MOREHOUSE SCHOOL OF MEDICINE	**Effective Date**	**10/01/2025**
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Morehouse School of Medicine (MSM) Investigational Drug Services (IDS) Standard Operating Procedures (SOP) Summary for Sponsors	Address	Morehouse School of Medicine Clinical Research Center 720 Westview Drive, SW, Suite F-123 & F-117 Atlanta, GA 30310-1458
	Email	IDS@MSM.EDU

Sections

Investigational Drug Service (IDS) Overview for Sponsors

The MSM IDS is the centralized pharmacy support unit for investigational products (IPs) used in clinical trials conducted through Morehouse School of Medicine. It ensures compliant receipt, storage, dispensing, accountability, returns, and destruction of study drugs in alignment with Good Clinical Practice (GCP), FDA regulations, and institutional policies.

This summary is intended for sponsors, CROs, and monitors as a reference to our operational practices, capabilities, and points of contact.

Key Services & Responsibilities

Receipt & Verification

All IP shipments are received by IDS, inspected, and logged into Vestigo. Shipments are reconciled against sponsor documentation, and discrepancies are documented and reported immediately. IDS staff acknowledge receipt of IP in the study-specific Interactive Response Technology (IRT) system when applicable.

Storage & Security

Investigational drugs are stored according to sponsor and protocol requirements (e.g., 2–8 °C, –20 °C, –80 °C, room temperature). Storage is secured under a double-lock system within badge-access controlled areas. Only IDS personnel carry keys and have routine access to IDS locations and containers. Controlled substances are stored per DEA and FDA regulations.

Temperature Monitoring & Excursion Handling

MSM IDS uses FusionLive (E-Control Systems), an enterprise IoT platform that records temperature data at 5-minute intervals and alerts IDS staff in real time when fluctuations occur. Temperature monitoring is continuous and integrated with manual daily checks.

In the event of a temperature excursion:

- The affected investigational product is immediately quarantined. IDS completes a Vestigo-generated excursion form to document the event, and sponsors are notified promptly with the excursion data.
- IDS do not complete sponsor-provided temperature monitoring deviation (TMD) forms, as MSM IDS maintains its own validated system. If a sponsor requires a specific form, their representative (e.g., CRA) may complete it using the Vestigo excursion report; IDS will review and sign. Final disposition of affected IP is determined by the sponsor.

Dispensing, Administration & Blinding

Dispensing occurs only upon receipt of a valid prescription from authorized study personnel. All prescriptions are verified by IDS pharmacists. Dispensing is documented both in the participant's record and in the IDS dispensation log within Vestigo. Blinded studies are dispensed per sponsor blinding procedures. Administration is performed only by licensed healthcare professionals.

Accountability & Documentation

All IP transactions—including receipt, dispensing, returns, and destruction—are documented in Vestigo, which is 21 CFR Part 11 compliant. Monthly inventory audits ensure accuracy. Study monitors may review accountability records, temperature logs, excursion reports, and calibration certificates. IDS does not use sponsor-provided accountability logs, as Vestigo serves as the validated system of record.

Returns & Destruction

Returns or destruction of unused, expired, or damaged IP require sponsor authorization. Onsite destruction is coordinated with Environmental Health and Radiation Safety (EHRS) and requires two IDS staff as witnesses. Certificates of destruction or return are generated in Vestigo and retained for sponsor and regulatory review. Offsite destruction (reverse distributor) is coordinated with Clean Harbors and a certificate of destruction will be obtained and maintained.

Sponsor/CRA Access & Monitoring Visits

Sponsors and CRAs may review records in Vestigo via remote or on-site access. On-site inventory checks are conducted under IDS supervision. Visits must be scheduled in advance to ensure staff availability. If sponsors/CRAs would like an on-site visit, please email IDS@MSM.EDU. IDS will confirm staff availability for the visit. Visits should be scheduled at least two weeks prior to the requested date.

Compliance, Training & Quality Assurance

All IDS staff complete protocol-specific training, including review of sponsor-provided pharmacy manuals, Investigator Brochures, and study-specific procedures. Training is documented in training logs maintained within regulatory files or Vestigo. Annual refresher training is required, and retraining occurs if significant protocol changes or variances are identified. Regular internal audits and sponsor monitoring visits ensure continuous compliance.

Best Practices & Standards

MSM IDS operations are aligned with:

- ASHP guidelines for investigational drug management
- HOPA investigational drug service recommendations
- FDA and ICH GCP standards

All investigational product labels must include protocol number, product name, lot/expiry, and storage conditions. Shipping materials must clearly indicate required handling conditions and study identifiers.

Contact & Operational Information

DEPARTMENT	CONTACT	NOTES
MSM IDS	IDS@MSM.EDU1	General inquiries, study coordination
IDS DIRECTOR	Noor Mohamed, PharmD Email: nmohamed@msm.edu	Sponsor-level discussions, escalations
SHIPPING ADDRESS	Morehouse School of Medicine Clinical Research Center 720 Westview Drive, SW, Suite F-123 / F-117 Atlanta, GA 30310-1458	Primary location

Additional Sponsor Expectations & Best Practices

In alignment with institutional SOPs and industry standards (ASHP, HOPA, FDA/ICH GCP), MSM IDS provides the following additional information to sponsors and contract research organizations (CROs) to clarify operational expectations and ensure study success:

- **Site Qualification & Pharmacy Assessment:** IDS participates in site qualification and study initiation visits to confirm capabilities. Relevant SOPs, equipment specifications, and workflows may be reviewed with sponsors as needed.
- **Labeling & Packaging Requirements:** Sponsor shipments must include protocol number, product name, lot/expiry, storage conditions, and sponsor details. Packaging must clearly indicate handling requirements (e.g., Refrigerate 2–8 °C). Shipments lacking this information may be quarantined until clarified with the sponsor.
- **IP Dispensing & Transport:** IDS will dispense IPs from F-123 to the PI's site, which is the MSM CRC building F-127. If needed, CRC staff will retrieve them for transport to an alternative site with maintained appropriate temperature. Licensed healthcare providers that provide IPs to study participants shall counsel the study participants on directions for the use of the investigational drugs.

- **Backup/Downtime Procedures:** If the continuous monitoring system (FusionLive) is unavailable, IDS follows downtime procedures using validated manual logs or redundant backup sensors to ensure uninterrupted oversight.
- **Calibration & Preventive Maintenance:** Temperature monitoring equipment and storage units undergo routine calibration and preventive maintenance. Certificates are retained and available for monitor review.
- **Segregation of Quarantined/Returned Inventory:** Returned, expired, or quarantined IPs are stored separately from active inventory, clearly labeled, and inaccessible for dispensing until sponsor disposition is determined.
- **Handling Participant Returns:** Returned IPs from participants (including empty or partially used vials) are documented under the patient profile and segregated until sponsor instructions are received. Certain hazardous materials may require special handling.
- **Remote/Satellite Site Oversight:** In the event of multi-site studies, MSM IDS oversees satellite storage and dispensing processes, including qualification, monitoring, and reconciliation of inventory.
- **Delegation of Authority & Training:** IDS pharmacists participate in study planning, pharmacy review of the protocol and Investigator Brochure, and are documented on the delegation of authority log as appropriate. Staff roles in IRT systems are restricted to trained personnel.
- **Sponsor Monitor Visits**: During monitoring visits, IDS provides accountability logs, temperature records, excursion reports, and calibration certificates for review. Sponsors should schedule visits at least two weeks in advance and coordinate patient returns separately from monitoring visits by emailing IDS@MSM.EDU.
- **Document Retention:** All pharmacy records—including packing slips, temperature logs, calibration and maintenance records, excursion reports, and destruction/return certificates—are archived per institutional and regulatory requirements and are available for sponsor or regulatory audits.

Revision History

- Review Cycle: Annually
- Current Version Published on: 10/01/2025
    - Approved by: Noor Mohamed, PharmD
- Last Revised: N/A
    - Approved by: N/A
- **Previous Versions**
    - Version 1: 10/01/2025