

Johns Hopkins Bayview Medical Center

GENERAL CLINICAL RESEARCH CENTER

Policy No.: 131
Original Date: 04/13/99
Previous Date:
Revised Date: 09/00

Protocol Orders

Purpose: To delineate the minimum content of the General Clinical Research Center Physician Orders.

Procedure:

1. Protocol orders are developed for both in and out patients.
2. The orders will be written or typed orders onto the Johns Hopkins Bayview Medical Center's Physician Order Sheet.
3. Inpatients Orders will include:
 - A. The full title of the protocol
 - B. The name of the principal investigator
 - C. The RPN number
 - D. The name of the participant
 - E. Addressograph stamp with participant identifiers
 - F. Date of the admission
 - G. Participant number or identifier
 - H. Allergies
 - I. Condition
 - J. Diagnosis (research volunteer)
 - K. Medications including research drug, holding of medication, and the mechanism for the admission of the participant's routine/daily medication (self administration, self administration with nurse documentation, staff administration and documentation)
 - L. Diet including time duration of fasting and special diets, fluid restrictions or requirements
 - M. Activity level such as bed rest or following the research interventions, off unit privileges, smoking privileges, telephone privileges.
 - N. Vital signs and frequency of other physiological monitoring
 - O. Protocol guidelines. This area should include basic information about the protocol such as frequency of blood draws.
 - P. Special instructions. This area should include instructions to expedite a protocol, prevent a unnecessary procedure or help assure participant safety, such as call investigator when participant returns from radiology or do not need pregnancy test, or recheck HCT in a.m.
 - Q. Discharge orders
 - R. Printed name of signer and their signature.
4. Outpatient Orders will include:
 - A. The full title of the protocol
 - B. The name of the principal investigator
 - C. The RPN number
 - D. The name of the participant

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- E. Addressograph stamp
- F. The participant's study number, medical record number, other identifier
- G. Allergies
- H. Medications of the study
- I. Protocol guidelines. This area should include basic information about the protocol such as frequency visits, the events of each visit including blood draws, testing procedures and the duration of the study.

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