

Johns Hopkins Bayview Medical Center

CLINICAL RESEARCH UNIT

Policy No.: 109
Original Date: 9/97
Previous Date: 08/02
Revised Date: 7/25/08

Institutional Review Board for Human Subject Research (IRB): Role and Responsibilities

Purpose: To provide the outline of the IRB responsibilities and describe the relationship of the IRB with the CRC.

Procedure:

1. All new research projects conducted in the CRU must be reviewed and approved by one of the Johns Hopkins Medicine Institutional Review Boards for Human Subject Research (JHM IRBs), or the Bloomberg School of Public Health Institutional Review Board (BSPH IRB), and the CRU Advisory Committee. CRU Advisory Committee approval is contingent upon IRB approval.
2. Current studies approved by the CRU Advisory Committee must maintain Continuing Review approval from the JHM IRBs, BSPH IRB, or Western IRB (if applicable).
2. The role of the IRB is to ensure that:
 - A. the rights and welfare of research participants are protected as stated in 45 Code of Federal Regulations 46.
 - B. the risks to subjects are justified by the potential benefits of the research.
 - C. the recruitment and enrollment of subjects is equitable.
 - D. informed consent will be obtained and, where appropriate, documented.
 - E. attendance records, membership and minutes are maintained for examination during the site visit for the CRU.
 - F. IRB documentation of project approval and copies of currently approved consent forms are forwarded for inclusion in the CRU administrative files.
 - G. research not conducted in accordance with IRB requirements or that has been associated with unexpected serious harm to subjects is suspended or approval is terminated

Reviewer: CRU Patient Care Manager
CRU Research Subject Advocate

References: General Guidelines for the General Clinical Research Centers Program of the National Center for Research Resources National Institutes of Health
Guidelines of the JHM Institutional Review Boards for Human Subject Research

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