

# Johns Hopkins Bayview Medical Center

CLINICAL RESEARCH UNIT

Policy No.:112  
Previous Date: 07/98  
Revised Date: 4/08

Medical Staff Coverage

Purpose: To define the procedure and process for providing medical coverage for participants on the CRU

Procedure:

1. Medical coverage is provided by the principal investigator or his/her physician representative on the research team. The CRU staff shall contact the designated medical representative for questions or concerns.
2. All research conducted on the CRU must have physician coverage. The physician must be named on the protocol and be credentialed in the Johns Hopkins Health System.
3. The principal investigator or physician representative documents the physician coverage on the participant's admission orders and/or as an on-call schedule. The information provided must include the name of the covering physician, office and home telephone numbers, pager number and dates of coverage.
4. In an emergency when the principal investigator or representative is not available, the CRU staff follows the following hierarchy to obtain medical coverage, the Associate Program Director, the Program Director, or the Program Director's designee.
5. On research protocols where drugs are investigational or administered on site for a new purpose or by a new route, or where a research procedure may place the participant at risk, the physician member of the research team must be present on the CRU throughout the initial phase of the study when an adverse effect is most likely to occur. Presence on the CRU is necessary for the investigator to gain insight into the results of the drug administration or research procedure, and to provide medical coverage should there be an emergency.

Reviewers: CRU Program Director  
CRU Associate Program Director  
CRU Patient Care Manager

References: JHBMC Medical Bylaws

---

Pamela Ouyang, MBBS  
Program Director, CRU

---

John Preto, MSN RN  
Director of Medical Nursing