Investigational Drug Services (IDS) Pharmacy

Standard Operating Procedures and Policies

Department: Fairview Investigational Drug Services Pharmacy

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Useful Links: IDS Pharmacy Video Walkthrough | IDS Pharmacy Infrastructure Details

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Introduction

Safeguarding Excellence in Investigational Medicine
The Investigational Drug Services (IDS) Pharmacy bridges innovative research and clinical application. Our mission is to:

- Support seamless clinical research,
- Foster medical advancement,
- Ensure participant safety and well-being.

This effort involves collaboration with the University of Minnesota, University of Minnesota Physicians, and Fairview Health Services. IDS Pharmacy ensures the safe and efficient handling of investigational medications in research settings.

Objective and Function
This document details the policies and procedures governing the IDS Pharmacy, aimed at conducting investigational drug studies with high standards of safety, effectiveness, and efficiency. Our objectives are:

- Compliance with legal, ethical, and financial standards, including FDA, state and federal laws, institutional policies, and GCP guidelines.
- Safe management of investigational drugs through strict inventory control, accurate accountability, and secure storage.
- Support for researchers in administrative, scientific, and clinical aspects, especially in handling investigational products.
- Enhanced reliability and timeliness of data submitted to sponsors, ensuring research integrity.
- Expanded understanding of investigational products, their chemistry, therapeutic potential, and pharmacology.
- Prioritized safety and welfare of clinical trial participants, with a focus on informed and protected involvement.

Where specific sections are identified as "being revised", daily operations are governed by existing institutional pharmacy policies and procedures that meet applicable regulatory requirements; detailed process descriptions are available from IDS upon request.

Revision List

See 'Amendment History' for additional change details.

Version #	Version Date	Summary of Changes
3.0	18-Dec-2025	Updated **Section 14: IMP Hazardous Handling**, to include biohazardous.
2.5	1-Dec-2025	New temp monitoring, cycle count dating, controlled substance handling.
2.0	03-Mar-2025	Update to reflect changes resulting from pharmacy relocation.
1.0	15-May-2024	Initial public release version.

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List of Abbreviations and Definitions of Terms

ACTG	**The AIDS Clinical Trial Group.** A global clinical trials network that conducts research to improve the management of HIV and its comorbidities; develop a cure for HIV; and innovate treatments for tuberculosis, hepatitis B, and emerging infectious diseases.
Affiliated Location, Site, Facility	Affiliated locations are investigational drug dispensing areas external to IDS Pharmacy. Dispensing is setup, facilitated, and overseen by IDS.
Beacon	An Epic software module specifically designed for oncology. It streamlines the management of complex cancer treatments, including chemotherapy regimens, radiation therapy, and supportive care. It facilitates protocol-driven care, automates chemotherapy ordering and dosing calculations, integrates with pharmacy systems for medication management, and enables efficient tracking of patient outcomes.
Blinded, Masked	Blinding, or “masking”, is the process by which information that has the potential to influence study results is withheld from one or more parties involved in a research study.
Clinical Investigation (Trial)	Clinical trials are voluntary research studies, conducted in people that are designed to answer specific questions about the safety and/or effectiveness of drugs, vaccines, other therapies, or new ways of using existing treatments.
Clinical Research Pharmacist (CRP), IDS Pharmacist	a licensed pharmacist designated by department leadership, by virtue of his or her education, training, and experience to be responsible for providing clinical pharmacy services to investigators in support of investigational drug studies.
Clinical Research Specialist (CRS), IDS Technician:	a registered pharmacy technician designated by department leadership, by virtue of his or her education, training, and experience to be responsible for providing pharmacy services to investigators in support of investigational drug studies.
CFR	**Code of Federal Regulation.** The official compilation of all rules and regulations (called "administrative law") issued by federal agencies in the United States.

CRA	**Clinical Research Associate.** Is a health care or life sciences professional who oversees clinical trials on behalf of pharmaceutical companies, medical research institutes and government agencies.
CRC	**Clinical Research Coordinator.** Manages and conducts the day-to-day activities of a clinical trial as outlined by the Principal Investigator. In general, the CRC ensures the clinical study maintains accordance with the protocol, applicable regulations, and Good Clinical Practice and Institutional Review Board requirements.
CRO	**Clinical Research Organization.** A company hired by another company (typically a drug manufacturer) or research center to take over certain parts of running a clinical trial. The company may design, manage, and monitor the trial, and analyze the results.
CSTD	**Closed System Transfer Device.** A specialized drug transfer device that mechanically prohibits the transfer of environmental contaminants into the drug preparation system and the escape of hazardous drug or vapor concentrations outside the system. CSTDs are often used in the preparation and administration of hazardous drugs, such as those used in chemotherapy.
DARF	**Drug Accountability Record Form.** An electronic or paper documentation of investigational agents from receipt to dispensing or administration to participants.
Delivery	Differentiated from **Transport**, this is in alignment with industry standards that do not consider investigational medication product (IMP) movement expected to regularly last ≤ 15 minutes as a transport. These deliveries are considered part of the 'Medical Center Complex' and IDS does not routinely temperature track nor provide specialized documentation for delivered medications.
DOA	**Delegation of Authority.** A formal process where a person with authority (e.g., a principal investigator) assigns specific tasks or responsibilities to another qualified individual. In clinical research, a DOA log documents which study-related tasks are delegated to specific study team members.
Epic	An electronic health records (EHR) system for hospitals and large practices. The Epic charting system includes features such as medical templates, patient history, and referrals for healthcare providers.
FDA	**Food and Drug Administration.** The United States federal agency responsible for protecting public health by regulating drugs, biologics, medical devices, the nation's food supply, cosmetics, and products that emit radiation.
GCP	**Good Clinical Practice.** An international quality standard for the design, conduct, recording, and reporting of clinical trials. GCP guidelines aim to protect the rights and well-being of trial participants and ensure the credibility of data generated from clinical trials.
IB	**Investigator's Brochure.** A compilation of all clinical and non-clinical data on the investigational product (drug, device, etc.) relevant for the study of the product in human subjects.
IDS	**Investigational Drug Services.** The department that oversees the Investigational Drug Services pharmacy. IDS manages investigational drug policy, sets research dispensing standards, and facilitates the safe dispensing of product throughout the system.
IMP, IP	**Investigational Medicine Product, Investigational Product.** A general term used to describe <u>any medicinal product used</u> under a clinical trial. IMPs include newly developed drugs but also licensed (FDA approved) drugs that are being tested against a new condition, or in a new formulation or packaging, or are being used to gather more information about the authorized form.
Investigational Drug, IND	**Investigational New Drug**. A drug or biological product that has not been approved by the FDA for marketing but is being studied in clinical trials to determine its safety and effectiveness. To conduct a study with an IND, a sponsor must submit an IND application to the FDA.

Investigational Drug	A pharmaceutical drug that is being studied to determine if it is safe and effective for human use.
ICF	**Informed Consent Form**. A crucial document that provides potential participants with comprehensive information about a clinical trial. It details the study's purpose, procedures, potential risks and benefits, participant rights, confidentiality measures, and contact information for questions or concerns.
Institution	University of Minnesota, UMP Physicians, Fairview Health Services; collectively referred to as M Health Fairview.
IRB, UMN IRB	Institutional Review Board, typically the University of Minnesota review board, but may also include external review boards of record.
ISBER	International Society of Biological and Environmental Repositories. Provides standardized guidelines for the management of biobank specimen collections and repositories. Publications are periodically reviewed and revised to reflect advances in research and technology.
IWRS, IVRS, IxRS, IRT, RTSM	Electronic technologies to manage patient enrollment, patient randomization, and study drug supplies. Collectively, these technologies can be referred to as Interactive Response Technologies (IRTs) or Randomization and Trial Supply Management (RTSM).
KOM	**Kick Off Meeting.** The initial meeting that brings together all key stakeholders involved in a clinical trial. The primary purpose is to align everyone on the study protocol, procedures, timelines, and responsibilities, ensuring a shared understanding of the project goals and a coordinated approach to their execution. It serves as a platform for open communication, clarifying doubts, and fostering collaboration among team members from the outset.
PI, Sponsor-Investigator	**Principal Investigator.** The individual responsible for the conduct of a clinical trial at a trial site. If a site has no designated principal investigator, the sponsor-investigator bears the responsibilities of a principal investigator. The PI oversees all aspects of the study at their site, ensuring it follows the protocol, protects participant safety, and that data is collected accurately.
PSN, Sequence No., Subject Number	**Participant-Subject Number.** This is a study specific identifier for the participant. These may follow a Sponsor outlined format or be assigned automatically via OnCore.
LP	**Lead Pharmacist.** A Minnesota Board of Pharmacy designated clinical research pharmacist that is assigned to managing and setting up the drug related components for a study within IDS.
Medical Center Complex	Denotes the East and West Bank UMMC hospitals and clinics and CSC (the Clinics and Surgery Center).
MN BOP, Board of Pharmacy, BOP	**Minnesota Board of Pharmacy.** The pharmacy licensing board for the state of Minnesota. The MN Board of Pharmacy has broad legal oversight of medication dispensing throughout the state of Minnesota.
Monitor	A representative of the sponsor responsible for overseeing the progress of a clinical trial and ensuring it's conducted, recorded, and reported in accordance with the protocol, GCP, and applicable regulatory requirements.
NCI	**National Cancer Institute.** The federal government's principal agency for cancer research and training.
OnBase	OnBase is an electronic storage and retrieval system to maintain electronic records in a HIPAA and 21 CFR Part 11 compliant fashion. Due to the underlying connection with the Epic EMR, it is on the highest priority level for redundancy and service possible. IDS is not able to provide external access to OnBase.
SIV	**Site Initiation Visit.** The formal meeting that occurs between the sponsor/CRO and the investigative site before the study can start, marking the official beginning of the trial at the site. This discussion gives the study time to review Epic builds, treatment plans, and final logistics prior to opening to accrual.

SOP	**Standard Operating Procedures.** A set of written instructions that describes the step-by-step process that must be taken to properly perform a routine activity.
Sponsor	The entity (individual, company, institution, or organization) that takes responsibility for initiating, managing, and/or financing a clinical trial.
SQV, PSV, SSV	**Site Qualification Visit**, AKA **Pre-site Visit** or **Site Selection Visit**; An assessment conducted by a sponsor/CRO before a site is selected for a clinical trial, to ensure the site has suitable facilities, staff, and resources to conduct the trial according to protocol.
Transport	Differentiated from **Delivery** and in alignment with industry standards, IDS considers the movement of investigational medication products (IMPs) for a standard duration lasting > 15 minutes to be considered "transportation" of the IMP. Transport of IMP often requires temperature monitoring and additional paperwork which are considered non-standard requests.
TERF	**Temperature Excursion Reporting Form.** A form used to report temperature excursions. Usually supplied by Sponsor. IDS generates these from within Vestigo.
UMN, UMMC	**University of Minnesota.** University of Minnesota Medical Center.
USP	**United States Pharmacopeia.** A scientific non-profit organization that sets quality standards (purity, strength, identity) for medicines, food ingredients, and dietary supplements manufactured, distributed, and consumed worldwide. USP's standards are enforceable in the United States by the FDA.
Vestigo	Research specific dispensing software that allows access to authorized Sponsor contacts (monitors) when needed. Vestigo may contain treatment assignments or randomization logs (if applicable), dispensing records, IMP accountability logs, IMP shipping and ordering records, correspondence and specific dispensing procedures, and instructions pertinent to pharmacy conduct.
Vestigo Verify	An online web portal (https://monitor.vestigo.biz/) allowing authorized Monitors, to conduct remote monitor visits. This system provides access to drug accountability, dispensing details, inventory information, licensure details, temperature records, and other protocol specific information. Vestigo Verify allows monitors to generate messages to IDS staff regarding follow-up actions within the system and see responses. This is the preferred method for monitor visits.
Willow	A pharmacy management module within the Epic EHR system. It handles medication dispensing, inventory management, and both inpatient and outpatient prescription processing.

Sponsor and Designated Personnel Engagement Expectations

Objective: To ensure a synergistic collaboration between IDS and study Sponsors, this section establishes clear expectations to facilitate efficient operations and uphold best practice standards.

1. **Knowledge and Responsiveness**:
    - Sponsors should assign knowledgeable monitors who understand the protocol, especially pharmacy requirements, to address inquiries promptly.
    - Communications should include study identifiers: **OnCore#** *(if known)* **| Protocol# | IDS#** *(if known)* **| PI_Last_Name | Site#** (ex: PEDS-2024-29254 | ST-920-201; STAAR | IDS 7000 | Whitley | 103).

2. **Protocol Changes or Updates**
    - Communicate any protocol changes affecting pharmacy operations or IMP management to IDS immediately, including dosage, administration, storage, and supply updates.

3. **Documentation Review**:
    - Submit all protocol amendments and study update documents to IDS for review before implementation to ensure compliance and safety. Note that updates may require Epic order and treatment plan updates, taking at least two weeks.

4. **Contact Information and Personnel Changes**:
    - Provide IDS with alternate contact and the study Monitor's supervisor details before study initiation. Promptly notify IDS of any contact changes.

5. **Monitoring Visit Coordination**:
    - Remote monitoring visits use **Vestigo Verify**, scheduled with IDS 24 hours in advance.
    - On-site monitoring visits must be scheduled two weeks in advance, with visits allocated to one-hour slots. Monitors must adhere to their scheduled times.

6. **Provision of Policies, Procedures, and Documentation**:
    - Upon site activation, IDS provides study CRA with **Vestigo Verify** access. Monitors should retrieve documents from Vestigo Verify during their scheduled visits.

Standard Operating Procedures

01 IDS Staff Qualifications and Responsibilities

1. **Role Definitions and Qualification Criteria**
    a. **CRP:** MN Board of Pharmacy licensed pharmacist trained to manage and dispense investigational drug products.
    b. **CRS:** MN Board of Pharmacy registered pharmacy technician trained to compound and process investigational drug products.
    c. **Lead Pharmacist:** A CRP assigned to oversee the setup and operation of an investigational drug study. Responsibilities include;
        i. Being the primary contact for pharmacy-related study concerns.
        ii. Ensuring adherence to protocol procedures, best practices, and regulatory requirements with the study team and Sponsor.
        iii. Creating and updating internal dispensing documentation and dispensing builds in Epic/Vestigo.

iv. Leading pharmacy training sessions to ensure adherence to protocol guidelines and verifying staff training in Vestigo.
v. Promoting participant safety, study efficiency, and data integrity.

2. **Staff Training Modules on GCP, Human Subject Protection, and Software Use**
    a. IDS personnel must complete and maintain all training and educational requirements necessary to perform their daily functions at an appropriate level.
        i. **MN BOP license or registration: Continuing education requirements must be completed promptly to maintain employment.** License and registration must be active and in good standing.
        ii. **CITI GCP and Human Research Protections for Biomedical Study Teams training:** Must be completed and kept current based on the cycle outlined for certification.
        iii. **HIPAA annual training:** Must be completed annually as scheduled by system level training modules.
    b. These documents will be provided in Vestigo Verify and are accessible to Monitors when using that system. IDS will not provide these documents directly.

3. **Competency Assessments and Continuous Education Plans**
    a. IDS staff must maintain minimal competence in investigational pharmacy. This includes reviewing and keeping current with relevant IDS literature (ASHP, HOPA, NCCN, etc.) timely.

02 Study Initiation and Protocol Assessment

Study Initiation: Prior to study initiation, IDS will conduct a general pharmaceutical review of the protocol, ICF, IB, and pharmacy manual, participate in an SQV, perform feasibility and compliance assessments, develop an IDS fee schedule, attend the SIV, develop protocol specific treatment order templates, create study specific drug order entries, facilitate investigational drug procurement, and provide protocol training to pharmacy staff. This process is further described below and is sequential.

1. **Pre-SIV or Site Qualification Visits (SQV):** Optional and may be conducted with a Study Coordinator. These 15-minute timeslots are scheduled with IDS at least 1 week in advance and allow for a virtual call to review infrastructure and feasibility.

2. **Protocol Feasibility Analysis:** Performed by the lead pharmacist to evaluate institutional capacity to conduct an investigational drug study efficiently and in compliance with applicable standards. This assessment encompasses personnel qualifications, facility resources, operational readiness, compatibility of institutional standards with protocol requirements, procedures for the receipt, transport, storage, preparation, and administration of investigational products (IPs), and the availability of essential equipment and technology. The goal is to ensure our site meets all necessary criteria for a successful and compliant investigational drug management processes.

3. **Compliance Review:** Conducted in tandem with the protocol feasibility analysis to help ensure that the pharmacy phase of the investigational study can adhere to FDA regulations, Good Clinical Practice (GCP) guidelines, state pharmacy laws, institutional standards, and specific protocol requirements.

4. **Kick-off Meeting (KOM):** Covers any information required by IDS to begin internal setup for a study.
    a. A KOM must occur before IDS can begin internal setup of a study. See below: **5. Study Setup within IDS**.
    b. The KOM is where IDS staff gather information required to create medication datasheets and to submit Epic Willow (electronic RX) and Epic Beacon (research plan) tickets.

c. The Study Coordinator (or study team representative) and at least one IDS CRP are required to attend the KOM.
d. For industry-sponsored trials, a clinical Sponsor representative must participate.
e. At least two weeks prior to the KOM the following documents must be provided to IDS: proposed protocol, IB, ICF, pharmacy manual (or equivalent), FDA Form 1572, and SDS (Safety Data Sheet) (if available).
f. Expectations regarding required documentation and study procedures must be discussed at KOM. Changes from what was relayed at KOM must be provided at SIV or earlier.

5. **Site Initiation Visit (SIV):** A time for site staff and IDS to review final study components and logistics prior to opening to enrollment. The following apply to the SIV:
    a. An SIV must occur before IDS can begin internal setup of a study. See below: **5. Study Setup within IDS**.
    b. The Study Coordinator (or study team representative) and at least one IDS CRP is required to attend the SIV.
    c. For industry-sponsored trials, Sponsor representatives must participate in person or via teleconference.
    d. At least three weeks prior to the SIV all final IRB (Institutional Review Board) approved and other supplementary documentation must be provided to IDS.
        i. Study Teams must send IDS updates to these documents as they receive them, regardless of whether there are pharmacy specific changes.
            1. Changes to Epic Willow/Beacon builds require additional time. Alerting IDS before changes will help ensure these occur as quickly as possible.
            2. Please note IRB status (i.e. pending approval, approved, etc.) of these documents.
    e. Prior to enrollment, IDS must have a finalized DOA log.
    f. IDS considers the SIV to be protocol specific training. Sponsor training forms, or the study team's specific log (e.g. Florence protocol and/or SIV attendance log), may be signed by the Lead Pharmacist and/or others attending CRP/CRS to document this training.
        i. Other IDS staff or pharmacy personnel will not sign Sponsor training forms. Protocol training for other IDS staff will occur as outlined in **Training and Competency Verification**.
            1. Additional Sponsor-mandated training sessions and/or t, such as when all personnel must complete training to access necessary workflow systems (ex. IRT portals), **will incur additional costs**.

6. **Study Setup within IDS:**
    a. **Pharmacy Training:** Lead Pharmacist will conduct initial and ongoing training for other pharmacy personnel and document completion of this training as described in **Training and Competency Verification**.
    b. **Delegation of Authority (DOA) Logs:** Lead Pharmacist will sign the DOA for pharmacy delegated tasks upon request. Per MN state law, CRS (technicians) work under the license of a CRP (pharmacist) and cannot sign the DOA log.
        i. IDS is not responsible for maintaining or supplying DOA logs.
        ii. Investigational drug orders are only valid if signed by an individual delegated to do so as outlined on the study's DOA log. See: **Delegation of Authority and Staff Responsibilities**.
    c. **Creation of drug datasheet (DDS):** Lead Pharmacist will compile and keep updated, a singular internal pharmacy reference guide from IRB approved and supporting study documentation.

This resource will be used by IDS staff for dispensing and other teams to perform actions specific to the study, such as building Epic drug builds. See: **Investigational Drug Datasheet (DDS) Creation and Maintenance**.

d. **Epic and Vestigo System Setup**
    i. **Epic:** All investigational drug orders will be built into Epic and identified as an investigational drug utilizing a standard format that contains the drug name and associated unique study number such as; "Study – NAME (IDS #1234)".
        1. **Willow (Electronic RX/Drug) Builds:** This process is initiated by the Lead Pharmacist after the KOM. Note: The Willow team requests a minimum of 2 weeks to complete a build request.
        2. **Beacon (Research Plan) Builds:** Initiated by the Study Coordinator, this occurs after the KOM. The Beacon team typically requests the datasheet built by the IDS pharmacist, so this should be completed first. Note: Beacon team requests a minimum of 2 weeks to complete this process.
    ii. **Vestigo:** Protocol specific Drug and Order builds will be entered into Vestigo and associated with the appropriate Epic build such that when a provider enters an Epic order it will be associated with the Vestigo protocol containing that order.
        1. IDS will utilize internal electronic IMP accountability logs and study forms to meet individual protocol accountability and documentation requirements.
        2. Sponsor-provided forms will only be used if IDS determines that internal forms cannot be modified to accommodate all necessary information. See: **IMP: Accountability and Documentation**.
    iii. **Validation:** Lead Pharmacist will coordinate the setup and validation of Epic Willow builds for investigational drug products. A secondary CRP will QA the Lead Pharmacist, validating the DDS and associated Vestigo drug and order entries.

e. **Documentation:** IDS will initiate filing and storage of study protocol documents in accordance with FDA regulations and GCP guidelines. Protocol specific documents will be maintained as described in Study Maintenance. See: **Handling of Essential Study Documents**.

f. **Other Processes:** IDS is also capable of providing randomization tables, development of paper prescription templates, compounding logs, acting as an unblinded member of the trial, etc. These needs should be identified at the KOM, where they can be confirmed, and processes solidified.

Variations from IDS SOPs requires agreement by the Sponsor, Study Team, and IDS prior to study initiation.

03 Handling of Essential Study Documents

1. **Management and Digital Storage Protocols**
    a. IDS will maintain all pharmacy documentation, such as shipping manifests, temperature excursion reports, accountability logs, training records, and correspondence, in accordance with 21 CFR 312.62, state, and local guidelines. Vestigo can generate a variety of different DARF (Drug Accountability Record Form) types including NCI, IDS, and ACTG..
    b. **Vestigo – IMP-level operational records:** Vestigo is the primary system of record for investigational product (IMP) operations, including receipt, storage, dispensing, destruction/return, temperature excursion TERFs, pharmacist training acknowledgements, and other pharmacy-generated study documents. These records are available to authorized Sponsor-designated personnel via Vestigo Verify during scheduled monitor visits.
    c. **OnBase – certified copies and long-term archiving:** Essential pharmacy records that originate on paper (e.g., signed protocols, IBs, training sign-in sheets) are scanned into OnBase, Fairview Health Services' HIPAA- and 21 CFR Part 11-compliant electronic document management

system. A designated IDS staff member verifies that the scanned image is a complete and legible representation of the original and electronically attests that it is a certified copy. Paper originals are then destroyed or returned to the Sponsor, consistent with IDS policy.

d. Documents that originate electronically (e.g., PDF protocols, IBs, pharmacy manuals, emails) are stored in OnBase in their original electronic format. These electronic-origin documents do not require re-certification.
e. IDS cannot grant external access to OnBase. When monitors require copies of documents that are stored only in OnBase, IDS will export those documents as PDF files and either: (1) place them within Vestigo under the relevant protocol, or (2) provide them via secure email or other institutionally approved mechanism.

2. **Procedure for obtaining authorized signatures on clinical study documents.**
   a. The Lead Pharmacist is the IDS individual responsible for signing documents related to the startup and function of their assigned study.
   b. Pharmacy staff will only sign documents electronically through Florence eBinders or via DocuSign. Paper documents can be scanned and emailed for electronic signature.

04 Investigational Drug Datasheet (DDS) Creation and Maintenance

The Investigational Drug Datasheet (DDS): is a consolidated reference document intended to aid pharmacy staff in the safe and accurate handling, preparation, and dispensing of investigational drug products. It is designed to serve as an internal reference and is not intended to replace or supersede the Protocol or other IRB approved documents. All clinical decisions and actions must align with the approved Protocol, applicable laws, regulations, and professional standards. The DDS does not override the professional judgment of the principal investigator, pharmacist, or other clinicians, who should refer to the Protocol and other IRB approved documents for comprehensive and authoritative information regarding the conduct of the study.

1. **Compilation:**
   a. The Lead Pharmacist compiles the initial DDS using the most recent, IRB approved versions of the Protocol, IB, ICFs, and incorporates information from supplementary material such as pharmacy manuals, dosing guides, slide decks, patient handouts, manuals of procedures, and other Sponsor/Investigator supplied documents, to be outlined in the DDS.
   b. The DDS may also reference information from startup discussions such as KOM, SIV, training sessions, Sponsor and study team meetings, Sponsor memos, and any logistics details.

2. **Compliance and Adherence:**
   a. Material outlined within the DDS must adhere to all relevant institutional, local, and federal laws, regulations, and policies to ensure the safety of the participants and integrity of the study.

3. **Review and Approval:**
   a. A pre-enrollment quality assurance review by a secondary pharmacist is conducted and annotated within the revision history of the DDS.
   b. The process for review and approval is outlined in the ‘Quality Assurance’ procedure.

4. **Maintenance and Amendment:**
   a. The Lead Pharmacist incorporates protocol amendments and other study updates into the DDS.
   b. Revisions are annotated in the ‘Revision History’ section accordingly.
   c. Discrepancies or missing updates must be reported to the Lead Pharmacist.

5. **Storage:**
   a. The DDS is stored electronically in OnBase, Vestigo, and a downtime binder.

6. **Accessibility and Distribution:**

a. While accessible in Vestigo to those with appropriate permissions, DDS are intended as an internal reference guide for pharmacy staff and may not be distributed unless authorized by IDS.

05 Clinical Trial Software Systems (IRT, RTSM)

IRT/RTSM: For this document's purposes, the terms IRT and RTSM will be used interchangeably. Below are guidelines for provisioning RTSM access to IDS staff;

1. Only the Lead Pharmacist will sign the DOA log and Sponsor training forms, however, all applicable IDS staff (CRP and CRS) must be provided access to RTSM.
2. All IDS staff (CRP and CRS) must be provided with appropriate RTSM accounts; either unmasked general (site user) or pharmacy specific system access.
    a. CRS work under the license of CRP and require RTSM access as they perform critical functions (ex: acknowledging drug receipt).
    b. IDS will provide a list of all staff requiring access and their contact details in a document titled **IDS RTSM List**.
    c. If Sponsor mandates all IDS staff to be added to the DOA to receive IRT access, this **will incur additional charges**.
3. If RTSM training is required, IDS staff will only complete the least number of modules necessary to conduct relevant pharmacy system functions.
    a. Required training outside of the scope of pharmacy and/or registration at secondary training portals **will incur additional charges**.
4. IDS will record IMP shipment and disposition via acknowledgement either within an RTSM system OR via secured email/fax. These processes must be clearly outlined at the SIV.
5. IDS will not utilize RTSM/EDC to document drug accountability. These details are already captured, stored, and accessible within Vestigo.
6. For participants assigned IMP, RTSM study drug assignments must be sent to all IDS individual emails (i.e., those registered to the RTSM) OR preferably via the department email at IDSPharmacy@Fairview.org.
7. IDS will not perform any additional tasks in RTSM other than shipment receipt.
    a. On a case-by-case basis, IDS may perform product assignments for masked studies, if the study team does not have an unmasked coordinator. This must be clarified at KOM.

06 Costs of Service

1. IDS will recoup the costs of provided services by submitting protocol specific billing statements to Fairview Research Administration (FRA). FRA will review and submit these to the study team for payment.
    a. IDS **does not** handle charges or payments directly.
    b. IDS **does not** have the capability to bill drugs or services to a participant's commercial insurance.
2. Additional requested services must be agreed to by IDS and will be billed to the study. These may include, but are not limited to; after hours support, direct-to-participant shipping, multi-site maintenance, non-standard preparation, compounding, storage, or other requests that fall outside of usual operational practice.
3. At the request of the study team, IDS will purchase study specific commercial medications and supplies that are specified in the protocol. The costs of IDS purchased items will be billed to the study and will include the mandatory MNSure tax.

07 Protocol Training and Competency Verification

1. **Study Training and Competency Verification** - The below process is applicable to new studies and subsequent updates:

a. IDS Training Basics:
    i. IDS will participate in Sponsor training on **general study information**, typically at KOM.
    ii. IDS will **not** participate in additional Sponsor provided or other training sessions unless formally agreed upon.
        1. Additional mandatory training sessions (including for future amendments or other updates) may incur additional costs.
    iii. Training documentation is to document when IDS staff have conducted internal training. It is not to denote the actual time of receiving updated materials.
b. Lead Pharmacists will create relevant training presentations for internal staff. The training will be based on IRB approved and other associated Sponsor documents.
c. IDS prepared training presentations will be stored and visible within Vestigo. Source documents will be referenced, but not stored in Vestigo.
    i. Vestigo competencies will be labeled in a fashion similar to the following: "**Initial training:** Protocol v__ dated ____; Drug name IB v___ dated_____; Pharmacy manual v___, dated____, etc"
d. When a Vestigo competency is built, it triggers a Vestigo 'Hard Stop' within that associated protocol. IDS staff will be blocked from accessing or performing protocol specific actions until they have electronically acknowledged their training on the referenced material.
    i. Date, time, and electronic IDS staff signature are stored within Vestigo. Acknowledgement is documentation of training completion and denotes that the IDS staff member has been trained sufficiently to perform protocol specific functions.
        1. Time and date stamped 'Protocol Competency' acknowledgements are logged in Vestigo and by design, cannot be modified or deleted by IDS.
e. Training materials will be attached to the acknowledgement for a refresher or if the staff member missed the weekly training session.
    i. **Protocol Competency: IDS staff may not perform protocol specific functions without first acknowledging that they have read and understood the training material and have sought questions or brought up concerns when needed.**
f. Review of training must be done within Vestigo Verify where monitors can verify compliance and print out training certificates.
    i. IDS will not provide documentation of training outside of Vestigo Verify. Study teams do not track internal IDS training and will not have that in their study binders or Florence.

08 IMP: Elements Required for Dispensing

1. Medication orders are not valid unless signed and dated by a duly licensed prescriber with active prescribing rights delegated by the PI via the DOA log.
2. IDS requires that all medications orders be placed through Epic by a DOA authorized prescriber. Paper/electronic orders are accepted if the prescriber does not have access to Epic.
    a. IDS will **not** maintain or externally share the master DOA log.
    b. IDS will update Vestigo with DOA delegated providers in Florence eBinders or provided by the study team.
        i. Study teams should ensure that delegated providers have been entered into the 'Staff' tab of the associated study in OnCore.
3. IDS cannot dispense IMP unless the protocol has an "active" IRB status.
    a. UMN IRB status is updated in OnCore and then pulled into Vestigo daily.
    b. External IRBs must still be reported timely to the UMN IRB and updated in OnCore.
    c. **Inactive or improperly updated IRB statuses may cause dispensing delays.**
4. IDS cannot dispense medications outside of protocol and supporting documentation parameters unless authorized by the PI in an emergency.

5. IDS adheres to MN State Statutes and MN BOP Rules, regulations, and guidelines for pharmacy. When an IRB approved protocol does not fit within these parameters, IDS must evaluate that instance and provide mechanisms to ensure the study can still proceed safely.

09 IMP: Inventory Control

1. **Electronic Record Maintenance**
    a. All IMP received, stored, dispensed, returned, or destroyed are tracked using the Vestigo inventory management system.
    b. Entries into the electronic system must be made on the same day the activity occurs to ensure real-time accuracy of inventory levels.
    c. Access to the Vestigo system is restricted to authorized IDS staff only, with individual user accounts and passwords to ensure security and traceability.
    d. System backups are continuously performed to ensure data recovery in the event of system failure or data loss.
    e. Vestigo system maintains a secure, computer-generated, time-stamped audit trail that records the date and time of each entry and identifies the person making the entry.
2. **Cycle Counts**
    a. A complete physical inventory of IMP is conducted on a rolling **30-day** schedule to verify the accuracy of the electronic inventory records, ensuring all unused investigational medications and supplies under IDS control are accounted for.
    b. Discrepancies between the physical inventory and the electronic records are investigated immediately.
        i. For discrepancies unresolvable at the pharmacy level, the PI and/or Sponsor representative will be contacted for further guidance. These discrepancies are documented, including the nature of the discrepancy, the investigation findings, and as necessary the corrective actions taken.
    c. The cycle count process includes:
        i. Verification of storage conditions.
        ii. Checking expiration/re-test dates. Medications nearing expiration (within 60 days) or requiring re-testing will be flagged for evaluation regarding reordering or removal.
            1. Replacement of expired medications will follow procedures specified by the PI/Sponsor.
        iii. Segregation of IMPs by protocol, investigator, and storage requirements, ensuring special attention to drug usage patterns and expiring items.
    d. The results of the inventory review, including any discrepancies and actions taken, are documented, and filed with the inventory records in Vestigo.

10 IMP: Receipt and Verification

1. **Shipping and Receiving Guidelines**
    a. **Receiving IMPs**
        i. IMPs are received at a designated secure area within IDS Pharmacy, accessible only to authorized staff.
        ii. The Lead Pharmacist is immediately notified upon receipt of the first IMP for any new study.
        iii. Initial checks for quality and temperature are performed before moving IMPs to their designated storage areas.
    b. **Label Standards**
        i. Each IMP must display a label with the following information: name, dosage/concentration, formulation, lot/batch number, expiration date, storage

conditions, manufacturer details, and the statement "*Caution: new drug - limited by US or Federal law*."

ii. Improperly labeled IMPs will be stored under appropriate conditions and quarantined within Vestigo until further clarification from the Sponsor.

2. **Quality Inspection and Temperature Control Protocols**
   a. Upon receipt, all IMPs undergo a thorough quality inspection to check for any signs of damage, tampering, or deviation from expected conditions.
   b. Temperature-controlled shipments are immediately inspected for adherence to required conditions.
      i. Temperature data loggers, if included in shipments, are downloaded, and reviewed to confirm IMPs were maintained within the specified temperature range during transit.
   c. Temperature excursions are documented and reported per Sponsor requirements and/or as specified at KOM/SIV. Communications will minimally include study PI, primary CRC, and CRA.
      i. IDS will quarantine the IMP under required storage conditions.

3. **Chain-of-Custody Maintenance**
   a. Upon receipt of new IMPs, IDS staff follow all unpacking requirements and log the transaction in Vestigo, under the associated protocol drug build within Vestigo.
      i. Details of captured information include IMP name, quantity, lot number, kit/bottle/vial number (if applicable), and expiration date.
      ii. IDS will verify shipping contents to the provided manifest.
         1. Discrepancies must be brought to the appropriate shipping and Sponsor contact.
      iii. The receiving IDS staff member must sign and date the shipping manifest and note when product was received and any other actions that occurred (such as receiving product in RTSM).
         1. Double Verification: A second member of IDS staff performs verification of all shipments, documenting by dating and initialing the shipping document.
         2. If RTSM receipt is done by a secondary individual, they must also sign and date the manifest.
            a. RTSM documentation should be done the same day that IMP was received in IDS.
         3. The completed manifest will be uploaded to the Vestigo associated inventory transaction. The entering IDS staff member must complete other Vestigo specified activities associated with receipt.
      iv. IDS must alert study teams when shipping discrepancies or issues are expected to interrupt scheduled or anticipated dosing.
   b. Vestigo barcodes are included on the Vestigo pharmacy label placed on the IMP during preparation. The individual picking up the prescription from IDS must scan this barcode and enter their name. This entry links handoff details to the dispensing transaction within Vestigo.
      i. The scan records the user's name, location, time, and date of the transaction.
      ii. In the event of a barcode scan failure, IDS staff are required to manually enter the dispensing details into Vestigo, maintaining the integrity of the chain of custody.
      iii. Vestigo stored chain-of-custody details are available for Monitor review within Vestigo Verify.

11 IMP: Storage and Handling

1. **Secure Storage and Restricted Access**

a. IMP is stored in a secure locked and limited access area that is alarmed when not staffed.
b. Entry to IDS operated space is restricted to IDS personnel and requires an individually assigned user-specific photo ID badge key card, unique user-specific pin code, and biometric facial recognition.
    i. Authorized user access to IDS space is logged internally and cannot be provided outside of official security concern requests by governing bodies (ex: FDA, DEA, MN BOP, etc.).
    ii. Guest access to IDS space is logged (name, date, time, reason) for a record of who has entered the space and why. This document will be stored in Vestigo for monitor access.
c. A licensed IDS pharmacist will be present in the IDS Pharmacy during hours of operation.
d. Forced entry into the pharmacy or tampering with the entry systems will alert on-premises security that monitors and responds to alarms 24 hours a day, 365 days a year.

2. **Safe Handling and Temperature Monitoring Procedures**
    a. Storage and monitoring
        i. IMP is segregated by protocol, PI, hazardous drug status, storage temperature requirements, dosage form, and strength.
        ii. All IMP storage areas are continuously temperature-monitored to document storage conditions. Where applicable (e.g., ambient storage), humidity is also monitored.
        iii. IDS uses **SonicU**, the institutionally supported continuous digital temperature and humidity monitoring platform. SonicU utilizes NIST-traceable, digital temperature sensors (including glycol-buffered probes for cold storage and S-Series temperature/humidity sensors for ambient areas) and records measurements every 5 minutes, with mean values stored at 15-minute intervals.
            1. Each monitored storage location has **dual probes** (primary and secondary) for redundant recording. The primary probe is the source-of-record exported into Vestigo; the second probe provides independent backup and alerting redundancy.
            2. SonicU devices have on-board memory and battery backup to maintain continuous monitoring and data capture during power or network interruptions; buffered data automatically synchronize to the cloud platform when connectivity is restored.
            3. Alerts are generated in real time via multiple channels (phone, SMS/voice, mobile app notifications, and email) to 24-hour security, facilities personnel, and the IDS distribution list, according to institutionally defined call trees. This enables rapid response to conditions such as unit door left open, temperature out of range, or device failure.
            4. SonicU readings are reviewed daily during IDS business hours.
            5. Temperature and humidity data are maintained in the SonicU database and summary temperature reports are transferred at regular intervals into Vestigo for CRA access during protocol audits.
        iv. Commercially available medications purchased for study usage will be stored under the parameters outlined in their respective package insert.
        v. Storage for more restrictive temperature/excursion ranges must be arranged specifically with IDS prior to study initiation.
    b. Sensor and unit maintenance
        i. All temperature sensors are certified by a National Institute of Standards and Technology (NIST) validated probe and transmitter
            1. Sensor certifications will be stored within Vestigo for monitor access. IDS is unable to email these out individually.

ii. All storage units undergo preventative maintenance in strict accordance with manufacturer guidelines. Maintenance is logged internally, but IDS does not provide these records.

c. Storage references
   i. IDS will comply with **USP <659> Packaging and Storage Requirements.**
      1. USP standards do not specify storage parameters for conditions lower than those defined in **USP <659>** as "Freezer".
         a. For these parameters, IDS will follow ISBER Best Practice Guidance in addition to manufacturer technical data sheets.

3. **Temperature Monitoring Parameters**
   a. **USP <659> storage details:** *All temperatures are listed in (°C) unless otherwise stated.*
      i. **Controlled room temperature**
         1. **Temperature Range:** 20˚ to 25° (68 to 77°F).
         2. **Temperature Setpoint:** 22°
         3. **Alarm Range:** < 21° and > 24°
         4. **Excursion Range:** < 15° and > 30° *(See a.)
            a. Per USP <659>, temperatures between 15° and 30° (59° and 86°F) are allowed provided the mean kinetic temperature does not exceed 25°.
            b. Per USP <659>, Transient spikes up to 40° are permitted if they do not exceed 24 h. Spikes above 40° may be permitted only if the manufacturer instructs.
      ii. **Refrigerator**
         1. **Temperature Range:** 2° to 8° (36 to 46°F)
         2. **Temperature Setpoint:** 4°
         3. **Alarm Range:** < 3° and > 6°
         4. **Excursion Range:** < 2° and > 8°
      iii. **Freezer** – Note: USP <659> defines Freezer as -25 to -10°C, however, our upper limit will be -15°C to conform with typical Sponsor requirements.
         1. **Temperature Range:** −25° to −15° (−13° and 5°F)
         2. **Temperature Setpoint:** -20°
         3. **Alarm Range:** < -23° and > -17°
         4. **Excursion Range:** < -25° and > -15°
   b. **ISBER Best Practice Guidance storage details:** *All temperatures are listed in (°C) unless otherwise stated.*
      i. **Ultra-Low (ULT) Freezer**
         1. **Temperature Range:** -86° to -60° (-122.8° and -76°F)
         2. **Temperature Setpoint:** -80°
         3. **Alarm Range:** < -90° and > -65°
         4. **Excursion Range:** < -90° and > -70°
      ii. **Liquid Nitrogen (LN2)**
         1. **Temperature Range**
            a. **Vapor Phase:** -190 to -150° (-310° and -238°F)
               i. LN2 temperature ranges cannot be directly controlled. IDS will closely monitor LN2 levels and use vapor temperatures > -160° as an alert level.
               ii. Probe will be placed at the highest point (at top of chamber).
         2. **Alarm Range:**

a. **LN2 Levels:** Electronically managed at the unit level. These values are not stored for review but are monitored by IDS.
b. **Alarm Range:** > -160°

3. **Excursion Range:** > -150°

4. **Excursion Management**
    a. When an excursion is noted, IDS will follow this process:
        i. **Create and document a TERF in Vestigo:** This allows for protocol level generation of TERFs that captures all identifiers; IMP details (lot and kit #), excursion periods, deviation amount, deviation notes, and other information.
            1. IDS will **not** use Sponsor provided temperature excursion reporting forms (TERFs) to document temperature excursions as this would duplicate what is already in Vestigo.
        ii. **Immediately quarantine affected IMP in Vestigo:** Quarantining within Vestigo immediately prevents dispensing of any affected IMP.
            1. IDS will **not** quarantine products in external systems (ex: RTSMs). This is to avoid quarantine delays and avoid the potential of dispensing affected IMP.
        iii. **Contact and supply details:** IDS will contact the study provided Sponsor designee, PI, and primary Study Coordinator within 24 business hours of becoming aware of the excursion. IDS will supply the TERF and other relevant details with product management.
        iv. **Post excursion action:** Once informed of Sponsor determination of excursion impact, IDS will update IMP inventory status and handle final disposition accordingly. Relevant details will be documented and stored as part of the study record.

12 IMP: Accountability and Documentation

1. **Electronic Recordkeeping Standards**
    a. The Vestigo inventory management system is utilized for comprehensive tracking of all IMP activities including receipt, storage, dispensing, return, or destruction of investigational products.
    b. Detailed documentation within Vestigo includes all pertinent IMP data including Sponsor's protocol number, IDS number, principal investigator, source, lot number (with separate records for different lot numbers or expiration dates), drug name, strength, dosage form, units per container, drug storage location, kit number (if applicable), and expiration/retest date are recorded within Vestigo.
    c. Electronic records are maintained in real-time to reflect current inventory and patient dispensing status accurately.

2. **Data Management and Reporting**
    a. Vestigo generates precise accountability reports, supporting IDS in meeting regulatory requirements and sponsor expectations for accurate and timely documentation.
    b. Regular data verification checks are performed to ensure the integrity of electronic records, including cross-referencing patient dispensing records and inventory levels.

3. **Special Considerations**
    a. Commercial medications dispensed from general inventory at any Fairview Pharmacy site are managed separately from investigational products and by default are not included in the IMP accountability records.

b. Commercial medication dispensed from IDS will be 'partially tracked' on accountability logs and will include drug name, lot number, and expiration dating.

4. **Vestigo as 21 CFR Part 11–compliant accountability system**
   a. Vestigo is implemented and used in a manner consistent with 21 CFR Part 11 requirements for electronic records and electronic signatures, including secure, role-based access control, unique user IDs and passwords, time-stamped audit trails, and the ability to generate accurate and complete copies of records in human-readable formats. A vendor Statement of Compliance is maintained in the facility documents section of Vestigo for monitor review.

5. **Sponsor-provided accountability logs and worksheets**
   a. IDS will not maintain separate sponsor-provided paper accountability logs, drug accountability record forms (DARFs), or paper dose-preparation worksheets when the same information is already captured within Vestigo. Maintaining parallel systems would introduce unnecessary manual transcription, increase the risk of discrepancy, and duplicate documentation efforts.
   b. All data elements normally requested on sponsor DARFs—such as receipt, lot number, kit/container number, quantity dispensed/returned/destroyed, expiration/retest dates, storage location, and running balances—are captured within Vestigo's accountability modules and associated dispensing records.
   c. If a Sponsor requires collection of additional, protocol-specific data fields that are not natively available in Vestigo, IDS will first attempt to configure internal Vestigo forms or data fields to capture those elements. Only if IDS determines that internal tools cannot be configured to meet a mandatory requirement will sponsor-specific forms be considered, and then only with IDS approval.

13 IMP: Hazard Assessment

Note: This SOP is being revised. Please connect with IDS for the existing SOP or clarification if more details are required.

14 IMP: Hazardous & Biohazardous Handling

This section governs the handling of hazardous drugs (per USP <800>) and biohazardous agents, including live/attenuated viruses, viral vectors, genetically modified organisms (GMOs), and genetically modified cells. All procedures comply with applicable USP <797>/<800> standards, NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, and University of Minnesota Institutional Biosafety Committee (IBC) requirements

1. **Scope and Classification**
   a. **Hazardous Drugs:** Agents identified via NIOSH List, Safety Data Sheet (SDS), or Investigator's Brochure requiring USP <800> handling precautions.
   b. **Biohazardous Agents:** Live/attenuated viruses, viral vectors (e.g., AAV, lentivirus), genetically modified cells, and other materials requiring IBC oversight or BSL-2 containment.
   c. Hazard classification is determined during protocol assessment (see **Section 13: IMP Hazard Assessment)** and documented in the Drug Datasheet (DDS).

2. **Engineering Controls and Preparation Environment**
   a. **Biohazardous Compounding:** All biohazardous agents are prepared in the Bioquell Qube Pharmaceutical Isolator, a closed-system isolator with hydrogen peroxide vapor (HPV) decontamination capability, located within the ISO 7 cleanroom suite.

b. **Hazardous Drug Compounding:** Hazardous drugs not classified as biohazardous are prepared in Class II, Type B2 Biological Safety Cabinets within negative-pressure ISO 7 space, per USP <800>.
c. **Containment Ventilated Enclosure (CVE):** Used for non-sterile hazardous drug handling (e.g., powder-based oral formulations).

3. **Personnel Protective Equipment (PPE) and Procedures**
   a. Personnel preparing or handling hazardous/biohazardous agents don appropriate PPE: chemotherapy-rated gown, double gloving (inner and outer gloves), face mask or N95 respirator, and eye protection (goggles or face shield) as necessary.
   b. PPE is donned before and doffed after exiting the preparation area per institutional gowning procedures.
   c. Product is removed from the isolator/BSC after outer surface decontamination and is then placed in sealed secondary container.

4. **Decontamination**
   a. Decontamination methods are protocol-specific and dictated by the Sponsor or IBC requirements; common methods include 70% isopropyl alcohol, 10% bleach solution, or HPV cycle (Bioquell Qube).
   b. The isolator/BSC is decontaminated after each preparation session and before any product changes.
   c. When required, decontamination activities are documented in the preparation record.

5. **Labeling, Packaging, and Transport**
   a. **Primary Label:** Bag label includes biohazard symbol and/or "Chemotherapy" auxiliary label as appropriate.
   b. **Transport Container:** Bagged product is placed in a sealed, hard-sided, insulated cooler containing absorbent material to prevent any potential leakage in the event of containment failure.
   c. **Chain of Custody and Delivery:** Transport follows Section 17 (IMP: Movement). All biohazardous/hazardous IMP deliveries are made directly to a known, responsible study team member or authorized designee—product is not left unattended or with unknown individuals. Receipt is documented in Vestigo.
   d. **Dry Ice:** If applicable, package is labeled "Dry Ice" on two sides per DOT requirements.

6. **Disposal and Inactivation**
   a. Unused or waste biohazardous material is inactivated per Sponsor/IBC direction (e.g., chemical inactivation, autoclave) prior to disposal.
   b. All hazardous and biohazardous waste is disposed of via institutional Environmental Health & Safety (EHS) protocols as hazardous pharmaceutical waste.
   c. Disposal activities are documented in Vestigo.

7. **Accidental Exposure and Spill Response**
   a. In the event of accidental exposure or spill, staff follow institutional Exposure Control and Spill Response procedures.
   b. Exposures are reported immediately to supervisor, Occupational Health, and IBC as required.
   c. Spill kits appropriate for hazardous/biohazardous materials are maintained in the preparation area.

15 IMP: Preparation and Dispensing

1. **Labeling and Blinding Protocols**
    a. **Standard Labeling Requirements:** All IMPs prepared and dispensed by IDS must adhere to labeling requirements that ensure patient safety and compliance with study protocols.
    b. **Blinding Procedures:** For blinded studies, IDS will maintain the integrity of the blinding. This includes the use of blinded labels for IMP and matching placebo.
    c. **Vestigo Integration:** Labeling information is recorded in the Vestigo system to ensure each IMP dispensed is accurately tracked, maintaining a link to the specific participant, study, and visit.
    d. **Sponsor Labels:** Study provided dispensing labels will not be used. All necessary information and identifiers (PSN, protocol numbers, etc.) will be added to the Vestigo dispensing label.

2. **Dosage and Administration Guidelines**
    a. **Customized Preparation:** IMP is prepared according to the specific requirements outlined in the study protocol, considering participant-specific factors such as weight, age, and condition.
    b. **Administration Instructions:** Clear and concise instructions for administration are provided with each dispensed IMP to ensure proper usage. This includes special instructions for storage, handling, and timing of administration relative to food or other medications.
    c. **Staff Training:** IDS staff receive training on the unique preparation, handling, and dispensing requirements of each study's IMPs, reinforcing adherence to standardized procedures and ensuring participant safety.

3. **Order Entry and Dispensing Compliance**
    a. **Order Verification:** All orders for IMPs are verified for accuracy and compliance with the study protocol before preparation begins. This entails a pharmacy specific review of the patient's eligibility, study visit alignment, and dosage accuracy.
        i. For IMP orders originating in Epic, all IMP will require documentation of at least (1) CRP verification. Chemotherapy orders necessitate documentation of a secondary CRP's verification signature.
            1. If another CRP is not available, the initial CRP may perform the second verification. This should only occur when necessary.
    b. **Dispensing Oversight:** A CRP oversees the dispensing of all IMPs. The process includes a final check of the prepared product against the original order to ensure accuracy before the IMP leaves IDS.
        i. This final verification is captured within Vestigo.
    c. **Record Keeping and Vestigo Documentation:** Detailed records of each dispensing transaction, including patient information, IMP details, dosage, and dispensing date, are maintained within Vestigo. This documentation supports an audit trail for compliance, inventory management, and future reference.
    d. **Non-compliance and Error Management:** Procedures are in place for identifying, reporting, and managing any instances of non-compliance or dispensing errors. This includes immediate corrective actions and, when necessary, notification of the Sponsor and IRB.
    e. **Dose preparation documentation within Vestigo:** For compounded or otherwise complex IMP preparations, Vestigo serves as the primary "dose preparation record." Details such as preparer and verifier, preparation date/time, lot and kit numbers, quantities used and wasted, and any compounding notes are captured either directly in the dispensing record or via protocol-specific Vestigo forms and attachments. These records are visible to authorized monitors via Vestigo Verify and are intended to replace sponsor-provided paper dose-preparation worksheets.

16 IMP: Controlled Substances Management

1. **Scope and regulatory framework**

a. This section applies to all Schedule I–V investigational medicinal products (IMPs) managed by IDS Pharmacy.
b. Controlled IMPs are handled in accordance with applicable federal (DEA), state (MN Board of Pharmacy), and institutional policies, in addition to the requirements of this SOP.

2. **Secure storage – DEA-rated vault**
   a. All Schedule I–V IMPs are stored in a DEA-rated Smart Series DEA / U.L.-compliant vault with a total weight of approximately 6,725 pounds and two Kaba 252V Auditcon electronic locks.
   b. The vault is located within the restricted-access IDS Pharmacy space and is equipped with dedicated HVAC to maintain appropriate temperature and humidity, and a 360-degree camera system providing continuous video coverage of the vault exterior.
   c. Access is restricted to IDS pharmacists. Entry requires: (1) individual photo ID badge access to the IDS area, (2) a unique user-specific PIN code to disarm the vault alarm, and (3) the pharmacist's unique code for the vault lock combination.
   d. The vault is alarmed to local law enforcement and 24/7 security monitoring. Forced entry attempts or tampering trigger alarms and security response in accordance with institutional policy.

3. **Receiving and documentation**
   a. Controlled IMP shipments are received in the designated secure IDS receiving area. Shipments are promptly transferred to the vault after inspection.
   b. Two IDS staff members (at least one pharmacist) reconcile the shipment against the shipping manifest, verifying product name, strength, dosage form, quantity, lot numbers, kit/container numbers (if applicable), and expiration/retest dates.
   c. The receiving staff member signs and dates the shipping manifest, documenting receipt; the second staff member documents independent verification.
   d. The receipt is entered into Vestigo under the appropriate protocol and drug build, and the annotated shipping manifest (or equivalent receiving documentation) is scanned and uploaded to the corresponding Vestigo inventory transaction.
   e. Where required by institutional controlled-substances policy, entries are also made in the institutional controlled-substance log or system (separate from Vestigo). These internal logs are available to regulatory authorities but are not routinely provided to Sponsors.

4. **Inventory control and reconciliation**
   a. Controlled IMPs are included in the general IMP cycle counts described in Section 09 and are reconciled at least every 30 days.
   b. In addition, running balances are verified at each dispensing, return, destruction, and shipment transaction.
   c. Any unexplained discrepancy is escalated immediately to the IDS Pharmacy Management and, as appropriate, to institutional controlled-substance compliance and security for investigation.

5. **Dispensing, transport, and chain-of-custody**
   a. Dispensing and chain-of-custody requirements for controlled IMPs during transport and delivery are described in Section 17 IMP: Movement (Delivery and Transport), including separate requirements for Schedule I and II vs Schedule III–V IMPs.
   b. Vestigo serves as the primary accountability record for controlled IMPs, supplemented by institutional controlled-substance logs where required. Monitors will see controlled-substance accountability in Vestigo; internal vault access logs and security records are maintained by the institution and are available to regulatory agencies upon request.

17 IMP: Movement (Delivery and Transport)

Note: These are IDS specific movement SOPs for both patient-specific doses for administration and for IMP to be dispensed at other affiliated facilities. Additionally;

- Study teams may have their own movement SOPs.
- Sponsor required IMP movement processes must be clarified by KOM/SIV.
- IDS is located approximately 1.5 miles from the Medical Center Complex. Therefore, all prepared IMP doses require courier transport to their final administration location.

1. **IMP Delivery**
    a. Participant-specific delivery of prepared IMP from IDS to site of administration that take ≤ 15 minutes are considered part of the 'Medical Center Complex' and will utilize standard courier delivery practices by default.
        i. **Standard courier deliveries:**
            1. Do not include documented temperature tracking or specialized transport forms
            2. Utilize sealed, protective, insulated containers to maintain ambient conditions and product viability during transit.
        ii. **Delivery Practices:**
            1. By default, IDS couriers deliver IMP either to a controlled, secured, and monitored central location (e.g., Clinics and Surgery Center [CSC], Clinical Research Unit [CRU], pharmacy, clinic) for subsequent pickup by the study or administering team, or directly to a designated study team member or their designee.
    b. Nonstandard delivery requests require prior approval by IDS and the study team and may incur additional charges. Chain-of-Custody:
        i. All deliveries are logged by IDS and courier personnel.
        ii. Logs include recipient name, date, time of receipt, and link to the dispense record within Vestigo.
2. **IMP Transportation**
    a. IMP transport from IDS to administration sites (> 15-minute transit):
        i. By default, temperature tracking is not performed. Temperature tracking is available upon Sponsor request.
        ii. Transport containers are sealed, protective, and insulated to maintain required temperature conditions (Controlled Room Temperature, Refrigerated, Frozen, or Dry Ice).
            1. **Couriers:** IDS utilizes contracted medical couriers (**Life Couriers**, formerly On Time Delivery), specifically trained and credentialed to deliver medical supplies, pharmaceuticals, and laboratory samples throughout the M Health system. Couriers are fully HIPAA-compliant, trained in biohazard spill response, maintain complete chain-of-custody tracking, and hold authorized access to all designated medical center delivery locations. Couriers operate under IDS oversight but are not delegated as study personnel under this SOP.
        iii. For biohazardous or hazardous IMP transport, see Section 14 (IMP: Hazardous & Biohazardous Handling) for additional packaging, containment, and chain-of-custody requirements.
3. **IMP Transportation: Controlled Substances**
    a. **Schedule I-II IMPs (C1-C2)**
        i. Dispensed IMP will be sealed in tamper-evident packaging (e.g., tamper-taped plastic bag).

ii. Delivery must occur directly into the custody of the Principal Investigator (PI) or an individual specifically delegated by the PI to accept and maintain controlled substance accountability.
iii. Chain-of-custody, including PI or delegate name, date, and exact time of receipt, will be logged and retained within Vestigo.

b. **Schedule III-V IMPs (C3-C5)**
i. Dispensed IMP will be sealed in tamper-evident packaging (e.g., tamper-taped plastic bag).
ii. Delivery must be directly to a designated study team member or authorized designee.
iii. Chain-of-custody, including recipient name, date, and exact time of receipt, will be logged and retained within Vestigo.

4. **Receipt and Verification by Affiliated Sites**
a. **Receiving Packages:** Affiliated sites are responsible for promptly receiving packages sent by IDS. Immediate unpacking and inspection are required to verify the integrity of the contents and adherence to temperature requirements.
b. **Confirmation of Receipt:**
i. Receipt of each package must be confirmed with IDS via fax or email. This confirmation includes noting the condition of temperature indicators, such as ice packs, to ascertain maintenance of appropriate shipping conditions.
c. **Documentation on Drug Accountability Record:**
i. Upon receipt, documentation of receipt will be stored within the site location's Vestigo profile and associated protocol.
d. **Storage:** Received IMPs are immediately stored under the conditions specified in the DDS to maintain drug integrity until dispensation.

5. **Preparation for Dispensing**
a. **Dispense Preparation:** Affiliated sites prepare and dispense the IMP as outlined in the DDS ensuring compliance with the study protocol requirements.
b. **Security and Compliance:** All procedures related to the handling, storage, and dispensation of IMPs adhere to strict security and compliance standards to maintain the integrity of the study and participant safety.

18 Direct-to-Participant Shipping

Note: This SOP is being revised. Please connect with IDS for the existing SOP or clarification if more details are required.

1. **Shipping Method:** IDS selects shipping methods that ensure the integrity of the IMP throughout transportation. This includes same-day delivery where possible and tracking and verification of shipment receipt.
2. **Documentation:** Each shipment includes detailed packing lists that outline the contents, including the IMP name, quantity, lot number, expiration date, and associated study protocol and IDS number.

19 IMP: Disposal, Destruction, and Returns

1. **General Destruction Procedures**
a. IDS must adhere to Environmental Health and Safety standards for pharmaceutical waste disposal.
b. IMP disposal methods will be based on known or suspected hazard levels determined by the Lead Pharmacist and may be based on Sponsor provided materials (IB & SDS) at SIV.

c. **IDS classifies drugs as:** chemotherapeutics, gene therapies OR other. Chemotherapeutics and gene therapies are treated as hazardous waste-. See: **IMP: Hazardous Handling**

2. **Receiving and Documenting Participant Returns**
    a. Study Coordinators or their agents deliver returned drugs and containers to IDS.
        i. IDS cannot accept visibly soiled and/or containers of questionable sanitary condition.
        ii. Containers must be placed in a sealed bag; no loose containers will be accepted.
    b. Once received, IDS will:
        i. Log the return date as:
            1. The date marked on the container by the Study Coordinator.
            2. If unmarked, the date the container was returned to IDS.
        ii. Count remaining dose units in the containers, including empty ones.
        iii. Record the return date, delivery individual, and remaining quantity (including zero) within the protocol returns area of Vestigo.

3. **Disposing and Destroying Investigational Drugs:**
    a. **Unused** (full bottles, bags, vials, etc.) **destruction**.
        i. IDS will retain unused IMP at their required storage conditions until authorized for destruction, unless specified otherwise by Sponsor.
    b. **Used** (vials used for compounding, participant returns, etc.) **destruction**.
        i. Compounding remnants: Due to institutional space restrictions and employee safety, IDS will not store boxes, labels, stickers, empty vials, or other items for IMP used during the compounding or preparation process.
            1. Discarded IMP usage and accountability records will be documented at the point of compounding and stored within Vestigo for Monitor review.
        ii. Participant Returns: IDS cannot validate the handling of participant returns and must treat them as waste substances to be immediately discarded upon reconciliation.
            1. All participant returns to IDS and must be placed into a container (bag) marked as hazardous.
            2. Study team should do an initial IMP count. IDS will perform a secondary count.
            3. IDS will log the quantity returned into Vestigo and immediately destroy per SOP.
    c. **Once authorized for drug destruction IDS will:**
        i. Have two (2) IDS staff members validate the IMP designated to be destroyed.
        ii. Remove/destroy any labeling with patient identifiers – including the prescription number.
        iii. Remove drugs from outer packaging, e.g., blister packs, bulk bottles.
        iv. Document the quantity of drug destroyed and the date of destruction within Vestigo. The validating IDS staff member must also record their acknowledgement in Vestigo.
        v. The date of destruction is defined as the day the medication is placed in the waste container.
        vi. Destroy per SOP.
            1. **IDS utilizes a systemwide waste handling company and is unable to provide individualized destruction documentation. A 'Certificate of Destruction' can be printed by Monitors from within Vestigo Verify.**

4. **Returning Investigational Drugs to Study Sponsor**
    a. When requested, IDS will return unused study drug to Sponsor. This process must be clarified at SIV.
    b. When applicable, IDS will;
        i. Send all returns via a trackable method.
        ii. If deemed hazardous, IDS staff coordinates with the sponsor for packaging and shipping.

iii. Complete required sponsor return documentation, keeping a copy in the study file.
iv. Document the quantity of drug returned and the date of return in Vestigo.

20 IMP: Unblinding Procedures

1. **Circumstances Necessitating Unblinding**
    a. Unmasking or breaking the blind of a clinical trial involving IMP should only be undertaken in circumstances where it is essential for the immediate care of the participant.
    b. Unmasking is typically necessitated under emergency situations where knowledge of the specific IMP administered is crucial for the participant's treatment or safety.
    c. The decision to unmask should be made in consultation with the study's PI and/or the study sponsor, except in cases where immediate action is required to prevent serious harm to the participant.

2. **Unblinding Process**
    a. **Emergency Contact:** In the event of a medical emergency requiring unblind, the physician or authorized representative should contact the IDS Pharmacy using the contact information provided on the IMP container's label, which includes the study's unique IDS#.
    b. **Verification:** The requesting party must provide the IMP name and the unique IDS# to the responding pharmacist.
    c. **Professional Judgment:** The pharmacist will use professional judgment to assess the emergency's validity and the necessity for unblinding.
        i. Consideration will be given to whether the information is crucial for the patient's care.
    d. **Attempt to Contact PI/Sponsor:** Prior to releasing any unblinding information, the pharmacist will attempt to contact the PI and/or the study sponsor for authorization.
    e. **Documentation:** If the decision is made to unblind, comprehensive documentation is required. This includes:
        i. Identity of the requestor and recipient of the unblinding information.
        ii. Rationale behind the request.
        iii. Date and time the request was made.
    f. **Notification:**
        i. Following an unblinding event, IDS Pharmacy must be informed promptly via phone, email (DEPT-IDS@fairview.org), or fax.
        ii. IDS Pharmacy will then communicate detailed circumstances of the unblinding event to the Sponsor, PI and/or study team member.
    g. **Aftermath of Unblinding:**
        i. The IDS Pharmacy, in collaboration with the study team, will determine the subsequent steps for the participant's management in the study.

21 IMP: Emergent Treatment Use

Note: This SOP is being revised. Please connect with IDS for the existing SOP or clarification if more details are required.

22 IMP: Shortages Management

Note: This SOP is being revised. Please connect with IDS for the existing SOP or clarification if more details are required.

23 Sponsor (Monitor) Visits

1. Remote monitoring via Vestigo Verify (preferred)

a. IDS Pharmacy utilizes Vestigo Verify, a secure web portal that allows authorized monitors to conduct remote review of:
    i. IMP accountability records (DARFs and inventory transactions)
    ii. Dispensing records and dose-level details
    iii. Facility documentation (licenses, GCP training, temperature monitoring calibration certificates, etc.)
    iv. IDS staff protocol-specific training acknowledgements
b. To request remote access, monitors email IDSPharmacy@Fairview.org

2. On-site monitoring visits
    a. On-site access to IDS, in addition to or instead of Vestigo Verify, must be requested by the local study coordinator.
    b. On-site visits must be requested at least two weeks in advance. Visits are generally scheduled in one-hour blocks, with Tuesday–Thursday morning (8:00–11:00) or afternoon (13:00–15:00) time slots preferred.
    c. All visitors must sign in upon entry to the pharmacy and follow current institutional infection-prevention and safety requirements.
    d. During on-site visits, monitors will be provided access to Vestigo and requested documents in a controlled environment; direct access to OnBase is not available. Copies of documents stored in OnBase can be provided as PDFs upon request, as described in Section 03.

24 Study Closeout

Note: This SOP is being revised. Please connect with IDS for the existing SOP or clarification if more details are required.

25 Audits

Note: This SOP is being revised. Please connect with IDS for the existing SOP or clarification if more details are required.

26 Handling and Reporting of Adverse Events and Protocol Deviations

Note: This SOP is being revised. Please connect with IDS for the existing SOP or clarification if more details are required.

27 Quality Assurance and Continuous Improvement

Note: This SOP is being revised. Please connect with IDS for the existing SOP or clarification if more details are required.

1. Ongoing Process Evaluation and SOP Review
2. MN BOP required QA process **(SOP 26)**

28 Management of Approved Affiliated Satellite Facilities

Note: This SOP is being revised. Please connect with IDS for the existing SOP or clarification if more details are required.

1. Allocation and Dispensing: IDS authorizes the allocation and dispensing of investigational products at satellite facilities that hold approved institutional affiliations, ensuring broad access and efficient participant care across multiple sites.
2. Use of Approved Logs and Containers: The principal investigator (PI) or designees at satellite facilities must utilize dispensing and IMP accountability logs, drug containers, and labels approved by the depot IDS. All materials must comply with local pharmacy regulations, Federal Law, and GCP guidelines.

3. Protocol and Dispensing Instructions: Detailed study protocol information, including dispensing instructions, is provided by the depot IDS to staff at satellite facilities to ensure uniform understanding and execution of study requirements.
4. Ancillary Pharmacy File: An ancillary pharmacy file is established between the satellite facility and the depot IDS for the purpose of maintaining comprehensive drug accountability and dispensing records in line with Study Initiation requirements.
5. Documentation and Record-Keeping:
    a. Documentation of subject enrollment, IMP dispensing and accountability, and, if applicable, subject randomization, is meticulously maintained and recorded by satellite facility staff in the ancillary pharmacy file.
    b. This documentation serves as a central record for tracking patient interactions and investigational product management at the satellite facility.

6. Study Termination and Product Return: Upon study termination, all investigational products and relevant documentation are returned to the depot IDS, ensuring a consolidated and final reconciliation of IMPs.
7. Compliance Audits: Periodic audits are conducted by depot IDS staff to verify records at the satellite facility and assess compliance with established policies and procedures. These audits help maintain the integrity of the investigational product management and ensure adherence to regulatory standards.

29 Downtime Management

Note: This SOP is being revised. Please connect with IDS for the existing SOP or clarification if more details are required.

30 Data Privacy and Security

Note: This SOP is being revised. Please connect with IDS for the existing SOP or clarification if more details are required.

31 Quality Control

Note: This SOP is being revised. Please connect with IDS for the existing SOP or clarification if more details are required.

Collaboration and Feedback

Note: This SOP is being revised. Please connect with IDS for the existing SOP or clarification if more details are required.

b. **External Review Process**: Outline the process for external parties, such as CROs and drug sponsors, to review and provide feedback on SOPs.
c. **Contact Information**: Include contact details for the SOP management team for queries or suggestions.

Change Control Process

Note: This SOP is being revised. Please connect with IDS for the existing SOP or clarification if more details are required.

d. **Change Management**: Outline steps for proposing, reviewing, and implementing SOP changes.

Risk Management and Mitigation

Note: This SOP is being revised. Please connect with IDS for the existing SOP or clarification if more details are required.

Technology and Software Management

Note: This SOP is being revised. Please connect with IDS for the existing SOP or clarification if more details are required.

Amendment History:

Note: This SOP is being revised. Please connect with IDS for the existing SOP or clarification if more details are required.

e. **Detailed Update Log:** Descriptive log of all revisions, including dates and descriptions of changes.

Appendices:

Note: This SOP is being revised. Please connect with IDS for the existing SOP or clarification if more details are required.

f. **Supporting Documents**: Attach any related documents, such as flowcharts, checklists, or reference materials.
g. **Glossary**: Provide a glossary of terms for clarity and consistency.

Distribution and Access:

Note: This SOP is being revised. Please connect with IDS for the existing SOP or clarification if more details are required.

h. **Access Control**: Detail how the SOP document will be made accessible to internal and external parties.
i. **Confidentiality and Data Security**: Address confidentiality concerns and data security measures, especially for sensitive or proprietary information.

Approval and Sign-off Page:

Note: This SOP is being revised. Please connect with IDS for the existing SOP or clarification if more details are required.

j. **Authorization**: Include a sign-off by the pharmacy leadership to authorize the SOP document.