BROOKHAVEN NATIONAL LABORATORY CLINICAL RESEARCH CENTER POLICY	CRC POLICY 5.3	PAGE 1 OF2
	PREPARED BY: W. GUNTHER	
SUBJECT: Release of CRC Subject Records	REVIEWED BY: G-J. WANG	
	APPROVED BY: F. HENN	
	EFFECTIVE DATE: 5/18/07 REVISION HISTORY: orig. 9/5/02 rev. 6/5/03 rev. 10/11/04	

1.0 POLICY:
All CRC Subject Records are deemed confidential and, as a result, access to such records is restricted.

2.0 PERSONS ELIGIBLE TO REVIEW OR OBTAIN A CRC SUBJECT RECORD:

2.1 The following individuals associated with the CRC may access a CRC Subject Record:

- The Principal Investigator
- The Responsible Physician
- The Participating Physician
- The Registered Nurse and/or other Non-licensed Technical staff assigned to the clinical study by the PI
- The CRC Manager;
- The CRC Secretary;
- The CRC Receptionist
- The Clinical Protocol Coordinator
- The Quality Assurance Physician, in the course of performing the records monitoring function.

2.2 In addition, the following other individuals may access the subject record, under supervision of the CRC Manager or his/her delegate:

- A properly authorized representative of the sponsor (funding) organization;
- The individual named by the CRC Subject Record. This same individual may request a copy of his/her medical records upon (1) execution of an Authorization for Release of Clinical Information (CRC Core Form C007) and (2) submission of proper identification.
- The next of kin of the individual named by the CRC Subject Record upon presentation of (1) proper evidence that the subject is deceased or otherwise unable to provide release authorization and (3) proper identification as next of kin. This same individual may obtain a copy of the medical record upon (1) providing a signed written request, (2) proper evidence indicating that the subject is deceased or otherwise unable to provide release authorization and (3) proper identification.

2.3 The research subject is not permitted to carry or deliver his/her subject record during the course of the study. This restriction is necessary to insure that the research data is not compromised.

3.0 PROCEDURE FOR RESPONDING TO A REQUEST FOR SUBJECT INFORMATION:

3.1 All requests regarding release of Subject Records/Information shall be forwarded to the CRC Secretary.

3.2 Upon receiving a request for access to a Subject Record, the CRC Secretary shall (1) if necessary, notify the requestor that his/her inquiry must be in writing, (2) obtain sufficient information from the requestor (i.e. subject's name, subject's date of birth, nature of participation, approximate date of participation) to determine if the individual was a CRC participant, and (3) locate the requested chart and provide the chart and related information to the CRC Manager.

3.3 Upon receipt of the signed written request, the CRC Secretary shall prepare copies of the required documents for submission to the requestor as instructed by the CRC Manager.

3.4 The CRC Manager, or his/her delegate, shall be accessible to the requestor to respond to inquiries regarding information contained in the Subject Record.

3.5 The executed request and any other related documents/correspondences shall be maintained in the original chart as evidence that chart information was released to the research subject or the subject's next of kin in accordance with the procedures of the CRC.