I. Purpose

To assure that all investigational and study 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) new chemical compound being evaluated under an Investigational New Drug Application (IND) 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."

2. **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, institution, governmental agency, private organization or other organization. The sponsor does actually conduct the investigation unless the sponsor is a sponsor-investigator (FDA 21 CFR 312.3).

III. Policy Statement

All investigational drugs returned to the IDS Pharmacy by study subjects or study personnel, and/or materials used to prepare investigational drugs, shall be destroyed after accountability, reconciliation, and documentation has been completed by IDS staff.

Investigational drugs will be destroyed by IDS Staff as is appropriate based on drug

classification and in full compliance with all applicable institutional policies (Section V) and relevant regulations and guidelines, which include those of:

- 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. At the time of the ***use of investigational drugs (i.e., injectables) or returns (empty or partially used)*** from study subjects or study personnel, two members of the IDS staff will perform drug accountability, reconciliation, documentation in the study-specific drug accountability record (DAR) and then destroy investigational drugs/materials. Under no circumstances will any biohazardous materials (i.e., containers from biologics, used needles, etc.) be stored in the IDS.

   Note: Under special circumstances and when justified (e.g., for controlled substances), drug returns may be held by the IDS Pharmacy until the sponsor/sponsor representative verifies drug accountability and provides instruction on the drug disposition (return to depot or destruction). If this is necessary, the sponsor will be responsible for sending a representative out at least every 60 days to perform the drug reconciliation. Used or returned investigational drugs or containers are not to be stored or destroyed outside of the IDS by investigators or other study staff.

2. Unless otherwise requested by the sponsor, ***expired investigational drugs*** will be inventoried and disposed of upon expiration in the appropriate waste containers. Under no circumstances will the IDS pharmacy store expired medications for more than 90 days.

3. The study sponsor may retrieve ***any unused, intact investigational*** drug or materials on or before the study close-out visit. Any investigational drug or materials remaining in the IDS Pharmacy after study close-out will be destroyed, with documentation in the study-specific DAR. Upon request, if necessary, a "Certificate of Destruction" will be requested from the outside destruction facility.

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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