

# Johns Hopkins Bayview Medical Center

CLINICAL RESEARCH UNIT

Policy No.: 127

INFORMED CONSENT

Previous Date: 2/10/1998

Revised Date: 1/30/08

## Purpose:

To assure subject's rights and safety while participating in research procedures.

## Policy:

1. CRU staff will comply with research protocol requirements when a copy of an appropriately signed and dated, currently IRB approved informed consent document(s) is provided for the subject's research record, and, if applicable, the subject's medical record.
2. The date for the Principal Investigator's (or consent designee) and subject's signatures should be the same. The IRB may grant approval of the informed consent process whereby the signature dates may be different. In all instances, the investigator and authorized research personnel must follow the IRB approved consent process
3. Protocol procedures will not be implemented until a signed and dated copy of the required informed consent is provided for the subject's research record, and, if applicable, the subject's medical record.
4. The Principal Investigator will be notified of any subject's unplanned departure

## Procedure:

1. The Principal Investigator, co-Investigator or his/her designee will assure that a signed and dated copy of the current IRB approved informed consent, displaying the most current IRB stamp or eIRB logo, for the protocol has been provided to the CRU staff prior to or at the time of the subject's visit to the CRU to participate in a study, and in all cases prior to protocol specific procedures being conducted on the unit.
2. The CRU nursing staff will verify the consent at the time of the subject's visit and/or prior to participation in a study. The consent will be examined for the following components;
  - The presence of the IRB stamp or eIRB logo
  - The presence of the subject's or legal guardians signature
  - Dates of the signatures (should be the same)
  - All planned procedures are listed
3. The CRU staff will inform the Principal Investigator if an appropriately signed informed consent document has not been provided or if any other consent form irregularities noted above are observed.
4. The Principal Investigator will be notified if the CRU staff perceives
  - that there is a deficit in the subject's understanding of the information in the consent
  - that the subject is unable to comply with the procedures outlined in the consent
  - coercion
5. If the CRU staff perceives coercion the Research Subject Advocate, Patient Care Manager, Department Manager or Director of the Core Service will be notified.
  - Study procedures will not be implemented until the deficit is corrected and noted in the subject's research record.
6. CRU staff will notify the Research Subject Advocate, or designated person in the Research Subject Advocate's absence, of any deficits related to informed consent.

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## Reviewers:

CRU Nursing Staff  
Research Subject Advocate  
Program Director  
Director Risk Management

## References:

Institutional Policy: <http://irb.jhmi.edu/Guidelines/informedconsentI.html>  
Federal Regulatory Citations: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116>;  
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=50.20>; ICH Good Clinical Practice, E6  
“Ethical and Legal Considerations of Patient Care”, The Warren G. Magnuson Clinical Center, National Institutes of Health, 1987  
C.C. Assurance of Compliance with HHS Regulations, Protection of Human Subjects, December 23, 1981, Medical Manual of Issuance

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