BROOKHAVEN NATIONAL LABORATORY CLINICAL RESEARCH CENTER POLICY	CRC POLICY 5.4	PAGE 1 OF 1
	PREPARED BY: W. GUNTHER	
SUBJECT: Confidentiality	REVIEWED BY: G-J. WANG	
	APPROVED BY: F. HENN	
	EFFECTIVE DATE: 5/18/07	
	REVISION HISTORY: orig. 9/5/02 rev. 10/11/04	

1.0 POLICY:
CRC staff shall ensure that the identification of human research subject at the BNL Clinical Research Center remains confidential.

2.0 PARTICIPANT IDENTIFICATION

2.1 All individuals participating in a clinical protocol at the CRC shall be assigned a subject ID number.

2.2 To the extent possible, this subject ID number should be used when referring to the participant to ensure that the individuals participation in the study remain confidential.

3.0 SECURITY OF MEDICAL RECORDS

3.1 In order to preserve participant confidentiality, CRC subject records, CRC participant logs and similar documents shall be maintained at the CRC Secretary's Office in a secure records holding area.

3.2 When CRC subject records are outside the CRC Central Records area, it is the responsibility of the study's Principal Investigator to ensure that the records are maintained in a secure location in order to (1) insure participant confidentiality and (2) minimize risk of loss.

4.0 ACCESSIBILITY TO MEDICAL RECORDS

4.1 Access to a CRC subject record is limited to the credentialed clinical staff and those authorized by the Principal Investigator.

4.2 Individuals associated with human subjects research shall not discuss the identification and/or other details of a CRC participant outside the purview of CRC operations.

5.0 CERTIFICATE OF CONFIDENTIALITY

5.1 Federal Law referred to as the Public Health Service Act, Section 301(d), provides Federal protection of confidentiality when the data collected during research is deemed "sensitive".

5.2 Sensitive information collected in conjunction with research is defined as research involving the collection of information falling into the following categories:

(a) information relating to sexual attitudes, preferences or practices;
(b) information relating to the use of alcohol, drugs or other addictive products;
(c) information relating to illegal conduct;
(d) information that if released could reasonably be damaging to an individual's financial standing, employability or reputation within the community;
(e) information that would normally be recorded in a patient's medical record, and the disclosure of which could reasonably lead to social stigmatization or discrimination; or
(f) information pertaining to an individual's psychological well-being or mental health.

5.3 If a Principal Investigator determines that his/her research may result in the collection of sensitive information, the PI should request a grant of confidentiality as required. The investigator should refer to the NIH Manual entitled "Protecting Human Research Subjects" for additional instructions regarding obtaining "PHS Certificates of Confidentiality".