

<b>BROOKHAVEN NATIONAL LABORATORY CLINICAL RESEARCH CENTER POLICY</b>	CRC POLICY 5.7	PAGE 1 OF 2
	PREPARED BY: W. GUNTHER	
SUBJECT: Subject Records: Storage and Access	REVIEWED BY: G-J. WANG	
	APPROVED BY: F. HENN	
	EFFECTIVE DATE: 5/18/07	
	REVISION HISTORY: orig. 10/11/04	

**1.0 PURPOSE**

To provide safe storage of and controlled access to Subject Records.

**2.0 SCOPE**

This policy applies to all human research subject records used and maintained by the CRC at BNL.

**3.0 POLICY**

It is the Policy of the CRC to have a system in place whereby the location of all subject records is known and access to such charts is limited to authorized personnel.

**4.0 REFERENCES**

**4.1** Joint Commission Comprehensive Accreditation Manual for Ambulatory Care Section IM2.10 and IM2.20

**4.2** 45 CFR 164.530(c)

**5.0 DEFINITIONS**

Subject Record: The collection of forms and documents containing identifiable information about a person who is a subject in a research project at BNL.

(Note: this is NOT the Case Report Form.)

Chart: Same as Subject Record.

Central Storage Area: The lockable cabinets in the CRC Secretary's office.

Remote Storage Area: The designated record storage area in the basement of bldg. 490.

Temporary Storage Area: A lockable drawer or cabinet in the office of an authorized Subject Record Accessor. The temporary Storage Area location must be approved by the CRC Manager and on file in the CRC Secretary's office.

Authorized Subject Record Accessor: Those people listed in Policy 5.3

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.

<b>BROOKHAVEN NATIONAL LABORATORY CLINICAL RESEARCH CENTER POLICY</b>	CRC POLICY 5.7	
	DATE 5/18/07	PAGE 2 OF 2
SUBJECT: Subject Records: Storage and Access		

**6.0 PROCEDURE FOR ACCESSING SUBJECT RECORDS**

- 6.1 The CRC Secretary's office, which contains the subject record Central Storage Area, shall be considered a controlled access area. Access shall be limited to the CRC Secretary, CRC Receptionist, CRC Manager or those given permission for access for a specific, time limited purpose. (e.g., signing or completing entries in charts.)
- 6.2 Charts may be signed out by authorized accessors by making submitting a list of requested charts to the CRC Secretary, CRC Receptionist, or CRC Manager.
- 6.3 Charts may be checked out for a maximum of 3 business days, after which they may be checked out again if necessary.
- 6.4 Charts checked out overnight must be left in a secure, locked desk or file cabinet which has been approved by the CRC Manager and the location of which is on file with the CRC Secretary.
- 6.5 Charts shall not be taken off BNL grounds without specific permission from the CRC Manager.
- 6.6 Charts may be returned to the CRC Secretary, CRC Receptionist or CRC Manager.

**7.0 PROCEDURE FOR STORAGE OF SUBJECT RECORDS**

- 7.1 Active Charts shall be maintained in the Central Storage Area.
- 7.2 Charts that have recorded no new activity for three years may be moved to the remote storage area.
- 7.3 When a properly signed out chart has not been returned after three days, the CRC Secretary will notify the person to whom the chart was checked out and request its return.
- 7.4 The CRC Secretary will notify the CRC Manager of overdue charts and the result of attempts to secure its return.

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.