CLINICAL POLICY

Compounding of Investigational Drugs

A. EFFECTIVE DATE :

December 23, 2021

B. PURPOSE :

To assure that investigational drugs are compounded in accordance with United States Pharmacopoeia (USP).

C. POLICY :

1. All investigational drugs must be compounded and prepared following guidelines of the USP specifically USP 797, USP 795, and USP 800.
2. All compounding ingredients must meet quality, identity, and purity expectations.
3. Appropriate stability data is determined from USP standards to ensure products have expected potency and purity.

D. SCOPE :

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

E. DEFINITIONS :

1. **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
2. **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
3. **United States Pharmacopeia (USP)** – an official public standards setting authority recognized by the Federal Food, Drug, and Cosmetic Act that contains legally recognized standards of identity, strength, quality, purity, packaging, and labeling for drug substances

F. MATERIAL(S) NEEDED :

None

G. PROCEDURE :

1. An internal lot number will be assigned to each batch of product compounded unless the entire batch product will be used immediately. The number will be assigned using the following pattern: month, day, year, and initials of compounder.
2. On accountability records, the internal lot number and manufacturer lot number will be noted. The actual expiration date of the compounded product will be noted on the accountability record.
3. Each product compounded will be labeled with a label including the following: drug name, strength/concentration, quantity in bottle, internal lot number, and expiration date of compounded product.
4. Expiration dating or beyond use dating will be determined by USP guidelines and/or manufacturer specifications per investigational protocol.

H. ATTACHMENTS :
None

I. REFERENCES :
Pharmaceutical Compounding Non-Sterile Preparations (USP Chapter 795)
Pharmaceutical Compounding Sterile Preparations (USP Chapter 797)
Pharmaceutical Compounding Hazardous Preparations (USP Chapter 800)

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: 12/23/2021
Dated Revised: 10/26/2015, 9/1/2017, 9/1/2020