

# Johns Hopkins Bayview Medical Center

**GENERAL CLINICAL RESEARCH CENTER**

**Policy No.: 106**  
**Original Date: 9/97**  
**Previous Date: none**  
**Revised Date: 06/03**

**Ethical Concerns in Research Practice**

**Purpose:** To delineate the policy and mechanisms within the GCRC for reporting, investigating, and resolving ethical issues in research application and care.

**Procedure:**

1. Concerns discovered by the GCRC staff will be immediately brought to the attention of either the Patient Care Manager or the Research Subject Advocate depending upon the nature of the concern.
2. Matters regarding patient care and safety will be reported to the Patient Care Manager and/or other designated personnel.
3. Matters involving research protocol implementation will be reported to the Research Subject Advocate, or designated person in the Research Subject Advocate's absence. Issues include but are not limited to: recruiting practices, informed consent, subject eligibility, study procedures, and adverse events.
4. The Patient Care Manager and Research Subject Advocate will share information as deemed necessary.
5. Concerns will be thoroughly investigated and methods of resolution will be sought with all parties including the Principal Investigator. Investigators may be requested to provide written clarification(s) or outline a plan of corrective action.
6. Concerns that remain unresolved will be referred to the Program Director and/or Associate Director. The research study may be placed on hold until issues are resolved. In the event of an administrative study hold, parties overseeing study conduct and human subject safety and those covering staff liability (JHBMC Risk Management, JHU Legal) will be notified.
7. The GAC and IRB may act as mediators for resolution. The IRB can suspend /terminate approval of research not conducted in accordance with IRB requirements or that has been associated with unexpected serious harm to the subject. Notification of resolution will be forwarded to all appropriate parties.

**Originator:** GCRC Clinical Nurse Specialist

**Reviewed by:** JHBMC Risk Management

**References:**

Guidelines of the Johns Hopkins Medicine Institutional Review Boards for Human Subject Research  
JHBMC Policy and Procedure Manual Patient Care Practices E-25

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