

Johns Hopkins Bayview Medical Center

GENERAL CLINICAL RESEARCH CENTER

Policy No.: 108
Original Date: 10/97
Previous Date: None
Revised Date: 08/02

Interruption or Discontinuation of Participant Services Related to Potential or Identified Safety Risk to Staff

Purpose: To delineate activities or events that can precipitate an interruption or discontinuation of a research subject's participation in a clinical research protocol on the GCRC related to her/his threatening or violent behavior.

Procedure:

1. The safety of the patient and staff is of primary importance to the GCRC and JHBMC Administration. The following have been identified as potential situations where a participant may be removed from the GCRC and/or further research involvement in order to protect staff.
 - A. Evidence of open drug traffic.
 - B. Evidence of the influence of non-research related mind-altering substances.
 - C. Evidence of a weapon.
 - D. Participant verbalization of potential violence from the participant or another person.
 - E. Witnessed threats of violence to the participant by other individuals.
2. All efforts will be made if possible to eliminate the safety concern and maintain the research participation. When it has been determined that the safety risk cannot be eliminated or when the GCRC staff feel at risk, the following steps are taken:
 - A. The Patient Care Manager, Associate Program Director, Program Director, Principal Investigator, and/or any other designated personnel, and JHBMC Security are immediately notified of the concerns and an intervention is outlined. This may include resolution of the threat, and/or removal of the participant from the GCRC.
 - B. JHBMC Security Officers may assist by escorting threatening individuals from the GCRC. In the event that the threatening individual has left the GCRC, Security is notified to assure that the individual does not return to the GCRC. The GCRC staff may implement the "Personal Safety Alarm Buttons" Policy.
3. The incident is documented per the JHBMC occurrence policy and procedure. If the situation implies domestic violence or abuse, the staff adheres to the JHBMC policy and procedure for referral, documentation and adherence to regulations.

4. The Principal Investigator notifies the participant when there is a decision to cancel or modify the participant's research status.

Originator: GCRC Clinical Nurse Specialist

Reviewed by: JHBMC Director of Security

References: None

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