

# Johns Hopkins Bayview Medical Center

## CLINICAL RESEARCH UNIT

**Policy No.: 111**  
**Original Date: 06/97**  
**Previous Date: 10/01**  
**Revised Date: 08/02**

## Medical Documentation Standards

**Purpose:** To outline the minimal expectations for medical documentation on the CRU inpatient and outpatient medical records.

**Procedure:**

1. Physician care and documentation of care on the CRU are held to the standards of the JHBMC acute care facility and the JCAHO.
2. Upon inpatient admission of research participants, orders are written, signed, and timed by the principal investigator or physician designee who has admitting privileges at JHBMC.
3. The chart is to reflect an admitting diagnosis, such as “research volunteer”.
4. A current IRB approved consent form, signed by the subject and Principal Investigator (or IRB approved designee), is obtained and witnessed prior to the CRU admission, and a copy placed in the medical record.
5. A complete medical history and physical examination are recorded on the day of admission. If a complete history and physical examination were performed during a screening visit (within 30 days of admission), a dated copy is placed in the medical record and an interim medical history and appropriate physical examination are performed on admission and recorded. The history and physical examination must include whether the subject is included or excluded from the study.
6. The CRU staff follow the JHBMC policy and practice on Advanced Directives: for inpatients, this includes signing the Advanced Directive algorithm and placing a copy in the progress note section of the chart; for outpatients, this includes answering participant’s questions on Advanced Directives, providing information on request and documenting the interaction in the progress notes.
7. All inpatients receive daily medical evaluations by a physician investigator or designated physician assistant or nurse practitioner starting within 24 hours of admission and documented in the medical record.
8. Physician investigators document all invasive procedures using standard procedure notes. The medical record includes protocol flow sheets to assure that the methods employed are standardized and accurately recorded.
9. All physician orders are timed, dated, and signed. For authentication, the physician is to print her/his name first, followed by her/his signature. Verbal orders are countersigned, dated, and signed within 24 hours of origin.

# Johns Hopkins Bayview Medical Center

CLINICAL RESEARCH UNIT

Policy No.: 111  
Original Date: 06/97  
Previous Date: 10/01  
Revised Date: 08/02

Medical Documentation Standards

10. All inpatient protocols require 24-hour access to a physician, and a written call schedule is required on the CRU that includes telephone numbers for office, home, and pager.
11. A discharge summary sheet is required at the time of discharge that included documentation of discharge instructions provided to the subject.
12. Studies that include only outpatient visits require that:
  - A. Consent is obtained before or at the first visit.
  - B. A medical record is established that includes a copy of the subject's consent form.
  - C. Protocol flow sheets, and a progress section in which nursing and physician assessments are recorded.
  - D. Patient care is monitored at intervals appropriate to the level of risk posed by the protocol, as determined by the principal investigator and approved by the CRU Advisory Committee.

Originator: CRU Program Director  
CRU Associate Program Director  
CRU Clinical Nurse Specialist

References: General Guidelines for the Clinical Research Unit Program of the National Center for  
Research Resources National Institutes of Health  
JHBMC Medical Staff Bylaws

---

Pamela Ouyang, MD  
Program Director, CRU

---

Cindy Walters, RN, MSN  
Director of Maternal Child Health & Research Nursing  
Manager if Ambulatory Oncology Services