

| Johns Hopkins Bayview Medical Center | |
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| GENERAL CLINICAL RESEARCH CENTER | Policy No. 152 |
| Research Subject Eligibility | Original Date: 9/12/02 Previous Date: None Reviewed Date: None |

Purpose: To provide policy and procedure for GCRC staff in assuring subject safety when enrolling in research procedures.

Deleted:

Policy: GCRC staff will implement research procedures when appropriate documentation reflecting eligibility status, based on inclusion/exclusion criteria detailed in the IRB approved protocol, is provided.

Procedure:

1. The Principal Investigator will assure that appropriate documentation of study eligibility is provided to the GCRC staff member prior to or at the time of the subject’s visit to the GCRC to participate in the study. This information will match the IRB and GAC approved protocols.
2. The investigator should provide a progress note, checklist, or another suitable form of documentation that clearly indicates the individual subject’s eligibility based on the inclusion/exclusion criteria outlined in the protocol approved by the IRB/GAC.
3. The GCRC staff will inform the investigator or his/her designee of any deficits related to the match in subject eligibility.
4. Protocol procedures will not be implemented until appropriate documentation confirming subject eligibility is provided for the subject’s medical record.
5. If the GCRC staff discovers discrepancies or omissions related to subject eligibility, the investigator or his/her designee will be notified and this will be documented in the medical record. Study procedures will not be implemented until the deficit is resolved and noted in the medical record.
6. GCRC staff will complete a Protocol Deviation form and notify the Research Subject Advocate, or designated person in the Research Subject Advocate’s absence and the appropriate manager/director of their area, of any deficits related to subject eligibility.

Originator: GCRC Research Subject Advocate
GCRC Patient Care Manager

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

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