

TITLE: RESEARCH DRUGS (INVESTIGATIONAL OR COMMERCIALY AVAILABLE) FROM PROTOCOLS ORIGINATING AT OTHER INSTITUTIONS

POLICY & PURPOSE:

The following policy and procedure was developed to outline the necessary steps required for the use of an investigational drug or biological agent in a patient admitted to NewYork-Presbyterian Hospital (NYP) who is participating in a research study at another institution.

DEFINITIONS:

"**Investigational new drug**" is synonymous with investigational drug and is defined as a new drug or biological product that is used in a clinical investigation.¹

APPLICABILITY:

Health care providers involved with the prescribing, dispensing, accountability, administration and monitoring of investigational drugs at NYP.

PROCEDURE:

- A. An order for an investigational drug can only be written or entered into the hospital computer system by an authorized prescriber
- B. In accordance with standards of practice, all orders for investigational drugs must be reviewed by a pharmacist.² Investigational drugs must also be stored and dispensed by the Investigational Drug Pharmacies located within the institution.
- C. Healthcare personnel will administer an investigational drug only if it has been dispensed by one of the Investigational Drug Pharmacies located within the institution.
- D. Within two business days of patient admission and administration of study drug, the following materials must be furnished to the Institutional Review Board (IRB) by the admitting attending physician or his designee:
 1. A copy of the protocol from the sponsoring institution;
 2. A copy of the signed consent form from the sponsoring institution;
 3. Documentation of Institutional Review Board (IRB) approval of the protocol from the sponsoring institution;
 4. Copies of these three documents must be placed in the progress notes section of the patients' medical record as soon as they are received by the

- admitting attending physician or his designee.
- E. The following materials must be furnished to the Investigational Drug Pharmacies (by the admitting attending physician or his designee) prior to administering the study drug to the patient:
1. Drug supply (likely furnished by the patient);
 2. Drug information about the investigational drug (when available), including:
 - a. Dosing and administration
 - b. Method of dose preparation
 - c. Adverse effects and other precautions
 - d. Storage requirements
 - e. Monitoring parameters
 - f. List of authorized prescribers
 - g. Any other information deemed necessary for the safe and proper use of the investigational medication
- F. Within two business days of patient admission and administration of study drug, the following materials must be furnished to the Investigational Drug Pharmacies by the admitting attending physician or his designee:
1. A copy of the protocol from the sponsoring institution;
 2. A copy of the signed consent form from the sponsoring institution;
 3. Documentation of Institutional Review Board (IRB) approval of the protocol from the sponsoring institution.
- G. If all required material is not producible within two business days, the IRB and admitting physician will make a decision as to whether or not it is in the best interest of the patient to continue the study drug.
- References:
1. CFR Title 21, Part 312 "Investigational New Drug Application", Emergency use of an investigational drug or biological, FDA Information Sheets, September 1998
 2. Joint Commission on the Accreditation of Health Care Organizations, Accreditation Manual

RESPONSIBILITY: Pharmacy

POLICY DATES:

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