

# Johns Hopkins Bayview Medical Center

## GENERAL CLINICAL RESEARCH CENTER

Elopement of Subjects

Policy # 165

Original Date: 03/19/04

Previous Date: None

Reviewed Date: None

**Purpose:** to outline the steps GCRC staff members are to take in the event that a subject leaves the center and/or abandons a study.

**Definition:** Elopement is defined as a situation when the whereabouts of a research subject is unknown. Abandonment is defined as the failure of a subject to return and participate in a study.

### Policy:

1. All subjects are to sign in and out of the GCRC. The sign out sheet includes time out, destination and the anticipated return time. All subjects will be informed to call the GCRC if they are going to be late returning to the center.
2. Subjects who are one hour beyond their anticipated return time without contacting the GCRC will be deemed as eloping and the elopement policy will be implemented.

### Procedure:

1. The nurse needs to know the anticipated return time and whereabouts of each subject. If the subject is late by one hour or their whereabouts unknown (e.g. failure to sign out, missing from the GCRC), the Investigator's Research Coordinator and the Patient Care Manager will be notified.
2. The research coordinator and the GCRC nurse together will plan a method of trying to locate the subject, e.g. phone calls, environmental checks, etc. Each attempt to contact the patient and the result of attempted contacts must be documented with time and date in the medical record.
3. If follow up activities fail to reveal the subject's location or the subject is found in an unauthorized location or engaged in a study compromising activity (e.g., non-adherence to diet regimen, recreational drug usage, etc), the Principal Investigator, Patient Care Manager and the Research Subject Advocate will be immediately notified. The Principal Investigator will talk with the subject to elicit the reason for elopement, correct the situation and/or decide on the next course of action. This contact will include information regarding the purpose of the study, any proposed benefit from the study if there is one, the risk of not receiving follow up research assessment, and provide instructions for follow-up care. Each attempt to contact the patient and the result of attempted contacts must be documented with time and date in the medical record.
4. If the subject does not return within 2 hours of anticipated return time and does not contact the GCRC or Research team, this will be deemed as abandonment. The subject may not be allowed to return for this visit and the research team may need to reschedule another admission time. If contact is not made, a letter will be written to the subject outlining information regarding the purpose of the study, the proposed benefit of study if there is one for the subject, the risk of not receiving follow up research assessment, and instructions for follow-up. A copy of this letter will

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be given to the GCRC Research Subject Advocate for the GCRC files. If this is the only subject, the GCRC may close the center and in case the subject returns, a note will be left on the door directing the subject to call the Research team.

5. The nurse will, per JHBMC policy and procedure on elopement, then notify Security and the Nursing Supervisor that a subject abandoned. The nurse will outline the steps taken and indicate if the GCRC is to close and if a note was left.
6. Nursing staff will complete a Protocol deviation form and a JHBMC Occurrence Report form regarding the steps taken to resolve the situation.

Reviewed by: JHBMC Risk Management  
General Clinical Research Center Advisory Committee

Originated by: Patient Care Manager, General Clinical Research Center

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