BROOKHAVEN NATIONAL LABORATORY CLINICAL RESEARCH CENTER POLICY	CRC POLICY 5.2	PAGE 1 OF 1
	PREPARED BY: W. GUNTHER	
SUBJECT: Review of Subject Records	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:

All CRC Subject Records shall be reviewed by the CRC Subject Records Reviewers (Compliance Monitor, Clinical Protocol Coordinator, CRC Manager) to insure that the records are complete and accurate and as a means of identifying areas for improvement and education regarding subject record documentation and charting.

2.0 PROCEDURE FOR REVIEWS:

2.1 The Compliance Monitor shall review subject records on an established schedule.
2.2 The Clinical Protocol Coordinator shall review charts for completeness of forms at the start and at the close of studies.
2.3 The CRC Staff shall review charts at the beginning of a study to assure that forms described in the study proposal match those in the subject record. The CRC Manager may also review charts at random to assess compliance, completeness, and adherence to regulatory agency standards.

3.0 RESPONSE TO SUBJECT RECORDS REVIEW PROCEDURES:

It is the responsibility of the Principal Investigator conducting the study to address the corrective actions identified by the Subject Records Reviewers.