1.0 POLICY

Subject Records shall follow a consistent format of forms and documents.

2.0 RESPONSIBILITY FOR SUBJECT RECORDS

2.1 It is the responsibility of the RP or the Participating Physician to initiate the preparation of a chart for each individual who participates in a research study within the CRC. It is also the RP or Participating Physician's responsibility to ensure that the completed subject record is returned to the CRC Reception Desk upon completion of the study.

2.2 It is the responsibility of the CRC Receptionist to log in all subject records and to maintain a system, which stores all subject records in a manner, which readily allows all charts to be accessed either by name or chart number.

3.0 LOCATION OF SUBJECT RECORDS

3.1 All completed Subject Records are to be maintained by the CRC Receptionist.

3.2 All people authorized access to Subject Records may check out records from the designated CRC Subject Records Storage area in accordance with Policy 5.7

3.3 All Subject Records stored outside the central CRC Subject Records storage area must be maintained in an area which is (1) secure in order to maintain patient confidentiality and (2) fire resistant to minimize the risk of loss.

4.0 MINIMUM CHARTING REQUIREMENTS

4.1 Each subject *record shall have at a minimum the following content and composition:*

Section 1
- Subject Information Form
- Radioisotope Summary/ Internal or External
- Inclusion Exclusion Criteria

Section 2
- Medical History and Physical
  - Mental Exam
  - Standing Order
  - Progress Notes
  - Informed Consent form
  - Laboratory Requests and STAT Reports
  - Volunteer Fee Payment receipt form
  - Subject Information Checklist

Section 3
- Subject Questionnaire Form

Section 4
- IRB protocol specific forms

Section 5
- Follow-up Form
- Prescriptions
- Adverse Event Forms

4.2 All information in the chart must be legible.

4.3 The Subject Record shall include a copy of the Standing Order.

4.4 The Subject Record shall include the appropriate consent forms.

4.5 The Subject Record shall include all CRC forms indicated on the Standing Order and documentation indicating that all tests detailed by the Standing Order were carried out.

4.6 Entries to the Subject Record shall only be made by members of the Medical Staff, Nursing staff or other authorized individuals.

5.0 Request for Social Security Number (SSN)

5.1 Subjects will be required to provide their SSN due to the IRS requirement that any monetary payment over $600 within a calendar year must be reported by BNL on form 1099-misc.

5.2 Subject SSN will be entered on the Subject Information Form.

5.3 Subjects will be informed during the initial screening phone call that they will be required to provide their SSN, and the reason will be explained.