

Johns Hopkins Bayview Medical Center

GENERAL CLINICAL RESEARCH CENTER

Policy No.: 110
Original Date: 9/97
Previous Date: None
Revised Date: 08/02

Masking of Research Participants and Data

Purpose: To provide guidelines for masking of participant data and maintaining the integrity of the research outcomes. All participants are assured of confidentiality per Johns Hopkins Bayview Medical Center policy and professional standards. Additional procedures may be taken to assure masking of data and subject identity to research investigators and GCRC staff.

Procedure:

1. At the time of protocol submission, the Principal Investigator will indicate the level of masking required for the study.
2. The GCRC staff will review the protocol and assure that steps are provided to maintain confidentiality of the masked data.
 - A. Patient logs, coding, identification numbers or other descriptors will be locked and maintained in a confidential manner.
 - B. Code numbers will be used as indicated on laboratory work, completed questionnaires, etc. as per protocol requirements.
3. As indicated, participants, their families, and others, will not be informed of their research status or treatment assignment.
4. Participant identity and treatment conditions may be unmasked in situations where the participant is at risk, or has experienced an adverse event that requires knowledge of the participant's complete medical history. Unmasking is conducted with permission of the Principal Investigator and/or IRB, GAC and /or Independent Safety Monitoring Board(s) of the NIH, industry, etc.

Originator: GCRC Clinical Nurse Specialist

References: Guidelines of the Johns Hopkins Medicine Institutional Review Boards for Human Subject Research

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