BROOKHAVEN NATIONAL LABORATORY CLNICAL RESEARCH CENTER POLICY	CRC POLICY 5.1	PAGE 1 OF 2
	PREPARED BY: W. GUNTHER	
SUBJECT: Maintenance of Subject Records	REVIEWED BY: G-J. WANG	
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	EFFECTIVE DATE: 12/01/07	
	REVISION HISTORY: orig. 9/5/02 rev. 10/11/04	

1.0 POLICY:
All participants in an IRB-approved clinical protocol must have a CRC Subject Record, which contains sufficient information to identify the participant and fully documents the nature of their participation. All Subject Records are to be controlled by the CRC and are treated as confidential documents.

2.0 **PROCEDURE FOR A NEW SUBJECT**:

2.1 The Principal Investigator or Clinical Protocol Coordinator shall notify the CRC Staff when a new subject has been identified for participation in a research study. Such notification should occur, at minimum, one day before commencement of the study. The PI/CPC shall provide the CRC Secretary with the Subject's name and birth date, IRB approved protocol number under which the research will be conducted, classification of subject (Control/Non Control), building number, and time subject will arrive/depart BNL.

2.2 The CRC Secretary, upon receipt of such notification, shall verify that the subject has not previously been involved with CRC research by reviewing the CRC Subject Cardfile/database and notifies BNL for entry.

2.3 Upon verification that the individual is a new subject, the CRC Secretary shall issue the individual a CRC Identification Number and create a Subject Record, and record information in the CRC Subject Cardfile/database.

2.4 Unless otherwise provided for in the Standing Orders, the PI/CPC or designated member of the Clinical Staff will notify the CRC main desk, Building 490 as to what building the new subject should report to, and the CRC Secretary will arrange transportation for the subject.

2.5 The PI or appropriate designee shall make arrangements to obtain the Subject Record prior to the Commencement of the study.

2.6 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 A RETURNING SUBJECT**:

3.1 The PI or appropriate designee shall notify the CRC Secretary that an existing CRC subject is returning for participation in another research study. Such notification should occur, at minimum, one day before commencement of the study. The PI/CPC shall provide the CRC Secretary with the subject's name and birth date, the IRB approved protocol number under which the research will be conducted, classification of subject (Control/Non Control), building number, and time subject will arrive/depart BNL.

3.2 The CRC Secretary shall retrieve the existing CRC Subject Record and prepare the chart for use in the newly scheduled study (i.e. insert Standing Orders, other applicable forms, etc.).

3.3 The PI or appropriate designee shall make arrangements to obtain the subject record prior to the commencement of the study.

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

4.0 **LOCATION/STORAGE OF SUBJECT RECORDS**:

4.1 All CRC Subject Records are to be maintained in the designated CRC Subject Records Storage areas unless approval to maintain them elsewhere is obtained from the CRC Secretary.

4.2 All CRC Subject Records are considered confidential and must be maintained in a secure area that minimizes risk of loss or damage.

4.3 In the event that CRC Subject Records are maintained outside the designated CRC Subject Records Storage area, the alternative area must provide security comparable to the designated CRC Subject Records Storage areas.

5.0 RETURN OF SUBJECT RECORDS TO THE CRC MAIN DESK:

5.1 It is the responsibility of the Physician conducting the study to insure that the Subject Record is returned to the CRC Main Desk following completion of the research study. The Subject Record shall be returned to the CRC no later than three (3) days after the completion of the research study.

5.2 Upon return of the Subject Record to the CRC Main Desk, the Clinical Protocol Coordinator or other member of the Clinical Staff shall determine that it is complete and tag it for review by the Subject Records Reviewers.

5.3 The CRC Secretary shall inform the CRC Manager of incidents when Subject Records are not returned in a timely manner.