Pharmacy Investigational Drug Service Clinical Policy
Receipt, storage and records of Inpatient and Outpatient Investigational Drugs

A. EFFECTIVE DATE:
   11/15/2021

B. PURPOSE:
   To ensure that all investigational and study drugs will be handled consistently with regard to procurement, storage, inventory control, and record retention.

C. POLICY:
   1. All investigational drugs and records must be stored in accordance with institutional policies and procedures, as well as state and federal laws.

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

E. DEFINITIONS:
   1. **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.
   2. **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.
   3. **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.
   4. **Protocol** – a document that describes the objectives, design, methods, statistical considerations, and organization of a trial.
   5. **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. Investigational drug shipments will be delivered to central pharmacy or the outpatient infusion pharmacy for studies to be overseen by Investigational Drug Services (IDS). Investigational drug shipments will be opened by Investigational Drug Service staff. Inventory of the shipment will occur to ensure information that is provided on
the invoices matches what exactly has been sent and discrepancies will be promptly brought to the attention of
the sponsor. Invoices will be signed and dated to verify shipment receipt. Invoices will be filed in the study
binder
2. All investigational drugs shall be labeled as such and stored separately from other pharmaceuticals in the
pharmacy.
3. All investigational drugs must be stored separately by each protocol.
4. Wasted medication that is required to be held will be marked as such and stored separately.
5. An accountability log will be maintained for each dosage form and strength of each investigational drug which
will be maintained whether electronically in a program such as Vestigo or written in the study binder on an
accountability form provided and deemed necessary from a sponsor.
6. Entries on study documents shall be written in black or blue ink to maximize legibility and facilitate copying. Any
errors shall be crossed out and initialized with the date using a single line so as not to obscure the original entry.
White-out is prohibited to be used on any study documents.
7. A periodic inventory will be taken to ensure that diversion is not occurring and the necessary quarantining of
expired medication. A report can be generated from a computerized investigational program such as Vestigo
with current inventory counts. See Appendix A for a pharmacy inspection form to indicate inventory counts
have been verified.
8. Binder(s) will be assembled for each study which will contain:
   a. A summary sheet explaining the study purpose and dispensing procedures, when applicable.
   b. Randomization list, when applicable.
   c. Subject/patient profile, when applicable.
   d. Accountability log(s), when applicable. A drug accountability record will be used electronically
      through a computerized program such as Vestigo if another document is not required by the
      sponsor.
   e. All invoices for receipt of drugs or supplies.
   f. Documentation of study drug return or destruction, when applicable.
   g. Billing information, when applicable.
   h. Written and email communication, when applicable.
   i. Current study protocol, when applicable.
   j. Current Investigator’s Brochure, when applicable
   k. Institutional Review Board (IRB) correspondence, when applicable.
   l. Any other documents pertaining to the study.
9. When a computerized program such as Vestigo is available, most documents that would be stored in the binder
may be stored on the computerized system up to 16mb unless mandated by the sponsor.
10. There should be maintenance of adequate levels of study drugs to keep up with enrollment and study visits.
11. Study record documentation will be maintained in the IDS office for each study at our site for approximately 2
years upon return of all study drug to the sponsor or destruction of all study drug. After approximately 2 years,
records will be sent to an offsite storage company for indefinite long term storage unless otherwise indicated by
the sponsor.

H. ATTACHMENTS:
   Appendix A: Investigational Pharmacy Inspection

I. REFERENCES:
   ASHP Guidelines on the Use of Investigational Drug in Organized Health-Care Settings
   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. **Andrew Agwunobi, MD (Signed)  12/14/2021**
   Andrew Agwunobi, MD, MBA  Date
   **UConn Health Chief Executive Officer**

2. **Anne D. Horbatuck (Signed)  11/16/2021**
   Anne D. Horbatuck, RN, BSN, MBA  Date
   **Clinical Policy Committee Co-Chair**

3. **Scott Allen, MD (Signed)  12/09/2021**
   Scott Allen, MD  Date
   **Clinical Policy Committee Co-Chair**

4. **Caryl Ryan (Signed)  11/16/2021**
   Caryl Ryan, MS, BSN, RN  Date
   **Interim Chief Operating Officer, JDH**
   **VP Quality and Patient Services & Chief Nursing Officer**

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