (or specialized programs providing clinical care) can be conducted in a manner compliant with the federal guidelines in 10 CFR 745 and provide a level of care commensurate with Joint Commission of Healthcare Organization (JCAHO) standards.

The jurisdiction of the Institutional Review Board (IRB) includes all research involving human subjects performed at or in conjunction with Brookhaven National Laboratory (BNL) and its employees, as defined by 10 CFR 745, regardless of the Principal Investigator's (PI) appointment or relationship with BNL. It's primary purpose is to review and approve each research experiment or procedure that involves human subjects to assure the appropriate evaluation of the informed consent process, risks, benefits, and safeguards to the subject's health, safety and right to privacy. The function of the Institutional Review Board (IRB) is to assure that risks to research subjects are minimized and that risks are reasonable in relation to the anticipated benefits and to protect the rights and welfare of research subjects in accordance with applicable rules and regulations of DOE, NIH and other sponsoring organizations. Currently, the IRB resides at University of New York at Stony Brook, called the Committee on Research Involving Human Subjects (CORIHS).

2.0 BNL REGULATIONS REGARDING HUMAN SUBJECTS RESEARCH

2.1 All research projects involving human subjects, as defined at CRC Policy 2.2, must first be reviewed and approved by the Institutional Review Board (IRB).

2.2 IRB approval is documented by the assignment of an IRB number by the Office of Research Administration (ORA).

2.3 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.

3.0 POINTS OF CONTACT WHEN CONDUCTING RESEARCH INVOLVING HUMAN SUBJECTS:

3.1 All inquiries regarding (1) the IRB application process or (2) activities of the IRB should be directed to the Office of Research Administration and/or the Chairman of the IRB.

3.2 All inquiries and concerns regarding administration or operation of an IRB approved protocol should be directed to the CRC Manager or the Quality Assurance Physician.