UNIVERSITY OF CHICAGO MEDICAL CENTER

POLICY NAME: Destruction of Investigational Medications
POLICY NUMBER: PH 04-308
ISSUE DATE: 01/18/10
REVISED DATE: 7/2/15

PURPOSE:

To assure that all investigational drugs used at the University of Chicago Medical Center (UCMC) and received by the Investigational Drug Service (IDS) Pharmacy are handled consistently with regard to destruction.

DEFINITIONS:

1. **Investigational Drug** – A drug, not FDA approved, which is being tested in a clinical trial for safety and efficacy. Investigational drugs also include FDA approved drugs which are being tested for a different formulation, strength, route of administration or packaging than is approved. An FDA approved drug may also considered an investigational drug if it is being tested for an indication which is not approved or to gain further information about an approved use. An investigational drug may also be referred to as “study medication” or “study drug.”

2. **Marketed drug** – A drug product for which marketing authorization has been granted in at least one indication in particular country by a government health agency. Once initial marketing approval is obtained, subsequent research may be ongoing for additional indications or formulations or as part of required safety follow up. A drug that is obtained through a pharmacy via an order or prescription written or sent electronically by an authorized prescriber (Approved by FDA).

3. **Chemotherapy** – The treatment of malignancies and other diseases with chemical agents; use of cytotoxic chemicals to destroy rapidly dividing cancer cells throughout the body; normal, rapidly dividing cells, including cells in the bone marrow and gastrointestinal tract, also may be killed. For simplicity, all used or partially used chemotherapy vials are to be considered “Chemotherapy Hazardous” waste and disposed of by a vendor using an Environmental Protection Agency (EPA) certified incinerator. The container is labeled “Chemotherapy Waste”. It must NOT be labeled “Biomedical, or Sharps.”

4. **Biohazardous waste** – Waste that contains materials that are considered infectious or potentially infectious and may include blood, bodily fluids, pathological waste, contaminated tissues or organs, feces, and used needles. Items which are sharp and could inflict a wound (e.g., needles, broken ampoules) are classified as “Sharps” and must be disposed of in a rigid, sealed, leak-proof container. Other drugs, such as partially used vials are not considered as hazardous waste because of the small volume involved. However, it is UCMC policy to dispose of all drugs and drug containing containers in rigid, leak-proof containers commercially available for “biohazardous” waste.
UNIVERSITY OF CHICAGO MEDICAL CENTER

5. **Hazardous waste** – Byproducts of society that can pose a substantial or potential hazard to human health or the environment when improperly managed. Possesses at least one of four characteristics (ignitability, corrosivity, reactivity, or toxicity), or appears on special Environmental Protection Agency (EPA) list.

6. **Persons Responsible:**
   a. **Principal Investigator (PI)** – Primary researcher responsible and accountable for the distribution of the investigational drug involved in the approved clinical study. The PI may delegate responsibility for the investigational drug to another qualified researcher involved in the study, but may not delegate accountability.
   b. **Investigational Drug Service (IDS) Staff** – IDS Staff is responsible for ensuring receipt, handling, storage, labeling and distribution of investigational agents in accordance with current regulatory requirements maintained by the FDA, the Joint Commission, and International Conference Harmonization (ICH) Good Clinical Practice (GCP) Guidelines.

7. **Protocol** – a document that describes the objective(s), design, methodology, statistical considerations and organization of a trial.

8. **Sponsor** – company that provides the medication and writes the research protocol

**POLICY:**

1. Investigational drugs will be destroyed through the UCMC Investigational Drug Service (IDS) Pharmacy in full compliance with regulations and requirements of the study protocol, Sponsor, FDA, The Joint Commission, Illinois Board of Pharmacy, and other applicable organizations (e.g., Environmental Protection Agency, Illinois Environmental Protection Agency).

2. The UCMC IDS Pharmacy will not retain or store returned investigational medications. All medications are to be destroyed.

**PROCEDURES:**

1. The IDS pharmacy shall dispose of empty containers or partially used containers of study medication and associated equipment at the time of use or upon return by the patient or clinical research staff after internal reconciliation and documentation takes place (Refer to Sponsor Specific Destruction Form or Appendix A: Certificate and Record of Destruction of Investigational Drug). The waste MUST be disposed of in accordance with the Sponsor’s Protocol.
   a. Used or partially used containers of injectable investigational drugs will be discarded at the time of use. Destruction must follow S04-10 Hazardous Materials and Waste Management and S04-10-01 Pharmaceutical Waste Management Plan.
   b. Non-Injectable Investigational Drugs
      i. This includes containers returned by the patient or clinical research staff.
UNIVERSITY OF CHICAGO MEDICAL CENTER

ii. Verification by IDS staff shall be performed if specified by study protocol. If the study protocol does not require verification of return by the IDS staff, then the clinical research staff shall destroy the investigational drug after verifying and documenting the quantities returned.

iii. If the study protocol requires verification of drug return by IDS pharmacy, then IDS staff shall check that the containers have been reviewed and its contents documented by a member of the clinical research staff. The date of return by the patient and quantity remaining shall be printed on each container.

iv. IDS staff shall note the date of return, verify the quantity indicated on the container and document on a study-specific return. If any information is missing, the container or containers shall be returned to the clinical research staff member. The information entered on the study-specific return form shall include:
   1. Patient’s initials
   2. Patient’s study identifier number
   3. Dose dispensed
   4. Quantity dispensed
   5. Date dispensed
   6. Date returned
   7. Quantity returned
   8. Bottle/container ID number when known
   9. Number of bottles returned
   10. Any relevant comments

   c. Unused, intact drug materials remaining at the end of a study are returned to the sponsor, or if authorized by the sponsor, destroyed by the IDS in a similar manner as described below, after documenting in study records and a “Record of Destruction of Investigational Drug” form has been generated.

2. If the Sponsor does not indicate how/where to dispose of the remaining medication, refer to S04-10-01 Pharmaceutical Waste Management Program and below for proper disposal of medications returned to the IDS Pharmacy:
   a. All investigational drugs, except live biologicals, used at UCMC, for the purpose of this standard and for destruction, are considered chemotherapy biohazardous waste.
   b. Chemical-only (no biologicals) pharmaceuticals are disposed in the black hazardous medication container.
   c. Live biologicals are disposed in a double red liner, goose neck tied, with an outside cardboard box from Environmental Service (EVS) marked for incineration only.
   d. Waste items (e.g., gloves, gowns) with slight contamination with investigational chemotherapy drugs are placed in the yellow chemotherapy container.
   e. Any bulk liquid waste for investigational chemotherapy drugs shall be disposed of in the black hazardous medication container.

3. UCMC contracts with an outside vendor to remove toxic waste. Refer to S04-10

4. In the event that a study sponsor has been provided with a written notice of the Investigational Drug Service’s intention to return or destroy any unused study drug, and has not responded to such notification within sixty (60) days, IDS shall interpret this inaction as a tacit authorization for destruction. The IDS shall notify any such sponsor that their lack of response to written request has led to drug destruction.

**INTERPRETATION, IMPLEMENTATION, AND REVISION:**
The Investigational Drug Service, in consultation with the Pharmacy Policy and Procedure Committee, is responsible for the interpretation, implementation, and revision of this policy.

**CROSS-REFERENCES:**
1. S04-10 Hazardous Materials and Waste Management
2. S04-10-01 Pharmaceutical Waste Management Plan

Jennifer Tryon, PharmD, MS
Executive Director of Pharmacy
CERTIFICATE AND RECORD OF DESTRUCTION OF INVESTIGATIONAL DRUG

Date of Destruction:  Click here to enter a date.

Protocol Title:

UCH IRB Number:

Principal Investigator:

Method of Destruction:  INCINERATION

3rd Party Vendor:  Stericycle

Drug Name/Description:

Quantity:  Reason for destruction:

Lot Number(s):

Name of Research Pharmacist/PI if dispensing party: ________________________________

Signature of Research Pharmacist/PI if dispensing party: ____________________________

Name and Title of Witness: ________________________________________________________

Signature of Witness: ____________________________________________________________
<table>
<thead>
<tr>
<th>Line No.</th>
<th>Date</th>
<th>Patient's Initials</th>
<th>Patient's ID No.</th>
<th>Dose</th>
<th>Quantity</th>
<th>BAL Fwd / Balance</th>
<th>Mfr/Lot</th>
<th>Recorder</th>
<th>Notes</th>
</tr>
</thead>
</table>

Dispense Comments: Void Reason: entry error


Sponsor notified


<table>
<thead>
<tr>
<th>Line No.</th>
<th>Date</th>
<th>Patient's Initials</th>
<th>Patient's ID No.</th>
<th>Dose</th>
<th>Quantity</th>
<th>Balance Forward/Balance</th>
<th>Mfr/Lot</th>
<th>Recorder</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>10/7/2014</td>
<td>Receive</td>
<td></td>
<td>1</td>
<td>0 / 1</td>
<td></td>
<td>Mfr: GSK Lot: n/a Exp: 1/31/2015</td>
<td>10/7/2014 5:58:21 PM</td>
</tr>
<tr>
<td>2</td>
<td>10/7/2014</td>
<td>Receive</td>
<td></td>
<td>1</td>
<td>1 / 2</td>
<td></td>
<td>Mfr: GSK Lot: n/a Exp: 1/31/2015</td>
<td>10/7/2014 5:58:22 PM</td>
</tr>
</tbody>
</table>

Subject Return: 5 CAP on 10/08/2014 by skew
Destroyed by Patel on 11/13/2014 Destruction Comments: Destroyed.
Current Disposition: Destroyed

Audit

- Generated: 11/19/2014 8:46:00 AM by Ami Patel