



## Pharmacy Investigational Drug Service Clinical Policy Destruction and Returns of Investigational Drugs

**A. EFFECTIVE DATE :**

October 19, 2021

**B. PURPOSE :**

To insure proper destruction of investigational and study drugs in accordance with local, state, and federal regulations.

**C. POLICY :**

1. If requested by the protocol sponsor, both used and unused study drug may be set aside for destruction and then removed for incineration. This should only be done if the medication cannot be sent back to the protocol sponsor.
2. If requested by the authorized physician with no sponsor for the study, both used and unused study drug may be set aside for destruction and then removed for incineration.
3. All destruction shall follow both DEA and DEEP regulations as they pertain to the ingredient of the investigational agent.

**D. SCOPE :**

This policy applies to all UConn Health 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 Services (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. **Investigational Pharmacist** – the pharmacist responsible for upholding the policies and procedures as well as the supervision of any support staff
4. **National Cancer Institute (NCI)** - coordinates the National Cancer Program, which conducts and supports research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer, rehabilitation from cancer, and the continuing care of cancer patients and the families of cancer patients
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
6. **Drug Enforcement Administration (DEA)** - federal organization in charge of enforcing the controlled substances laws of the United States
7. **Department of Energy and Environmental Protection (DEEP)** – agency charged with conserving, improving and protecting the natural resources and the environment of the State of Connecticut

**F. MATERIAL(S) NEEDED :**

None

**G. PROCEDURE :**

1. This will only be done after reconciliation of all remaining inventory and verification of all drug disposition records by the protocol monitor if an industry sponsored study
2. If provided by the sponsor, a drug destruction form can be signed by the protocol monitor and the IDS pharmacist (or IDS technician). An original or copy of this form will be maintained with the study material.
3. If not provided by the sponsor, information for destruction will be noted in a computerized program such as Vestigo.
4. For NCI sponsored studies, a return drug list form is filled out by the IDS pharmacist (or IDS technician) and a copy is returned with an inventory at close out of the study or expired investigational drug. Upon receipt of the drug at NCI, a received date and verification of the returned drug is stamped on a copy of the returned drug list and mailed or faxed back to IDS. This form is maintained with the study material.
5. Investigational drug will be placed in an appropriate waste container labeled for destruction.
6. A call will be made to research safety at 679-2723 once either container is full for removal.
7. Investigational drugs are transported by an authorized contractor to be incinerated at a facility licensed by the United States Environmental Protection Agency (EPA)

**H. ATTACHMENTS :**

None

**I. REFERENCES :**

Code of Federal Regulations, Good Clinical Practice, CFR 21:312.62c  
Pharmacy Policy A-039, Pharmaceutical Waste Management  
Resource Conservation and Recovery Act (RCRA) of 1976  
Title 21 Code of Federal Regulations; Part 1317 - Disposal

**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) 10/21/2021  
Andrew Agwunobi, MD, MBA Date  
**UConn Health Chief Executive Officer**
  
2. Anne D. Horbatuck, (Signed) 10/21/2021  
Anne D. Horbatuck, RN, BSN, MBA Date  
**Clinical Policy Committee Co-Chair**
  
3. Scott Allen, MD (Signed) 10/21/2021  
Scott Allen, MD Date  
**Clinical Policy Committee Co-Chair**
  
4. Caryl Ryan (Signed) 10/20/2021  
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, 1/20/2021, 8/5/2021

Date Reviewed: