I. Purpose

To assure that all investigational medications used at Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's) and received by the Investigational Drug Service (IDS) Pharmacy are handled consistently regarding destruction.

II. Definitions

1. **Investigational Drug –** a new drug or biological agent that is used in a clinical investigation (FDA 21 CFR 312.3). An investigational drug can be: (a) a new chemical compound being evaluated under an Investigational New Drug (IND) application which has not yet been approved by the Food and Drug Administration (FDA) for marketing, or (b) an FDA approved drug that is being studied for a different formulation, strength, route of administration or indication. An investigational drug may also be referred to as "study medication", "study drug" or "investigational product (IP)".

2. **Vestigo®** – A 21 CFR Part 11 compliant electronic accountability software application designed specifically for investigational pharmacy use and utilized by Lurie Children's IDS Pharmacy. Refer to https://www.mccreadiegroup.com/solutions/vestigo/ for additional information.

3. **Persons Responsible**
   i. **Investigator** - an individual who conducts a clinical investigation (i.e., under whose immediate direction the drug is administered or dispensed to a subject). The Principal Investigator (PI) is the responsible leader of the study team (FDA 21 CFR 312.3). The PI may delegate select responsibilities to other qualified personnel (i.e., the IDS Staff).
   ii. **Study Personnel** – one or more individuals who are appropriately trained and who are delegated study responsibilities by the PI.
   iii. **Investigational Drug Service (IDS) Staff** – is the Pharmacy Staff responsible for ensuring the proper receipt, handling, storage, labeling, dispensing, accountability, and destruction of investigational drugs.
   iv. **Sponsor** – a person who takes responsibility for and initiates a clinical investigation. The sponsor may be a person, pharmaceutical company, academic institution, governmental agency, private organization, or other organization. The sponsor does not actually conduct the investigation unless the sponsor is a sponsor-investigator (FDA 21 CFR 312.3).

III. Policy Statement

IDS Pharmacy will not store empty or used product containers, labels from packaging/containers, tear-off labels, or ancillary supplies for accountability purposes.

Sponsor-specific destruction forms will not be utilized to document IP destruction. Documentation of IP destruction will occur and be maintained solely in Vestigo®. A certificate of destruction from Vestigo® is available upon request.

All pharmaceutical waste is properly handled and disposed of by Stericycle®, an outside contracted waste vendor. Certificates of destruction are not available from Stericycle®.

IP will be appropriately destroyed by IDS Staff based on drug classification and in full compliance with all applicable institutional policies (Section V). Destruction of these drugs will also adhere to the relevant regulations and guidelines of the following agencies/organizations:

- FDA
- The Joint Commission
- Illinois Board of Pharmacy
- Environmental Protection Agency (EPA) and Illinois EPA
- National Institute for Occupational Safety and Health (NIOSH)
- International Conference Harmonization (ICH) Good Clinical Practice (GCP)

IV. Procedures

1. All used or partially used IP vials will be treated as hazardous materials with disposal occurring immediately after use into the proper waste containers. Two members of the IDS Staff will perform drug accountability, reconciliation, and documentation in Vestigo®, and then destroy the IP. Under no circumstances will any used or partially used vials of antineoplastic, gene therapy/gene transfer IP, or biohazardous materials (i.e., containers from biologics, used needles, etc.) be stored in the IDS Pharmacy due to health concerns and/or risk of staff exposure to residual hazardous materials.
    a. After admixing any IP, IDS Pharmacy will not collect or store samples of the diluted IP, and we will not retain any samples from packaged products.

2. For controlled substances I through IV only, drug returns may be held by IDS Pharmacy until the sponsor/sponsor's representative verifies drug accountability and provides instruction on drug disposition (i.e., return to depot or destruction onsite). If this is a necessary process, then the sponsor will be responsible for sending out a representative at least every 60 days to perform drug reconciliation. A *Special Monitoring Fee* will be charged to the sponsor for this service. If a sponsor representative does not come onsite in 60 days, then drug destruction will proceed as outlined below. Used or returned IP containers of controlled substances are not to be stored or destroyed outside of IDS Pharmacy by investigators or other study personnel.

3. All IP returned to IDS Pharmacy (e.g., containers that have been dispensed for patient

use) by study subjects or study personnel, shall be destroyed after accountability, reconciliation and documentation have been completed in Vestigo® by two members of IDS Staff. IDS Pharmacy will not re-dispense any used or unused IP. All returned containers of IP will be treated as hazardous materials with disposal occurring only after full documentation is complete within Vestigo®.

4. Destruction of all expired IP will be documented in Vestigo® and a certificate of destruction regarding the disposal may be generated upon request. Expired IP will be inventoried and disposed of upon expiration in the appropriate waste containers. If necessary, IDS Pharmacy will only store expired medications for up to 30 days past expiry dating before proceeding with onsite destruction.
    a. If, for any reason, expired IP needs to be shipped back to the depot, the sponsor/sponsor's representative is responsible for covering the cost of the shipment and providing all the necessary shipping materials within 30 days of the IP's expiration; otherwise, IDS will proceed with onsite destruction as stated above.
    b. If a retest date is available for any IP, the sponsor/sponsor's representative is responsible for forwarding this information to the IDS Pharmacy's inbox (idspharmacy@luriechildrens.org) in a timely manner. If IDS Pharmacy does not receive written communication from the sponsor/sponsor's representative by the current expiration date, we will proceed with onsite destruction of the expired IP.

5. The study sponsor may retrieve any unused, intact IP or materials that never left IDS Pharmacy control, on or before the study closeout visit. Any IP remaining in IDS Pharmacy after study closure will be destroyed and documented within Vestigo®. If necessary, a certificate of destruction can be generated from Vestigo® upon request.

V. **Related Lurie Children's Pharmacy Policies**
- SOP – Handling and Preparation of Study Biological Agents
- SOP – Pharmaceutical Waste Management
- SOP – Controlled Substances: Disposal and Auditing Procedures
- SOP – Chemotherapy Preparation and Handling of Cytotoxic Agents

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Approvals **[as applicable]**:

Key Stakeholders (e.g., ACRO for Clinical Trials, Pharmacy, etc.):
Director, Research Compliance: 4/30/2019, 4/26/2023
Director, Clinical and Community Trials (OCCT): 5/18/2023
Manager, IDS Pharmacy: 5/18/2023
Chief Operating Officer, Manne Research Institute: N/A