



Pharmacy Investigational Drug Service Clinical Policy

Inpatient/Outpatient Dispensing and Labeling of Investigational Drugs

A. EFFECTIVE DATE :

11/15/2021

B. PURPOSE :

To ensure that investigational and study drugs are dispensed from the Investigational Drug Service (IDS) according to applicable regulations, sponsor guidelines, and standing pharmacy policies.

C. POLICY :

1. Prior to IRB application submission, all necessary information will be submitted to the Investigational Drug Service (IDS) pharmacist for approval. The IDS pharmacist will verify appropriate dose, frequency, route, duration and use of the medication.
2. Any clinical research project performed at UConn Health involving the use of an investigational drug in an outpatient setting when drug will not be stored in the IDS pharmacy will require the IDS pharmacist to approve the plans for control of investigational drugs.
3. All investigational drugs must have Institutional Review Board (IRB) approval before they are dispensed from the pharmacy.
4. Documentation of informed consent shall be obtained prior to dispensing of the investigational drug.
5. IDS must receive a written order from a principal investigator or co-investigator in order to dispense an investigational drug to a patient.
6. Investigational drugs are study and/or patient-specific and are not to be diverted for other use.
7. Administration and dispensing of investigational drugs will be per protocol.
8. An implementation plan must be prepared for studies using investigational agents for which it is anticipated that 2 or more patients will be enrolled.

D. SCOPE :

This policy applies to all UConn Health areas in which investigational drugs are used.

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. **Dispensing** – when a supply of drug that is non-patient specific or requires manipulation (counting, mixing, preparing, etc) is given to a specific patient. By law, dispensing can only be done by a pharmacist, physician, nurse practitioner, podiatrist, or dentist
3. **Good Clinical Practice** – a standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate and that rights, integrity, and confidentiality of trial subjects are protected

4. **Inpatient** – shall be defined as all research subjects whose condition is such that they meet criteria for inpatient admission
5. **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
6. **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
7. **Institutional Review Board (IRB)** – the committee that conducts oversight for all research involving human subjects at UConn Health
8. **Investigators' Brochure** – a compilation of clinical and nonclinical data on an investigational product that are relevant to the study of the product in human subjects
9. **IRB number** – the number assigned by the IRB to each study protocol submitted for approval
10. **Outpatient** – shall be defined as all research subjects that have investigational medication used in an outpatient setting
11. **Principal Investigator (PI)** – the faculty of UConn Health who is responsible for overseeing the conduct of a protocol
12. **Protocol** – a document that describes the objectives, design, methods, statistical considerations, and organization of a trial
13. **Vestigo** – a web-based software for the management of Investigational Drug Services (IDS). It is fully HIPPA Compliant as well as 21 CFR Part II (electronic signatures) compliant for auditing

F. MATERIAL(S) NEEDED :

None

G. PROCEDURE :

1. The IDS pharmacist may give their approval to the IRB via email, an electronic program sanctioned by the IRB, or signature on the IRB application.
2. A copy of the current up to date IRB-approved protocol will be maintained in the pharmacy. The current up to date protocol can be maintained electronically in a computerized program such as Vestigo or in the study binder if deemed necessary by the sponsor.
3. A training log will be completed for each study which is anticipated to enroll 2 or more patients (see Appendix A).
4. During specified working hours Monday through Friday, the IDS will sign out and dispense a patient specific supply of study drug upon receipt of an authorized physicians order or a prescription. During hours other than those covered by the IDS, the pharmacist will compare the physician's order to the drug supply to identify and verify the source. The pharmacist will obtain the necessary number of dosage units to fill the order. The number of units will be signed out of the accountability log whether electronically in a computerized program such as Vestigo or in the study binder if deemed necessary by the sponsor.
5. Investigational summary sheets detailing study information will be available to all pharmacists for inpatient studies (see Pharmacy IDS Policy for Inpatient Utilization of Investigational Drugs for further detail).
6. The authorized physician shall:
 - a. If needed, transfer the drug supply to the hospital pharmacy for registration and storage.
 - b. Provide hospital pharmacy personnel with:
 - i. Current up to date IRB approved investigational protocol
 - ii. Proof of IRB approval
 - iii. Relevant information about the clinical use of the drug (Investigator's Brochure)
 - iv. A copy of the patient's signed consent form
 - v. A dated prescription faxed or delivered detailing Subject name or initials, Subject Study Number (if applicable) Allergies, Date of Birth, Protocol name and number, Medication name, Dosage, Route of Administration, Schedule of drug administration, Subject Weight (if applicable) and signature of

principal investigator or co-investigator (see Appendix B for a sample). Inpatient subjects may have their orders placed in the Computerized Physician Order Entry (CPOE) system or written orders as per hospital policy

7. Orders may be faxed or delivered to IDS Pharmacy
8. Inpatient orders will be validated through the CPOE system by either the investigational pharmacist or staff pharmacist. Written orders shall be placed in pharmacy system by either the investigational pharmacist or staff pharmacist clearly designating it is an investigational drug.
9. Outpatient and inpatient orders may be placed electronically in a computerized program such as Vestigo for accountability records and to generate prescription label
10. The IDS staff will:
 - a. Ensure that the IRB approval has been obtained.
 - b. 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. The label for the dispensed product will contain the following information except when the information would violate the double blind nature of a study:
 - i. Subject Name
 - ii. Subject's Study Number
 - iii. Date prepared
 - iv. Protocol name and/or IRB number
 - v. Name of drug
 - vi. Dose
 - vii. Directions for use
 - viii. Amount of drug
 - ix. Physician name
 - x. Pharmacist initials
 - xi. Pharmacy name and address
 - xii. Expiration Date
 - xiii. Expiration Time (Intravenous Investigational Drugs)
 - xiv. Concentration of drug, if applicable
 - xv. Cytotoxic label, if applicable
 - xvi. Storage requirements, if applicable
 - xvii. The following statement "Caution: New Drug-Limited by Federal Law to Investigation Use."
2. The final product must be labeled and the labeling must be verified by a licensed pharmacist.
3. Product may be transported by pharmacy such as to an outpatient clinic under proper storage conditions for delivery.
4. Dispense the medication only directly to the patient, an authorized agent of the patient, or study personnel. IDS staff must obtain a signature from the person receiving the drug on a signature log confirming receipt of the drug (see Appendix C).

H. ATTACHMENTS :

1. [Appendix A: Site Personnel Training Log for Investigational Drugs](#)
2. [Appendix B: Investigational Physician Order Form](#)
3. [Appendix C: Signature Log for Investigational Drugs](#)

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.06.01.05

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. <u>Andrew Agwunobi, MD (Signed)</u>
Andrew Agwunobi, MD, MBA
UConn Health Chief Executive Officer | <u>12/14/2021</u>
Date |
| 2. <u>Anne D. Horbatuck (Signed)</u>
Anne D. Horbatuck, RN, BSN, MBA
Clinical Policy Committee Co-Chair | <u>11/16/2021</u>
Date |
| 3. <u>Scott Allen, MD (Signed)</u>
Scott Allen, MD
Clinical Policy Committee Co-Chair | <u>12/09/2021</u>
Date |
| 4. <u>Caryl Ryan (Signed)</u>
Caryl Ryan, MS, BSN, RN
Interim Chief Operating Officer, JDH
VP Quality and Patient Services & Chief Nursing Officer | <u>11/16/2021</u>
Date |

O. REVISION HISTORY :

Date Issued: 12/28/2012

Date Revised: 10/26/2015, 9/1/2017, 9/1/2020, 8/5/2021, 11/15/2021

Date Reviewed: