CLINICAL POLICY

Receipt, Storage and Records of Inpatient and Outpatient Investigational Drugs

A. EFFECTIVE DATE :
December 23, 2020

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 :
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 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 7 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 off site storage company for indefinite long term storage unless otherwise indicated by the sponsor.

H. ATTACHMENTS :

Appendix 7: Investigational Pharmacy Inspection

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 (Sign) 01/12/2021
   Andrew Agwunobi, MD, MBA Date
   UConn Health Chief Executive Officer

2. Anne D. Horbatuck (Signed) 01/11/2021
   Anne D. Horbatuck, RN, BSN, MBA Date
   Clinical Policy Committee Co-Chair

3. Scott Allen, MD (Signed) 01/11/2021
   Scott Allen, MD Date
   Clinical Policy Committee Co-Chair

4. Caryl Ryan (Signed) 01/11/2021
   Caryl Ryan, MS, BSN, RN Date
   VP Quality and Patient Service & Chief Nursing Officer

O. REVISION HISTORY :

Date Issued: 12/28/2012
Date Reviewed: 12/23/2020
Date Revised: 10/26/2015, 9/1/2017