CLINICAL POLICY

Inpatient Utilization of Investigational Drugs

A. EFFECTIVE DATE :

March 16, 2021

B. PURPOSE :

To ensure the proper distribution and administration of investigational and study drugs for inpatient use. Each study conducted at John Dempsey Hospital will be performed in a manner which protects the integrity of the study, the well-being of research subjects, and meets the ethical and legal responsibilities of the Institutional Review Board (IRB), the Food and Drug Administration (FDA), and the Joint Commission of the Accreditation of Healthcare Organizations (TJC).

C. POLICY :

1. All investigational drugs shall be registered and stored in the hospital pharmacy. Investigational drugs from other institutions will be handled according to the Inpatient Patients' Personal Medications nursing procedure and Department of Pharmacy Policy A-021.
2. All investigational drugs must have Institutional Review Board (IRB) use approval before they are administered to patients.
3. When study design permits, the distribution of investigational drugs shall be in concert with the Pharmacy Department's unit dose distribution system.
4. Documentation of informed consent shall be obtained prior to administration of the investigational drug.
5. Adequate information about investigational drugs shall be provided to nurses who administer investigational drugs.
6. An implementation plan must be prepared for studies using investigational drugs when it is anticipated that two or more patients will be enrolled.

D. SCOPE :

This policy applies to all areas in which investigational drugs are used for inpatients.

E. DEFINITIONS :

1. **Co-Investigators (Co-PI)** – one or more faculty who have been approved to participate in the conduct of the Protocol under the overall direction of the Principal Investigator
2. **Inpatient** – shall be defined as all research subjects whose condition is such that they meet criteria for inpatient admission
3. **Investigational Drug** – any drug, chemical, or biologic product as an active ingredient or placebo that is being used in the context of a clinical investigation. It has been granted Investigational New Drug (IND) status by the Food and Drug Administration
4. **Investigational Drug Service (IDS)** – a division of the UConn John Dempsey Hospital Department of Pharmacy that provides support for clinical drug studies including IRB consultation and dispensing services
5. **Institutional Review Board (IRB)** – the committee that conducts oversight for all research involving human subjects at UConn Health

6. **Principal Investigator (PI)** – the faculty of UConn Health who is responsible for overseeing the conduct of a protocol
7. **Protocol** – a document that describes the objectives, design, methods, statistical considerations, and organization of a trial

F. MATERIAL(S) NEEDED :

None

G. PROCEDURE :

1. The Principal Investigator shall:
   a. Transfer the drug supply to the hospital pharmacy for registration and storage
   b. Identify those individuals authorized to prescribe investigational drugs used in their study. Orders may be placed via Computerized Physician Order Entry (CPOE) or written orders as per hospital policy clearly designated as an investigational study.
2. The pharmacy department will:
   a. Ensure that the IRB use approval has been obtained.
   b. Verify that the prescriber is authorized to prescribe the investigational drug prior to dispensing.
   c. Supply the investigational drug in unit-dose packaging, if appropriate, and label the product as an investigational drug. To ensure study integrity, pre-randomized, pre-packaged patient-specific drugs are not to be repackaged.
   d. Ensure that administration and dispensing of investigational drugs will be per study protocol.
3. The first dose of an investigational drug shall not be administered without assurance from the pharmacy that IRB approval has been obtained
4. Investigational drugs shall be administered only after:
   a. Determining that informed consent has been obtained and is available in the pharmacy department and/or in the medical record.
   b. Being provided with written complete and concise clinical information about the drug (see appendix 5). This information includes administration guidelines, known side effects, contraindications, usage, and ranges of doses. This information shall be provided by the pharmacy department.
5. Unused investigational drugs must be returned to the pharmacy

H. ATTACHMENTS :

Appendix 5: Investigational Drug Data Sheet

I. REFERENCES :

ASHP Guidelines on the Use of Investigational Drug in Organized Health-Care Settings
Code of Federal Regulations, Good Clinical Practice, CFR 21:312.62c
Connecticut Pharmacy Law
TJC Standard, MM.7.40, Investigational medications are safely controlled and administered

J. SEARCH WORDS :

None

K. ENFORCEMENT:

Violations of this policy or associated procedures may result in appropriate disciplinary measures in accordance with University By-Laws, General Rules of Conduct for All University Employees, applicable collective bargaining agreements, the University of Connecticut Student Code, other applicable University Policies, or as outlined in any procedures document related to this policy.

L. STAKEHOLDER APPROVALS :

On File

M. COMMITTEE APPROVALS :

None

N. FINAL APPROVAL :

1. Andrew Agwunobi, MD (Signed) 3/31/2021
Andrew Agwunobi, MD, MBA Date
UConn Health Chief Executive Officer

2. Anne Horbatuck (Signed) 3/31/2021
Anne D. Horbatuck, RN, BSN, MBA Date
Clinical Policy Committee Co-Chair

3. Scott Allen. MD (Signed) 3/26/2021
Scott Allen, MD Date
Clinical Policy Committee Co-Chair

4. Caryl Ryan (Signed) 3/24/2021
Caryl Ryan, MS, BSN, RN Date
VP Quality and Patient Services & Chief Nursing Officer

O. REVISION HISTORY :

Date Issued: 12/28/2012
Date Reviewed:
Date Revised: 10/26/2015, 9/1/2017, 9/1/2020, 1/20/2021, 3/16/2021