

BROOKHAVEN NATIONAL LABORATORY CLINICAL RESEARCH CENTER POLICY	CRC POLICY 4.2	PAGE 1 OF 1
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SUBJECT: Maintenance of Clinical Program Logbooks; "Clinical Diaries"	REVIEWED BY: G-J. WANG	
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1.0 POLICY:

Each clinical program operating within the CRC is required to maintain a logbook in order to provide a means of documenting self-assessment and improvement; and to insure a path of communication between the clinical programs, the CRC Manager, Quality Assurance Physician and the Medical Department Chairperson.

2.0 ESTABLISHMENT OF LOGBOOKS

2.1 It is the responsibility of the Responsible Physician (RP) to establish the program logbook and to assign one individual as responsible for maintenance of the logbook. The RP shall notify the CRC Secretary as to the identity of this responsible person.

2.2 The responsible individual shall insure that entries are made to the logbook.

3.0 MAINTENANCE OF LOG BOOKS

3.1 Entries to the logbooks may include:

- an occurrence not listed as part of the risks described in the consent form;
- an occurrence which although listed in the consent form, produces discomfort to the participant;
- a problem with a vendor or subcontractor which effects or may effect a participant's welfare; or
- an unresolved or on-going facility maintenance issue that pertains to care of the subject.

3.2 Any individual involved in the clinical program may make an entry to the logbook. Each entry should be initialed and dated by the individual making the entry.

3.3 An entry must be made for each day for which the clinical program is operational. If no events exist, an entry stating such should be made.

4.0 REVIEW OF LOGBOOKS

4.1 The individual designated as responsible for each logbook shall submit a copy of the logbook entried to the Quality Assurance Physician on a monthly basis. The Quality Assurance Physician is responsible for reviewing all program logbooks.

4.2 Items of concern or areas for improvement noted in the logbooks should be brought to the attention of the appropriate Principal Investigator and/or Responsible Physician.

4.3 Corrective action, as necessary, shall be the responsibility of the Responsible Physician. Corrective action steps/methods should also be documented in the logbook.

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.