POLICY:
The pharmacists and pharmacy technicians of the Investigational Drug Service (IDS) are responsible for coordinating investigational/clinical drug studies approved by the Biomedical Sciences Institutional Review Board (IRB), James Cancer Institutional Review Board, or an external IRB. Operational activities performed by IDS staff include drug acquisition, inventory management, investigational drug distribution, and investigational drug accountability. Investigational drug supplies are handled and dispensed in accordance with applicable legal, institutional, professional, and agreed upon sponsor requirements.

These procedures incorporate the standards established by Alliance of Dedicated Cancer Centers (ADCC) Investigational Drug Service (IDS) Subcommittee.

ABBREVIATIONS:
- DARF: Drug Accountability Record Form
- eDARF: electronic Drug Accountability Record Form
- C: Celsius
- CFR: Code of Federal Regulations
- CITI: Collaborative Institutional Training Initiative
- CSTD: Closed System Transfer Device
- DOA: Delegation of Authority
- EDC: Electronic Data Capture
- F: Fahrenheit
- FDA: Food and Drug Administration
- GCP: Good Clinical Practice
- HIPAA: Health Insurance Portability and Accountability Act
- ICH: International Council of Harmonisation
- IDS: Investigational Drug Service
- IIT: Investigator Initiated Trial
- IP: Investigational Product
- IRB: Institutional Review Board
DEFINITIONS:

Ancillary staff: All pharmacy staff other than the IDS pharmacists responsible for oversight of the investigational drug study as denoted on the delegation of authority. Ancillary staff includes all other pharmacists, pharmacy technicians, residents, and interns. The pharmacy technicians and pharmacy interns shall work under the direct supervision of a licensed pharmacist.

Authorized prescriber: An individual who is eligible to prescribe IP based on sponsor requirements and meets state and federal requirements for prescribing IP.

Co-investigator: An individual who has appreciable involvement in the design, conduct, and/or analysis of a research project.

Control pharmacy (location): Refers to the IDS location, where investigational drug is received, stored, and central accountability is maintained. It is the pharmacy listed as the shipping designee on the FDA form 1572; the control pharmacy is therefore authorized by the study principal investigator to deliver (transport) investigational agents to the institution’s satellite pharmacies.

Expiration Date: Date beyond which ideally stored medications in the unopened manufacturer's storage container or in most circumstances, the unopened and intact manufacturer's storage container, should not be used.

Expired Drug: Drug whose expiration date has passed.

Institutional Review Board: Committee comprised of scientists, physicians, clergy, and consumers to protect subjects who take part in research studies. The IRB reviews protocols to ensure the study is well-designed, does not involve undue risks, and includes safeguards for human subjects. Upon review, the IRB must approve all studies before protocols become open for accrual and investigational medication can be received.

Investigational approval: Determination of the IRB that the clinical investigation has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and Federal requirements.

Investigational drug/product: Pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about approved use.

Investigational protocol: An action plan for a clinical trial. The plan states what will be done in the study and why. It outlines how many people will take part in the study, what types of subjects may take part, what tests they will receive and how often, and the treatment plan.

Joint Commission: Accreditation body that certifies health care organizations and programs in
the United States.

**Principal investigator**: Scientist or scholar with primary responsibility for the design, conduct, and analysis of a research project.

**Production label**: Label printed with each dispense that is the pharmacy record of that dispense. The production label includes who prepared and checked the final product.

**Satellite pharmacy (location)**: Decentralized pharmacy dispensing location of investigational drug within The Ohio State University Department of Pharmacy. Each satellite pharmacy shall maintain their own DARFs, designated as “satellite DARFs” which reconcile with the inventory of the control location.

**Sponsor**: A person or other entity that takes responsibility for and initiates a clinical investigational trial.

**Supplier**: A person or organization that provides IP or supplies to IDS.

**Unused drug**: Drug remaining after all patients are off of drug treatment.

**United States Pharmacopeia**: A scientific nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed, and consumed worldwide. Standards are enforceable in the US by the FDA.

**TABLE OF CONTENTS**:

**SOP-01: Inventory Management of IP**
- A. Ordering of IP
- B. Ordering IP from NCI
- C. Ordering IP from the Pharmaceutical Industry
- D. Ordering IP from a Wholesaler
- E. Receipt
- F. Dispensing
- G. Electronic or Paper DARFs
- H. IRT
- I. Expiration/Re-test Dates
- J. Temperature Monitor Devices During Shipment (e.g. TempTale®)
- K. Product Labeling by Suppliers
- L. Maintaining Inventory of Drug Supplies
- M. Study Supplied Tubing and Supplies
- N. Laboratory Use of IP
- O. Mailing of IP to Patients
- P. Storage and Security
- Q. Reporting of Adverse Drug Reactions to IP

**SOP-02: Temperature Monitoring and Excursion Procedures**
- A. Temperature Monitoring
- B. Temperature Settings
- C. Temperature Excursions

**SOP-03: IP Returns and Destinations**
- A. Hazardous Substance Determination
- B. Empty and Partially Used IP Containers
- C. Used IV Bags and Supplies
- D. Oral Patient Returns
- E. Unblinded/Open label Tear Off Labels
- F. Samples
- G. Expired/Unused IP (Excluding NCI IP)
- H. Destruction
I. NCI IP

SOP-04: Satellite Transfers
   A. Control Location
   B. Internal Transfers
   C. External Transfers

SOP-05: Safe Handling and Compounding
   A. Hazardous Drugs
   B. Sterile Compounding
   C. Gene Therapy
   D. Investigational Radiopharmaceuticals
   E. Investigational Cellular Therapies

SOP-06: Regulatory Items
   A. Delegation of Authority
   B. Ancillary Staff
   C. Training of Ancillary Staff
   D. Study-Specific Time Points and Documentation Items
   E. Preparation Worksheets
   F. Documentation of IDS Staff Qualifications
   G. Record Requirements
   H. Pharmacy Access to Protocols
   I. Authorized Prescribers
   J. Other Record Storage

SOP-07: Sponsor Personnel Expectations
   A. Prior to Study Opening
   B. Scheduling a Monitor Visit
   C. During the Monitor Visit
   D. After the Monitor Visit
   E. Other Expectations

SOP-08: IP Protocol Review
   A. Initial Review
   B. Study Opening

SOP-09: Terminated Studies
   A. Study Closing
   B. Close Out Visit
   C. Record Requirements

SOP-10: Emergency Use of IP
   A. FDA Criteria
   B. Investigator Responsibilities
   C. IDS Involvement

SOP-11: Handling Patient’s Own Medication of IP Not Managed by IDS
   A. IP from Another Institution
   B. Non IDS-Managed OSUWMC Studies

SOP-12: Request for Waiver of OSUWMC IDS SOPs
   A. Waiver Process
1. Objective
To ensure that IDS and all pharmacy personnel involved in the conduct of clinical research are aware of their obligations and responsibilities as they pertain to GCP, the investigational plan, applicable regulations, guidances, and institutional policies.

This SOP describes the inventory management of IP for clinical research conducted at OSUWMC. These detailed, written instructions create consistency in conducting clinical research at OSUWMC to ensure compliance.

2. Attachments
1. Sample Non-Oral IP Accountability Log
2. Sample Oral IP Accountability Log

3. Definitions
Please refer to the definitions provided at the beginning of the OSUWMC IDS SOPs. Additional, information can be found by referring to the GCP SOP Glossary document.¹

4. Procedures
IDS will assure that the receipt, accountability, disposition, and all record keeping concerning IP complies with FDA and institutional requirements as well as those of state and local guidelines. IDS will maintain drug accountability in compliance with 21 CFR §312.62 and the FDA’s Compliance Guidance Manual for drug accountability requirements. No sponsor-based forms will be utilized for drug accountability.

A. Ordering of IP
IP is typically obtained via:
- National Cancer Institute (NCI)
- Pharmaceutical Industry
- Wholesaler (e.g. Cardinal)

Protocol inventory must be received in IDS before the pharmacy’s study activation can take place. Exceptions include those protocols in which patient registration is required prior to shipment of inventory by the Sponsor or Supplier.

IP shipments are to be delivered directly to the appropriate IDS pharmacy control location.
- For Non-Oncology studies: IDS Main (Doan Office) in 342 Doan Hall
- For Oncology studies: IDS James (James Office) in C150N
  - Please reference cover page for full shipping addresses.
In an instance when IP is shipped directly to a physician’s office, or other location, it is the responsibility of the individual receiving the shipment to arrange delivery to IDS.

**B. Ordering IP from NCI**
Upon receiving full approval from both IRB and NCI, IDS can order IP provided by the NCI. IDS must verify the protocol has been approved and activated prior to ordering IP. Once a study is activated a member of IDS will place an order for IP through the NCI’s OAOP system. The NCI may restrict ordering until a patient is in screening.

**C. Ordering IP from the Pharmaceutical Industry**
For IP from pharmaceutical companies the ordering process will be discussed with individual sponsors at the SIV or coordinated through the study monitor. Upon receiving full approval from the IRB and at the PI’s request to activate the study, the study will be activated. Once IDS is notified that inventory is to be ordered, designated pharmacy personnel will complete the required documentation.

When able a member of IDS will place an order for IP through the sponsor’s preferred mechanism. In cases where the initial supply of IP is sent automatically from the sponsor, a member of IDS will notify the study team when IP is available on site. IDS will be responsible for securing and reordering drug supplies for all research protocols with inventory managed by IDS. This does not include inventory managed outside of IDS (sponsor uses an electronic system that automatically generates orders).

**D. Ordering Commercially Available IP from a Wholesaler**
This may occur in rare scenarios such as:
- IITs
- Sponsor will reimburse the wholesale acquisition cost

Purchases from a wholesaler are based on a package size. The study will be charged for the entire package size ordered at the time of purchase. An invoice will be provided upon request. Prior to the commercially available IP’s expiration or at study closure an attempt will be made to transfer remaining inventory to another area of the pharmacy department and the study reimbursed for the cost relative to the transferred inventory. However, there is no guarantee that this can occur.

**E. Receipt**
Upon receipt of a shipment of IP, an IDS staff member will verify the following items against the protocol and shipping invoice:
- drug name
- strength
- formulation
- quantity
- manufacturer name and address
- lot or batch number
- patient-specific information, if applicable
- expiration/retest date
- storage conditions

If any discrepancies are noted upon receipt, the technician will notify an IDS pharmacist and study sponsor immediately and appropriate actions will be taken according to specific instructions provided by the sponsor and/or protocol in accordance with applicable regulations.
Upon receipt of a shipment of IP, the IDS staff member must acknowledge shipment by following the steps outlined by the sponsor on the shipping information.

**F. Dispensing**

All IP administered or dispensed to an OSUWMC patient for inpatient use must contain an OSUWMC prescription label. All IP administered or dispensed to an OSUWMC patient from IDS for outpatient use must have an OSUWMC prescription label or similar prescription label that complies with labeling requirements dictated by the Ohio State Board of Pharmacy.

IP is dispensed through OSUWMC’s electronic medical record, Epic© upon pharmacist receipt and review of an authorized prescription, in compliance with applicable legal, institutional, and professional standards.

For oral IP, if dispensing an intact bottle is required, the minimum sufficient quantity using intact bottles will be dispensed. If the quantity to be dispensed is not outlined in the protocol, the dispensing pharmacy staff will dispense the minimum sufficient quantity.

For studies where IDS prepares IP for off-campus clinics/infusion suite locations without an on-site pharmacy, IDS uses Best Courier, an OSUWMC partnered local bonded courier company for deliveries.

**G. Electronic or Paper DARFs**

IDS uses an electronic accountability system Vestigo™ (McCreadie Group) for the majority of studies. In rare cases an OSUWMC developed paper DARF may be used instead. The default accountability format uses the NIH drug accountability record form (NIH-2564) for all IP receiving, dispensing, transferring and disposal. No sponsor-based forms will be utilized for drug accountability.

All OSUWMC accountability forms capture the essential elements as outlined in the IDS best practice standards.² Elements include:

- Institution Name
- PI Name
- Protocol Title and Number
- Agent Name, Strength, and Formulation
- Dispensing Location
- Recorder Initials and Date
- Transactions (receipts-date, quantity, lot number, and expiration; dispensing-subject information, date, dose, quantity, lot number; transfers-date, quantity, location; disposition-unused drug returns and/or destruction)
- Lot number and quantity on hand

For Vestigo™, the initial risk analysis was conducted by the hospital's Data Security team. This risk analysis is available for review upon request. After this initial analysis the software developer releases version changes when updates are made to the system. These version changes are sent to the IDS team. Each version change is reviewed by a member of IDS and Pharmacy IT team to determine if any change may impact the risk analysis. If any changes are flagged as a potential impact then the institution's Data Security team is consulted and the risk analysis adjusted accordingly.
The control location will be IDS James or IDS Main. A satellite DARF will be maintained at each location where IP is stored other than the control location. Separate DARFs will be prepared for each agent, strength, and formulation. DARFs will be available to the study sponsor upon request and may be reviewed as part of the site-visit monitoring.

For some studies at OSUWMC, double accountability may be required. Double accountability means that two IDS or pharmacy personnel sign off on the accountability. Accountability is not the same as dispensing and therefore different individuals may be involved in the two processes. OSUWMC does not dictate that both accountability checks must be completed by pharmacists or that the pharmacist must be the second check for accountability. This differs from dispensing where the IP check must be completed by pharmacists only, which aligns with institutional and state requirements.

Drug accountability will only be maintained for the IP supplied by the sponsor or procured by IDS as study-supplied on behalf of the sponsor for use on the clinical research trial (these are agents provided at no cost to the patient). IDS will not provide accountability, lot numbers, or expiration dates to sponsors for non-study-supplied commercial agents or standard of care medications.

Ancillary supplies (e.g. standard syringes, infusion bags, tubing, etc.) provided by the sponsor may be tracked at the discretion of IDS for an additional fee.

**H. IRT**

The primary function of IDS will be to provide verification in the IRT system of IP receipt. IDS will not utilize the IRT/EDC to document IP accountability, which is already documented in the DARF. Instead, if this is required by the sponsor, the study team may make an arrangement with the sponsor to fulfill this requirement.

IDS must be provided with an adequate number of access codes determined by IDS for IRT access prior to the initiation of a trial and if required, will participate only in pharmacy-based training. The sponsor must ensure IP assignments from IRT will be sent to IDS. A mechanism must be designed by the sponsor and/or study team to allow assignments to be relayed to IDS via a secured fax system or email. However, fax is preferred.

**I. Expiration/Re-test Dates**

The sponsor is required to provide IDS with an expiration or re-test date for the IP at the time of shipment or upon request. This can be labeled on the container or equivalent documentation. Not receiving an expiration or re-test date in a timely manner could result in the IP being placed into quarantine, and this may result in unavailability of the IP to patients.

In the event that the IP container needs to be re-labeled with updated re-test information, IDS will not assume the responsibility of the re-labeling. Instead, the sponsor shall send a representative/study monitor to IDS for re-labeling purposes. This task shall be completed in a timely manner before the expiration. Otherwise, the IP could be quarantined and may result in unavailability of the IP to patients.

In cases where it is determined that there is no other option but to use supply waiting to be re-labeled, IDS may choose to dispense the IP labeled with a sticker that says “Do not use after (new expiration or re-test date)”. This may be done at the discretion of the IDS personnel in an effort to prevent delays in therapy.
In cases where a multi-month dispense of intact bottles is required per protocol, IDS may dispense a supply of IP that will expire prior to the dispense being filled as long as all three of the following conditions are met:

- The patient is scheduled to return prior to the IP’s expiration date.
- The study team is aware of the upcoming expiration.
- A sticker that says “Do not use after (expiration date)” is applied.

**J. Temperature Monitor Devices During Shipment (e.g. TempTale®)**

IDS staff will follow sponsor instructions regarding reporting of in-transit temperature. The temperature monitor product should enable the staff to retrieve the necessary information and submit as outlined on the shipping documentation. If a temperature monitoring device is noted to be out of range the IP will be placed in quarantine until otherwise directed by the sponsor. A printed copy of the temperature report will be retained in the IDS study binder/folder. IDS will not retain any temperature monitors after shipment for review by study personnel at a later time. Should the sponsor require return of the temperature monitoring device, a prepaid shipping method must be provided at the time the IP is shipped.

**K. Product Labeling by Suppliers**

The supplier must deliver inventory with labeled containers (individual bottle or vial). Unlabeled containers will not be accepted. The Alliance of Dedicated Cancer Centers proposed the following labeling requirements.

- It is recommended that a minimum size 8 font with name in bold be used.
- Mandatory items:
  - Complete Name of Product (e.g. nab-paclitaxel, or salt form when more than one exists)
  - Dosage/Concentration
  - Formulation
  - Quantity
  - Lot/Batch Number
  - Storage Conditions
- Additional items:
  - Name and Address of Manufacturer
  - Expiration Date (if available)
  - CFR Statement: Caution; new drug – limited by US or Federal law to investigational use.

Inventory that does not include labeling as described above will be reviewed by IDS and a decision will be rendered as to its acceptability. This may result in unavailability of the IP to patients. If bottles do not contain appropriate labeling, it will be the responsibility of the sponsor or sponsor’s representative to ensure the bottles are appropriately relabeled prior to use.

All IP dispensed must have OSUWMC-specific labeling that complies with all prescription labeling requirements set by the Ohio State Board of Pharmacy. The previous statement does not apply to IP dispensed patient-specific from a non-OSUWMC pharmacy (e.g. Biologics) where OSUWMC IDS receives the already dispensed IP. OSUWMC-specific labeling will not obscure the study sponsor’s labeling. OSUWMC-specific labeling includes:

- patient name or initials
- medical record number
- date
- prescription number
- study drug name
o directions for use
o quantity
o name of prescribers (take home investigational only)
o initials of individual preparing IP
o Initials of dispensing pharmacist(s).

**L. Maintaining Inventory of Drug Supplies**

Under no circumstances shall any IP bearing the label "Investigational Drug: Limited by Federal Law to Investigational Use" be used as regular pharmacy stock.

To initiate the trial in a timely manner, the sponsor shall supply sufficient IP as designated by institutional target accrual. In those rare instances where starter supply cannot be shipped prior to opening of the trial, the study team will be notified and confirm agreement to proceed.

If the sponsor is controlling IP re-supply, it is the sponsor’s responsibility to ensure that the IDS pharmacy has adequate supply on hand for trial continuation and future enrollment.

For IP stored in an IDS control location inventory is maintained perpetually. For IP stored in a satellite location a physical inventory must be conducted once every quarter.

**M. Study Supplied Tubing and Supplies**

It is preferred that OSUWMC provided ancillary supplies are used as this provides for staff familiarity with the product, and ensures that the product works with OSUWMC infusion pumps and devices. Appropriate exceptions to this practice include known compatibility issues. Lack of data from the sponsor is not a sufficient reason for requiring other supplies as these supplies may not work with OSUWMC devices. If sponsor ancillary supplies are required due to incompatibility, sample supplies must be provided in advance for testing and training.

**N. Laboratory Use of IP**

When laboratory needs to obtain IP for use in non-human studies that are being conducted, the laboratory shall contact the appropriate supplier for that IP and request that the IP be shipped. No IP supplied for clinical use will be supplied to a laboratory from IDS unless the sponsor and/or the IND holder authorize the release of that IP for non-clinical use. If verbal authorization is obtained from the sponsor, written documentation of such authorization shall be made immediately and a copy retained.

**O. Mailing of IP to Patients**

This option should only be used in emergencies or when the study team determines that a patient would be unable to receive their IP in person. IP can be mailed to patients if all of the following conditions are met:

- Mailing of IP is permitted per protocol and authorized by the PI and study sponsor.
- The drug will be mailed to a patient within the state of Indiana, Kentucky, Ohio, or West Virginia.
  - Rare exceptions to mail to a patient within another state may be made at the discretion of a member of the pharmacy leadership team.
- The drug will be mailed using a traceable method such as UPS or FedEx.

Please note that mailing of NCI-sponsored IP is prohibited.

**P. Storage and Security**

In pharmacy locations where both IP and commercial drug is stored, IP will be stored separately from commercial supplies. IP will be stored as directed by the study protocol, the study sponsor,
or package insert. IP yet to be dispensed will only be stored in pharmacy locations. Access is limited to pharmacy personnel via badge access or keys.

Investigational controlled substances will be handled in accordance with institutional policies, state, and federal requirements.

Q. Reporting of Adverse Drug Reactions to IP
It is the responsibility of the investigator to report to the study sponsor and the IRB any adverse effects that may reasonably be regarded as caused by, or probably caused by an IP.

5. References
Attachment 1: Sample IP (Non-Oral) Accountability Record

<table>
<thead>
<tr>
<th>Line No.</th>
<th>Date</th>
<th>Patient's Initials</th>
<th>Patient's ID No.</th>
<th>Dose</th>
<th>Quantity Dispersed or Received</th>
<th>Balance Forward</th>
<th>Manufacturer and Lot No.</th>
<th>Recorder's Initials</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Attachment 2: Sample Oral IP Accountability Record

<table>
<thead>
<tr>
<th>Line No.</th>
<th>Date</th>
<th>Patient’s Initials</th>
<th>Patient’s ID No.</th>
<th>Dose</th>
<th>Quantity Dispensed or Received</th>
<th>Balance Forward</th>
<th>Balance</th>
<th>Manufacturing Lot No.</th>
<th>Recorder’s Initials</th>
<th>Expiration Date (if available)</th>
<th>Date Patient Returned</th>
<th>Quantity Patient Returned</th>
<th>Recorder’s Initials</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
IDS SOP-02
Temperature Monitoring and Excursion Procedures

1. Objective
To ensure that IDS and all pharmacy personnel involved in the conduct of clinical research are aware of their obligations and responsibilities as they pertain to GCP, the investigational plan, applicable regulations, guidances, and institutional policies.

This SOP describes temperature monitoring and excursion procedures of IP for clinical research conducted at OSUWMC. These detailed, written instructions create consistency in conducting clinical research at OSUWMC to ensure compliance.

2. Attachments
1. Sample Temperature Log

3. Definitions
Please refer to the definitions provided at the beginning of the OSUWMC IDS SOPs. Additional, information can be found by referring to the GCP SOP Glossary document.

4. Procedures
IDS will assure that all IP is maintained at the appropriate temperature.

A. Temperature Monitoring
IDS uses a continuous temperature monitoring system, Isensix©. The system will be calibrated on an annual basis by a manufacturer trained representative. Please note that the calibration certificate does not include an expiration date, rather it lists the last date of calibration. Each calibration is good through the end of the month one year after calibration (e.g. calibration on April 20, 2016 is good through April 30, 2017). Further, the calibration device used for calibration may expire prior to the end of the calibration range. However, per manufacturer trained representatives, as long as the device is not expired at the time of calibration then the 1 year allowance remains in effect.

In addition to the continuous temperature monitoring system the refrigerators and freezers are wired into a Hospital Security Department system that provides continuous 24-hour surveillance. Staff is notified as soon as possible via telephone or paging system if, at any time, the temperature varies from the acceptable range. If a refrigerator or freezer malfunctions and temperatures exceed the acceptable range, IP will be transferred to a similar, working, monitored unit within the Pharmacy Department. A 48-hour observation period will occur in case of a unit malfunction. The temperatures and condition of the unit will be observed prior to return of inventory to the unit. In the event of a temperature deviation, any IP inventory in question will be quarantined in the appropriate storage conditions until the IP is deemed appropriate for use.
The quarantined inventory will be segregated from other IP and clearly marked as not for patient use.

Laboratory specimens and food are not permitted in IDS refrigerators or freezers. All refrigerators or freezers used for storing to-be-dispensed IP will be plugged into receptacles with emergency back-up power or have a battery backup.

Refrigerators on patient care units have temperature monitoring devices that meet Joint Commission requirements. However, these refrigerators are not connected to continuous monitors. Temperature reports will not be provided for these refrigerators.

A sponsor-provided temperature monitor will not be used in addition or in place of OSUWMC’s system.

B. Temperature Settings
- Controlled Room Temperature: 20° to 25° C (68° to 77° F)
- Refrigerated Temperature: 2° to 8° C (36° to 46° F)
- Freezer Temperature: -25° to -20° C (-13° to -4° F)
- Currently, there are not established USP standards for Ultra Low Freezer Temperatures. As such, IDS will follow: Ultra Low Freezer Temperature: -80 to -70° C (-112 to -94° F)

C. Temperature Excursions
IDS will provide notification of temperature excursions via the sponsor required process. However, in determining an excursion, the temperature will be rounded to the nearest degree (e.g. a room temperature at 14.5° C will not be considered an excursion since it rounds to 15° C.). Based on USP temperature standards controlled room temperature medications reportable excursions are defined as a temperature deviation of >±5°C from the acceptable temperature range as defined above, sustained for a contiguous time period of up to 24-hours as experienced in pharmacies and hospitals. For refrigerated and frozen medications we define reportable excursions as a temperature deviation of >±1°C, sustained for a contiguous time period of up to 30 minutes. IDS will quarantine IP until sponsor-representative approval is received from the sponsor.

5. References
Attachment 1: Sample Temperature Log
1. Objective
To ensure that IDS and all pharmacy personnel involved in the conduct of clinical research are aware of their obligations and responsibilities as they pertain to GCP, the investigational plan, applicable regulations, guidances, and institutional policies.

This SOP describes the procedures related to returns and destruction of IP for clinical research conducted at OSUWMC. These detailed, written instructions create consistency in conducting clinical research at OSUWMC to ensure compliance.

2. Attachments
NA

3. Definitions
Please refer to the definitions provided at the beginning of the OSUWMC IDS SOPs. Additional, information can be found by referring to the GCP SOP Glossary document.¹

4. Procedures
Beginning in 2018 the pharmacy department is required to comply with USP <800> standards.² These standards were created to minimize employees’ exposure to hazardous medications. USP <800> also requires comprehensive training on hazardous drug handling. These standards apply to all employees including visitors to the OSU pharmacy department that comes into contact with drugs (e.g. monitors).

A. Hazardous Substance Determination
During the study opening phase, an IDS pharmacist will review all of the available information about the IP and make a determination whether the IP should be considered a hazardous substance or not. This decision will follow the guidelines dictated by USP <800>, NIOSH, and OSUWMC’s Hazardous Substances List. When IDS is not able to determine clearly whether an IP is considered a hazardous substance or not we will defer to classifying it as a hazardous substance as stipulated in USP <800>.² USP <800> requires specific considerations for the receipt, storage, handling, preparation, and administration of all hazardous IP.

B. Empty and Partially Used IP Containers
In order to mitigate unnecessary staff and sponsor personnel drug exposure all empty and partially used containers of IP will be disposed of immediately after use into the appropriate hazardous waste stream containers. This includes empty boxes. Containers originally storing oral IP where the remaining dosage units will be dispensed at a later time will be will be retained until empty, at which time the container will be disposed of into the appropriate hazardous waste
stream container. To ensure appropriate accountability (without saving vials) the pharmacy may require double accountability (two signatures) for all accountability records. A separate record of destruction will not be maintained for used or partially used vials during IP preparation.

C. Used IV Bags and Supplies
Once the IP is administered to the patient it is considered hazardous waste and therefore will be disposed of immediately after use into the appropriate hazardous waste stream containers. IDS will not under any circumstances accept the return of used injectable agents such as syringes and IV bags.

D. Oral Patient Returns
Oral IP patient returns will be accounted for by both the study team and pharmacy. The study team will provide the first count followed by a second count performed by IDS staff. IDS staff will reconcile the count returned with the research coordinator. After reconciliation the IP will be immediately discarded as part of the waste stream system. A sponsor requirement to retain oral patient returns for further reconciliation by a monitor may be assessed an additional charge if approved by IDS. The return date listed by pharmacy will be the date that the return is processed. This means the return date may not match the date listed by the study team as the study team’s return date will be the date the study team processed the order.

E. Unblinded/Open Label Tear Off Labels
Due to double accountability performed by pharmacy, IDS does not retain unblinded/open label tear off labels. IDS may agree to retain unblinded/open label tear off labels for an additional charge.

F. Samples
Samples derived from prepared doses or packaged products will not be retained for sponsor purposes (i.e. testing for bioavailability, stability, etc.)

G. Expired/Unused IP (Excluding NCI IP)
IP that expires and unused IP remaining after all patients are off treatment will be retained for 60 days after expiration, unless the sponsor makes a prior agreement with IDS to store IP for a longer period. At the end of the 60 days or agreed extension any remaining expired IP will be destroyed per the Hazardous Waste Disposal Policy. A note indicating that the medication was destroyed per OSUWMC policy will be added to the appropriate DARF.

H. Destruction
All empty containers/vials or partially-used non-oral IP, including any ancillary supplies used in their preparation will be disposed of immediately after use into the appropriate hazardous waste stream containers. All potential patient identifiers on IP packaging will be removed, concealed, or destroyed per institutional guidelines. These containers are collected by Stericycle®, the OSUWMC contracted toxic waste company. Stericycle is responsible for transport of returned IP to an offsite location for final destruction by incineration. This is completed in accordance with institutional waste control policies, OSHA and USEPA regulations. Since IP is prepared in various dispensing pharmacy locations it may be combined with commercial supply waste.

I. NCI IP
Any unused/unopened or expired IP will be, transferred to another appropriate NCI protocol, returned to the NCI, or destroyed onsite per institutional guidelines within 90 days following the completion of research IP dosing by the last subject on the protocol. Any IP labeled a
Dangerous Good (as notated on shipping documentation) will be destroyed per institutional guidelines. All other returns will be sent back to the NCI within the 90-day timeframe. To facilitate timely returns a member of the research team must notify IDS when the last subject on the protocol at that site has completed IP dosing.

5. References
IDS SOP-04
Satellite Transfers

1. Objective
To ensure that IDS and all pharmacy personnel involved in the conduct of clinical research are aware of their obligations and responsibilities as they pertain to GCP, the investigational plan, applicable regulations, guidances, and institutional policies.

This SOP describes the procedures related to satellite transfers of IP for clinical research conducted at OSUWMC. These detailed, written instructions create consistency in conducting clinical research at OSUWMC to ensure compliance.

2. Attachments
1. Example Satellite Transfer Sheet

3. Definitions
Please refer to the definitions provided at the beginning of the OSUWMC IDS SOPs. Additional, information can be found by referring to the GCP SOP Glossary document.1

4. Procedures

A. Control Location
For all Oncology studies, IDS James is considered the control location. This means that all IP shipments are initially received at the location and transferred to satellite locations as appropriate. All transfers are documented on the relevant drug accountability record form.

For all Non-Oncology studies, IDS Main is considered the control location. This means that all IP shipments are initially received at the location and transferred to satellite locations as appropriate. All transfers are documented on the relevant drug accountability record form.

B. Internal Transfers
Transfers to satellites located within the walls of the medical center are considered “internal” transfers. This means that the transfer can occur without ever exiting the building and therefore preventing any exposure to the external temperatures. All internal transfers occur quickly as all locations are within 5 minutes of each other and drug is directly transported from the control location to the satellite location. Due to the limited time and exposure no temperature monitoring is conducted during transfer.

C. External Transfers
Transfers to satellites not located within the walls of the medical center are considered “external” transfers because IP cannot be moved from one location to another without exiting
the walls of the medical center. The majority of external transfers occur within a five-mile radius. Even for further locations most deliveries occur within half an hour. OSUWMC has partnered with Best Courier, a local bonded courier company for external deliveries. These transfers are considered stat and the courier is expected to pick up and deliver the IP within 1 hour of receiving a call to pick up. In rare cases, an OSUWMC pharmacy member will transport the product when urgency necessitates.

At the time of transfer the IP is prepared and checked by two IDS pharmacy personnel. A Satellite Transfer Sheet (Attachment 1) is filled out with all IP being transferred per receiving location. At the time of receipt a pharmacy ancillary staff member from the satellite location reviews the transferred IP, Satellite Transfer Sheet, and indicates on that sheet the final status of the IP. This form is then signed and faxed back to the control location. A copy of this fax is retained.

During transfer room temperature items are transferred in a box or empty cooler. Refrigerated items are transferred in a cooler with frozen ice packs to maintain the appropriate temperature. Frozen items are transferred in an appropriate container with dry ice. Due to the short transit time no temperature monitoring is conducted during transfer.

5. References
Attachment 1: Example Satellite Transfer Sheet

Ohio State University Medical Center
Department of Pharmacy-Investigational Drug Service
Satellite Transfer Sheet

☐ Satellite: JamesCare (MMMP)
Address: 2050 Kenny Rd. Rm 1103
Telephone: 3-5326

☐ Satellite: Comprehensive Breast Center (CGB) 1145 Olentangy
River Rd. Rm 4200
Telephone: 3-5350

☐ Satellite: Mill Run
Address: 3651 Ridge Mill
Hilliard, OH 43026 Ph: 5-6842

Sent by: IDS Pharmacy

Date sent: ________________ Time sent: ___________ am / pm Initials ________________

<table>
<thead>
<tr>
<th>Physician</th>
<th>Protocol</th>
<th>Drug</th>
<th>Strength / Form</th>
<th># Vials / Bottles</th>
<th>Lot #</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

☐ send chemotherapy in a chemo transport bag

PLEASE CHECK THIS DOCUMENT AGAINST THE SUPPLIES THAT YOU HAVE RECEIVED. COMPLETE THE INFORMATION REQUESTED BELOW AND FAX THIS FORM TO IDS @ 685-5013. IF THERE ARE PROBLEMS, OR YOU HAVE ANY QUESTIONS, PLEASE CONTACT:

IDS Pharmacy Technicians
Investigational Drug Service-Department of Pharmacy
Ohio State University Medical Center
460 West Tenth Avenue, Room C150N
Columbus, OH 43210
(614) 293-4560 Fax: (614) 685-5013
Pharmacy.ids@osumc.edu

Received by: ___________________________ Condition of supplies received:

Date Received: ___________________________ Satisfactory: ______

Time Received: ________________ am / pm Unsatisfactory: _____ (Explain below)
1. Objective
To ensure that IDS and all pharmacy personnel involved in the conduct of clinical research are aware of their obligations and responsibilities as they pertain to GCP, the investigational plan, applicable regulations, guidances, and institutional policies.

This SOP describes the procedures related to safe handling and compounding of IP for clinical research conducted at OSUWMC. These detailed, written instructions create consistency in conducting clinical research at OSUWMC to ensure compliance.

2. Attachments
NA

3. Definitions
Please refer to the definitions provided at the beginning of the OSUWMC IDS SOPs. Additional, information can be found by referring to the GCP SOP Glossary document.

4. Procedures
Per USP <800> IP must be handled as hazardous unless adequate information becomes available to conclude that the IP is not hazardous. Specific precautions, staff training and competency, and other procedures are outlined as below. For applicable studies a copy of each policy will be made available upon request.

IDS will comply with institutional guidelines regarding hazardous drug management. OSUWMC requires the use of CSTDs for all hazardous drug preparation and administration. At OSUWMC we use PhaSeal™ products. In compliance with USP <800>, IDS will utilize PhaSeal™, unless indicated otherwise by the sponsor. IDS may request that a sponsor test their IP for compatibility with PhaSeal™. IDS may request data supporting a sponsor’s request to not use PhaSeal™. A lack of data about compatibility with PhaSeal™ will not be considered a sufficient reason for a sponsor’s waiver request regarding the use of CSTDs. Due to pharmacy and nursing unfamiliarity with other CSTD products, OSUWMC IDS will not use an alternative CSTD product if requested by the sponsor.

A. Hazardous Drugs
Reference the Hazardous Drugs which Require Medication Exposure Precautions policy

B. Sterile Compounding
Reference the Compounded Sterile Preparations (CSPs) Policies and Procedures policy
C. Gene Therapy
Reference the *Handling Recombinant DNA Agents (Gene Therapy) policy*\(^5\)

D. Investigational Radiopharmaceuticals
Investigational radiopharmaceuticals are not handled by IDS. Such agents are handled by the OSUWMC Nuclear Pharmacy.

E. Investigational Cellular Therapies
Investigational cellular therapies may or may not be managed by IDS. This determination is made with input from the appropriate department (e.g., apheresis/therapeutic phlebotomy or blood bank) prior to study opening.

5. References
1. Objective
To ensure that IDS and all pharmacy personnel involved in the conduct of clinical research are aware of their obligations and responsibilities as they pertain to GCP, the investigational plan, applicable regulations, guidances, and institutional policies.

This SOP describes the procedures related to regulatory items regarding IP for clinical research conducted at OSUWMC. These detailed, written instructions create consistency in conducting clinical research at OSUWMC to ensure compliance.

2. Attachments
NA

3. Definitions
Please refer to the definitions provided at the beginning of the OSUWMC IDS SOPs. Additional, information can be found by referring to the GCP SOP Glossary document.1

4. Procedures

A. Delegation of Authority
Essential IDS personnel complete study-required training and are listed on the DOA. These individuals assume responsibility for those items delegated to him or her by the PI and oversight of ancillary staff for completing study-related procedures.

B. Ancillary Staff
Pharmacy staff not listed on the DOA is considered “ancillary staff”. Ancillary staff is defined as all pharmacy staff other than those individuals listed on the DOA. This may include all other pharmacists, pharmacy technicians, pharmacy residents, and pharmacy interns. IDS pharmacy technicians are not listed on the DOA. Per Ohio Revised Code (ORC) 4729.42 “a qualified pharmacy technician means a person who is under the personal supervision of a pharmacist”. In Ohio, pharmacy technicians are not licensed health care professionals and as such, all technician activities require general oversight by a pharmacist. Since a pharmacy technician requires the oversight of a pharmacist, all IDS pharmacy technicians are considered ancillary staff.

C. Training of Ancillary Staff
All OSUWMC pharmacists are trained by IDS on proper procedures for dispensing IP, how to complete accountability records, and how to read investigational-related documents. To provide study-specific training to ancillary staff, IDS prepares a procedure summary that outlines the key
parts of the protocol and pharmacy manual that a verifying or dispensing pharmacist must follow
to successfully dispense the IP. There may be isolated studies where additional training is
provided live or via a weekly departamental communication. Up-to-date versions of the procedure
summary are maintained on the pharmacy’s intranet. Updates and changes from previous
versions are highlighted, as well as the new version date added to notify the reader that the
study was recently updated. The step-by-step IP preparation instructions (from procedure
summary) are also included on the production label (label that prints with each dispense) to
instruct staff how to prepare the product. Ancillary staff is required to review the relevant pieces
of the procedure summary and/or step-by-step drug preparation instructions on the production
label prior to verifying/dispensing an IP. Documentation of training is captured by the following:
- Order verification: Verifying pharmacist(s) is captured in Epic®
- Accountability: Captured in DARF or eDARF
- Compounding: The compounder signs the production label
- Final check: The pharmacist(s) signs the production label

D. Study-Specific Time Points and Documentation Items
Often there are study-specific time points and documentation items requested. Some examples
include: time removed from freezer, time of preparation, and infusion start and stop times. Some
of these time points may already be collected in Epic®. For example, the nursing staff
documents infusion start and stop times in the medication administration record. This is
considered source documentation and IDS will not duplicate this information elsewhere.

For other study-specific time points and documentation items requested not already collected in
source documentation IDS will work with the sponsor to identify a place to document this
information. In most cases this information will be added to the OSUWMC accountability log or
documented on the production label.

E. Preparation Worksheets
For all IP an electronic prescription is built in Epic®. The prescription build includes all of the
necessary calculations. This process is automatic and void of human error that can occur during
manual calculations. As such, IDS will not use sponsor-provided preparation worksheets.
Instead, all calculations will occur within Epic®.

F. Documentation of IDS Staff Qualifications
All regulatory items will be maintained in the study team’s regulatory binder. This includes:
- Pharmacist CVs
- Pharmacist proof of CITI training
- Pharmacist proof of GCP training
- Pharmacist license (if requested)
- Pharmacy license (if requested)
- Proof of DOA-listed pharmacist study-required training
- DOA
- Printed versions of protocols, amendments, Investigational Brochures, etc.
These items may be viewed by scheduling time with the study team to review the regulatory
binder. The pharmacy will not retain duplicate copies of source documents maintained by
regulatory or the study team. Study related IRB-approved documents, such as protocols are
stored electronically via the relevant trial management office’s clinical trials management
system.

G. Record Requirements
All study-related records will be maintained for two years after approval of the marketing application by FDA or two years after discontinuation or withdrawal of the application and FDA has been notified (21 CFR §312.62). Pharmacy records will be maintained within the IDS pharmacy while the study is open and for one year after. After a one year period all pharmacy study records may be transferred to a secure off-site location that is readily retrievable. OSUWMC uses Fireproof for off-site record storage. Fireproof’s address is 3827 Brookham Drive, Grove City, OH 43123.

**H. Pharmacy Access to Protocols**
For oncology studies all protocols are available via OnCore®, an electronic clinical trial management system managed by the OSUWMC Clinical Trials Office.

For all Non-Oncology studies the pharmacy department maintains a shared folder, accessible only to pharmacy and IDS staff, housing all active protocols with IDS involvement. The initial and subsequent versions of the protocol are distributed to IDS via the Clinical Research Coordinator.

**I. Authorized Prescribers**
For Oncology studies a list of authorized prescribers is included in the “Staff” tab of OnCore®, an electronic clinical trial management system managed by the OSUWMC Clinical Trials Office.

For all Non-Oncology studies where electronic drug accountability record forms are used the pharmacy department maintains a list of authorized prescribers. For non-Oncology studies with paper drug accountability forms, the study team completes a paper order form that requires the signature of an authorized prescriber. The study team is responsible for ensuring that only authorized prescribers are writing for IP.

**J. Other Record Storage**
Receipts, invoices, packing slips, and other related study documents will be kept with study specific paperwork in the IDS pharmacy. In an effort to go “green” and conserve storage space IDS tries to store most records electronically rather than in printed form. In many cases IDS has created an electronic study folder with relevant documents and records.

5. **References**
1. Objective
To ensure that IDS and all pharmacy personnel involved in the conduct of clinical research are aware of their obligations and responsibilities as they pertain to GCP, the investigational plan, applicable regulations, guidances, and institutional policies.

This SOP describes the procedures related to sponsor personnel expectations for clinical research conducted at OSUWMC. These detailed, written instructions create consistency in conducting clinical research at OSUWMC to ensure compliance.

2. Attachments
NA

3. Definitions
Please refer to the definitions provided at the beginning of the OSUWMC IDS SOPs. Additional, information can be found by referring to the GCP SOP Glossary document.\(^1\)

4. Procedures
In order to balance patient care needs and ensure successful pharmacy operations, the following will be required of sponsor personnel.

A. Prior to Study Opening
The monitor, or back up support to the monitor, that is sent to the pharmacy, should be well versed with the protocol and have thorough understanding of study-related pharmacy requirements. If the monitor cannot readily address a question or issue, he or she is expected to acquire needed information and respond to IDS in a timely manner. Failure to respond in a timely manner may result in IDS escalating the question or issue further. Contact information for an alternate responsible person, as well the immediate supervisor for the study monitor, shall be available to IDS prior to study initiation and IDS will be informed in a timely manner regarding changes in aforementioned responsible personnel.

IDS will provide the sponsor with appropriate SOPs only once at the time of initiation or if an update occurs. Sponsor personnel are expected to share these documents with the sponsor and any monitors that are assigned to OSUWMC. A sponsor representative will sign the \textit{Acknowledging Receipt of OSUWMC IDS SOPs} document acknowledging that a copy of the IDS SOP was provided. For any procedures deemed unacceptable by the sponsor, a \textit{Request for Waiver of OSUWMC IDS SOPs} form must be requested in writing prior to the study opening date. These requests should only be made when patient safety, research or IP integrity will be compromised by adherence to the OSUWMC IDS SOPs. Supporting documentation including
sponsor SOPs, ICH, or GCP guidance may be requested by OSUWMC as justification for waiver requests. IDS personnel will review all waivers and work with the sponsor personnel to reach a mutually agreeable resolution. In some cases waivers may be reviewed and approved/denied by pharmacy and/or hospital leadership. Waiver requests may incur additional fees not included in the original budget. Please allow 2 weeks for review and approval. In the event that no waiver of policies is requested prior to study opening then it will be assumed that all policies are acceptable to the sponsor for IP management.

B. Scheduling a Monitor Visit
To accommodate the high volume of clinical trials, the monitor shall schedule a visit two weeks in advance. Pharmacy monitoring visits are scheduled separately from the study team. In instances where the study requires an immediate visit after the first patient is enrolled this two week notice may be waived. The monitor is expected to let IDS know as early in advance for these visits. IDS spends a significant amount of time preparing for a monitor visit. Therefore, the monitor shall respect the schedule of other study monitors and IDS staff and arrive on time for his/her visit. Cancelling or rescheduling a visit should be done with at least 48-hours’ notice of the visit. Rescheduling of the visit is done at the discretion and availability of IDS staff. If a monitor is running more than 20 minutes late for a scheduled appointment then the monitor shall call or email IDS to let IDS know that they are running late. Should a monitor run late, their visit time may be limited to the time slot that was scheduled or may need to be re-scheduled at a later time. Rescheduling of the visit or increase in time allowance is done at the discretion and availability of IDS staff.

C. During the Monitor Visit
Each monitor visit is scheduled to last no more than two hours. If more time is needed the monitor may request two hour visits on two subsequent days. Extending the time allowance for a visit is left to the availability and discretion of IDS staff. IDS personnel will set up a space for the monitor to work. The monitor is expected to bring a laptop to the visit to access the electronic accountability records during the visit. Paper copies of electronic accountability records will not be provided. Most documents are provided in a pdf format so the monitor can save the file, print at a later time, and share with other sponsor personnel.

During the visit, monitors will be assisted by IDS technicians. A pharmacist will be available for any questions or issues. If any significant issues are identified during the monitor visit, then a pharmacist must be notified prior to the monitor leaving the pharmacy. The monitor may not remove any documents from the study binder (if applicable) or study folder other than to make a photocopy. The monitor assumes responsibility for de-identifying any patient information (if needed). The study binder/folder and any of its documents may not be removed from the pharmacy.

Depending on the dispensing location, IP may remain stored in its usual location. To view the IP the monitor may need to visit the dispensing pharmacy. If this is needed the monitor will be accompanied by IDS personnel or satellite pharmacy staff. When entering sterile areas (e.g. IV rooms) the monitor will be required to garb appropriately. IDS personnel will be available to help with this. During the monitor visit he or she may be exposed to hazardous drug. In accordance with USP <800> the monitor will be expected to comply with institutional policies around hazardous drug handling. IDS personnel will be responsible for notifying sponsor personnel of this requirement. Any non-compliance with this requirement may be reported to the monitor’s manager or sponsor personnel. Continued failure to comply with these requirements may result in the monitor not being allowed to visit IDS in future visits.
Many regulatory items are maintained in the study team’s regulatory binders. Copies of these items are not maintained in the pharmacy binder. SOP-6 contains more specific information about these items. The regulatory binder can be viewed by setting up time with the study team. IDS will not have the regulatory binder present during the pharmacy monitor visit.

At the end of each monitor visit, the monitor is expected to provide notice of any findings or concerns to IDS staff. Every attempt should be made to rectify issues prior to the end of the visit. The monitor is also expected to leave notation within the accountability records of what was reviewed.

D. After the Monitor Visit
The monitor is expected to provide IDS with a monitoring report that includes a summary of items reviewed and the monitor’s statements concerning significant findings/facts, deviations and deficiencies, conclusions, actions taken or to be taken, and/or actions recommended to secure compliance. IDS will address all findings, deviations and deficiencies presented by the monitor within a specified timeline that is acceptable to the sponsor and the investigational site. Any corrective actions will be documented and filed appropriately.

E. Other Expectations
IDS shall be notified when a change in monitor occurs. It is expected that all documents provided to the previous monitor will be passed to the new monitor. It is expected that the current monitor will file documents such that they will be available to future monitors. Specific temperature logs will only be provided once per time point. Requests for records previously provided may incur an extra charge. Documents requested after the close out visit is complete may incur an extra charge to the sponsor.

The monitor is expected to ensure that inventory on site is sufficient, inventory on hand is accurate, and that all IP is stored appropriately. This is extremely important for automatic supplied IP since IDS is not involved in managing the inventory. The monitor shall ensure that IDS has the most up-to-date version of the pharmacy manual.

5. References
1. Objective
To ensure that IDS and all pharmacy personnel involved in the conduct of clinical research are aware of their obligations and responsibilities as they pertain to GCP, the investigational plan, applicable regulations, guidances, and institutional policies.

This SOP describes the procedures related to investigational drug protocol review for clinical research conducted at OSUWMC. These detailed, written instructions create consistency in conducting clinical research at OSUWMC to ensure compliance.

2. Attachments
NA

3. Definitions
Please refer to the definitions provided at the beginning of the OSUWMC IDS SOPs. Additional, information can be found by referring to the GCP SOP Glossary document.¹

4. Procedures

A. Initial Review
Proposed IP studies are reviewed by IDS pharmacists and relevant ancillary staff (e.g. clinical pharmacy specialist) for feasibility and compliance with applicable institutional and professional standards. Some of these feasibility items include, but are not limited to:
- pharmaceutical and clinical pharmacy requirements
- assessment of IP handling issues
- implementation requirements
- development of procedures for IP preparation at each dispensing site
- packaging, labeling, and storage requirements
- inventory records
- computer entries
- pharmacy reimbursement procedures

To aide in this review IDS will submit a feasibility review form for the sponsor to complete. Failure to respond may extend the time to study opening. IDS pharmacists and specialty practice pharmacists are responsible for reviewing proposed IP studies as members of or consultants to the Biomedical Sciences IRB, James Cancer IRB, Clinical Scientific Review Committee (CSRC of The James Cancer Hospital and Solove Research Institute), and other committees, as applicable. A proposed IDS service fees summary (budget) will be provided to the relevant budget office. Budgets including IP acquisition costs are subject to change as IP pricing is not static. Budgets may be adjusted from the initial proposed budget to account for
sponsor request for a waiver of OSUWMC IDS policies. Additional budget adjustments may occur for required after hours or OnCall IDS services.

**B. Study Opening**

IDS creates a procedure summary that outlines important pieces of the protocol and pharmacy manual for ancillary staff. Included in the procedure summary are items such as IP location, preparation instructions, and randomization/blinding information. The procedure summary is uploaded to the pharmacy intranet, which is available to all pharmacy staff. IDS works with the pharmacy informatics team to complete electronic prescription builds for each IP. An electronic prescription in Epic® is required for any dispense of a study with IDS participation. Paper order forms may be used for some Non-Oncology studies for locations where Epic® is not commonly used. However, the order will be transcribed by a pharmacist into Epic® prior to dispensing.

IDS will work with the study team and sponsor representatives to resolve any outstanding items prior to study opening.

**5. References**

IDS SOP-09
Terminated Studies

1. Objective
To ensure that IDS and all pharmacy personnel involved in the conduct of clinical research are aware of their obligations and responsibilities as they pertain to GCP, the investigational plan, applicable regulations, guidances, and institutional policies.

This SOP describes the procedures related to terminated studies for clinical research conducted at OSUWMC. These detailed, written instructions create consistency in conducting clinical research at OSUWMC to ensure compliance.

2. Attachments
NA

3. Definitions
Please refer to the definitions provided at the beginning of the OSUWMC IDS SOPs. Additional, information can be found by referring to the GCP SOP Glossary document.¹

4. Procedures

A. Study Closing
Upon notification of the last patient completing treatment or study closing, IDS will contact the monitor to schedule a close out visit within 60 days of said notification. All IP and supplies will be returned or destroyed based on the sponsor’s requirements. IP remaining after a study is closed will be retained for 60 days to allow the monitor to complete the close out visit. At the end of the 60 days, IP will be destroyed per OSUWMC’s Hazardous Waste Disposal Policy, unless a prior agreement is reached with IDS. A note indicating that the IP was destroyed per OSUWMC policy will be added to the appropriate DARF. For IITs, when there isn’t a monitor, IDS will document and destroy any unused/expired IP and supplies.

B. Close Out Visit
It is expected that the monitor will request all needed documents and information prior to or during the close out visit. Requests occurring after the close out visit for additional copies or data may be subject to additional charges. No IP will be retained on site once the close out visit has occurred.

C. Record Requirements
Refer to SOP-06: Regulatory Items.

5. References
1. Objective
To ensure that IDS and all pharmacy personnel involved in the conduct of clinical research are aware of their obligations and responsibilities as they pertain to GCP, the investigational plan, applicable regulations, guidances, and institutional policies.

This SOP describes the procedures related to emergency use of IP for clinical research conducted at OSUWMC. These detailed, written instructions create consistency in conducting clinical research at OSUWMC to ensure compliance.

2. Attachments
NA

3. Definitions
Please refer to the definitions provided at the beginning of the OSUWMC IDS SOPs. Additional, information can be found by referring to the GCP SOP Glossary document.¹

4. Procedures

A. FDA Criteria
The FDA criteria² permitting an IP to be used for treatment under a treatment protocol or treatment IND are:

- The IP is intended to treat a serious or immediately life-threatening disease;
- There is no comparable alternative drug or other therapy available to treat that stage of the disease in the intended patient;
- The IP is under investigation in a controlled clinical trial under an IND in effect for the trial, or all clinical trials have been completed; and
- The sponsor of the controlled clinical trial is actively pursuing marketing approval of the investigational drug with due diligence.

B. Investigator Responsibilities³
To obtain an IP/biologic for “emergency use” a physician must contact the sponsor or the FDA with specific information about the proposed circumstances for use. The clinical investigator is required to obtain informed consent from the subject or the subject’s legally authorized representative (except in certain situations), and an IND for the drug’s use is also necessary. Emergency use of an IP or biologic is exempt from FDA requirements for IRB review if the emergency use is reported by the physician to the IRB within five working days. Approval is limited to the single emergency use of the IP for the treatment of one subject by one clinical investigator.
C. IDS Involvement
IP for emergency use should be shipped directly to IDS. IDS should be contacted prior to the expected arrival of the IP. The treatment team should notify the IDS as soon as possible if additional IP supplies will be needed following the initial treatment course.

IDS is responsible for the proper storage, labeling, dosage preparation, dispensing, and accountability of all IP and for ensuring that adequate information about the IP is available. IDS will obtain verification of informed consent (or its waiver) prior to initial dispensing of the IP.

The clinical investigator is responsible for completing all sponsor documentation of the IP’s use; DARFs can be completed by IDS, as applicable.

5. References
IDS SOP-11
Handling Patient’s Own Medication of IP Not Managed by IDS

1. Objective
To ensure that IDS and all pharmacy personnel involved in the conduct of clinical research are aware of their obligations and responsibilities as they pertain to GCP, the investigational plan, applicable regulations, guidances, and institutional policies.

This SOP describes the procedures related to how a patient’s own medication of IP should be handled conducted at OSUWMC. These detailed, written instructions create consistency in conducting clinical research at OSUWMC to ensure compliance.

2. Attachments
NA

3. Definitions
Please refer to the definitions provided at the beginning of the OSUWMC IDS SOPs. Additional, information can be found by referring to the GCP SOP Glossary document.

4. Procedures
This SOP provides guidance on how to handle IP not managed by IDS during an inpatient/observation visit at OSUWMC. This SOP is based on FDA guidance regarding when subjects enter a second institution. For purposes of this SOP, OSUWMC serves as the second institution.

A. IP from Another Institution
This may occur when a subject in a research study conducted by non-OSUWMC faculty becomes a patient of the medical center, and the OSUWMC physician has determined that it is appropriate to continue study participation. Since OSUWMC is providing incidental medical care and is not participating as a research site the OSUWMC IRB does not need to review the protocol. Further, the responsibility of IP administration, follow-up, and conduct, remains with the research site. Therefore, the research site should be notified of the patient’s admission as follow-up may be required (e.g. reporting of an adverse event).

Ultimately, the patient’s OSUWMC treatment team is responsible for determining the appropriateness of continuing the patient’s IP upon admission. It is highly recommended that the treatment team contact the originating institution’s study team to provide notification of the admission and request relevant information about the study including specific information about the IP (e.g. side effects, drug interactions, monitoring parameters, and adverse effects).
If the OSUWMC treatment team deems continuation of the IP to be necessary then the pharmacy may proceed as described in the pharmacy policy “Handling of Patients’ Own Medications”.

Here are some tips for finding more information about a patient’s clinical trial:
1. Review the patient’s medication to see if a phone number, emergency contact, or research site information is provided.
2. Ask the patient or patient’s family members if they possess an emergency contact or phone number.
3. Ask for a copy of the informed consent. The informed consent gives basic information about the trial including risks.
   - The patient or patient’s family member may have this information readily available.
   - If not, ideally this should be obtained from the research site once contacted.
4. Review clinicaltrials.gov to see what other relevant study information is publicly available.
5. Is the drug available in another study managed by OSUWMC? If so, some information including side effects and monitoring parameters should be discussed in the protocol, Investigator’s Brochure, and/or pharmacy manual for the OSUWMC-managed study.

Please note that the research site may require a release of information form signed by the patient prior to providing any information.

**B. Non IDS-Managed OSUWMC Studies**
This may occur when a subject in a research study conducted by OSUWMC faculty becomes a patient of the medical center and the OSUWMC treatment team has determined that it is appropriate to continue study participation. However, the patient is on a study not managed by IDS. The OSUWMC treatment team should contact a member of the study team to provide notification that the patient is admitted and discuss continuation of treatment. Basic information about the study and a study contact can be found by reviewing the Research tab in Epic®.

**5. References**
1. Objective
To ensure that IDS and all pharmacy personnel involved in the conduct of clinical research are aware of their obligations and responsibilities as they pertain to GCP, the investigational plan, applicable regulations, guidances, and institutional policies.

This SOP describes the procedures related to requesting a waiver of OSUWMC IDS SOPs for clinical research at OSUWMC. These detailed, written instructions create consistency in conducting clinical research at OSUWMC to ensure compliance.

2. Attachments
1. Request for Waiver of OSUWMC IDS SOPs

3. Definitions
Please refer to the definitions provided at the beginning of the OSUWMC IDS SOPs. Additional, information can be found by referring to the GCP SOP Glossary document.¹

4. Procedures
A waiver process is in place for any OSUWMC IDS procedures deemed unacceptable by the sponsor. These requests should only be made when patient safety, research, or IP integrity will be compromised by adherence to the OSUWMC IDS policy. Supporting documentation, including sponsor SOPs, ICH, or GCP guidance, may be requested by OSUWMC as justification for waiver requests.

A. Waiver Process
Waivers must be requested prior to study opening and may incur an additional charge. Completing a waiver request does not guarantee approval. IDS personnel will review all waivers and work with the sponsor personnel to reach a mutually agreeable resolution. In some cases waivers may be reviewed and approved/denied by pharmacy and/or hospital leadership. The PI or study team may be consulted to aide in determining a resolution. Please allow 2 weeks for review and approval.

All waivers and budget adjustments should be addressed and completed prior to study opening. In the event that no waiver of policies is requested, it will be assumed that all policies are acceptable to the sponsor for IP management.

Amendments may require a waiver. In those cases IDS personnel will assume responsibility for identifying that a waiver is required. Additional charges may be incurred.
5. References
A sponsor representative will sign the *Acknowledging Receipt of OSUWMC IDS SOPs* document acknowledging that a copy of the OSUWMC IDS SOPs was provided. For any procedures deemed unacceptable by the sponsor, there must be a waiver of policies requested in writing prior to the study opening date. These requests should only be made when patient safety, research or IP integrity will be compromised by adherence to the OSUWMC IDS SOPs. Supporting documentation, including sponsor SOPs, ICH, or GCP guidance, should be submitted along with this request as justification for waiver requests. IDS personnel will review all waivers and work with the sponsor personnel to reach a mutually agreeable resolution. In some cases waivers may be reviewed and approved/denied by pharmacy and/or hospital leadership. Waiver requests may incur additional fees not included in the original budget. Please submit all forms to pharmacy.ids@osumc.edu. Please allow 2 weeks for review and approval. In the event that no waiver of policies is requested prior to study opening then it will be assumed that all policies are acceptable to the sponsor for IP management.

### Section 1: (To be completed by sponsor personnel)

<table>
<thead>
<tr>
<th>Sponsor Protocol #:</th>
<th>PI:</th>
<th>OSU Assigned #:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submitted By:</td>
<td>Title/Role:</td>
<td></td>
</tr>
<tr>
<td>Phone:</td>
<td>Email:</td>
<td></td>
</tr>
<tr>
<td>Signature:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Section 2: (To be completed by sponsor personnel)

<table>
<thead>
<tr>
<th>Specific SOP Section Affected (e.g. SOP-12 4A)</th>
<th>Reason for Request</th>
<th>Additional documentation provided**</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Section 3: (To be completed by IDS, pharmacy, or hospital leadership)

<table>
<thead>
<tr>
<th>OSUWMC Decision</th>
<th>Additional Fees Required</th>
<th>Signature/Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Only 1 request per form
**Additional documentation (e.g. sponsor SOP, ICH, GCP guidance) should be sent with this request as an attachment.*
This form is documentation that the sponsor’s representative received a copy of the OSUWMC IDS SOPs. Completion of this form is required prior to study opening. It is the expectation of IDS that the sponsor’s representative share the OSUWMC IDS SOPs with the sponsor.

For any procedures deemed unacceptable, there must be a completed Request for Waiver of OSUWMC IDS SOPs prior to the study opening date. These requests should only be made when patient safety, research or IP integrity will be compromised by adherence to the OSUWMC IDS SOPs. Supporting documentation, including sponsor SOPs, ICH, or GCP guidance, should be submitted along with the request as justification for waiver requests. IDS personnel will review all waivers and work with the sponsor personnel to reach a mutually agreeable resolution. In some cases waivers may be reviewed and approved/denied by pharmacy and/or hospital leadership. Waiver requests may incur additional fees not included in the original budget. Please submit all forms to pharmacy.ids@osumc.edu. Please allow 2 weeks for review and approval.

In the event that no waiver of policies is requested prior to study opening then it will be assumed that all policies are acceptable to the sponsor for IP management.

**Sponsor Representative Section**

<table>
<thead>
<tr>
<th>Printed Name</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**IDS Representative Section**

<table>
<thead>
<tr>
<th>Printed Name</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Revision Date of OSUWMC IDS SOPs Provided: 

Effective Date: 07/01/2017  Revision Date: 07/01/2017