OHSU

Research Pharmacy Services: Research Medication and Study Management Policy

Doc. #: HC-PHR-256-POL Rev. 031622	Category: Pharmacy Services: Research Related	
Origination Date: 03/21/2017	Effective Date: 03/16/2022	Next Review Date: 03/15/2023
Reviser (Title): Pharmacy Compliance	Owner (Title): Research Pharmacy Manager	

PURPOSE:

This policy describes processes that must be observed for research medication management and record keeping by Research Pharmacy Services.

PERSONS AFFECTED:

This policy applies to OHSU Healthcare Pharmacy workforce members involved in research studies that involve medications managed by the Research Pharmacy.

POLICY:

Medications utilized in research at OHSU are overseen by the Research Pharmacy. These include studies involving medications in all phases of evaluation. Research Pharmacy will follow regulatory, institutional, and study specific requirements regarding the initiation, maintenance, termination, and archiving of study documents involving medications. Board of Pharmacy and OHSU policies will be followed when dispensing research medications.

DEFINITIONS:

1. Dispensed medications: Investigational product assigned to a specific patient
2. Electronic Clinical Research Information System (eCRIS): An electronic system used to manage clinical research studies at OHSU
3. Electronic Accountability System (Vestigo™): A web based software program that records research medication disposition and maintains protocol documents and training logs.
4. Epic: OHSU electronic health record software
5. IP: Investigational product
6. OHSU Logistics and Transportation Services: Departments on the OHSU campus responsible for supply chain management and delivery needs
7. Principal Investigator (PI): The person with primary responsibility for a research study
8. Research Medication: Investigational, repackaged or relabeled medication intended for administration to research subjects in OHSU Healthcare facilities or medications that must be charged to a research account
9. RPS: Research Pharmacy Services
10. Satellite Pharmacy: A Pharmacy which provides research medications and which is dependent upon the Research Pharmacy for administrative control and drug procurement. Satellite Pharmacies will be responsible for on-site drug inventory accountability, order verification, and research medication preparation and dispensing.
11. SOP: Standard Operating Procedure

12. Study Regulatory Binder: A study specific file maintained by the study team containing all of the required regulatory documentation for the study
13. Willow: OHSU Outpatient/Retail Pharmacy electronic health record software

KEY WORDS:

Research Pharmacy, RPS, Vestigo™

RESPONSIBILITIES:

It is the responsibility of all Research Pharmacy staff, Pharmacists working in Satellite Pharmacies with research medications, and research study personnel for studies involving research medications to comply with this policy and procedure.

POLICY REQUIREMENTS:

1. Staffing and Hours of Operation
    a. Research Pharmacy Services (RPS) hours are 0800 to 1630, Monday through Friday. The Pharmacy is closed on weekends and on OHSU recognized holidays.
        i. Hours of operation for Satellite Pharmacies vary.
    b. An RPS Pharmacist is on pager call 24 hours a day and 7 days a week to answer study related questions.
    c. On site appointments for auditors and inspectors are available Tuesday – Thursday between 0900 – 1200 and 1300 – 1600. Auditors and inspectors will not have access to RPS on Mondays or Fridays. On-site appointment requests appointments at least 6 weeks in advance to guarantee availability.
1. All routine monitoring and audit preparation will be done remotely using Vestigo™ access and email communication only. Remote access to Vestigo™ is available at any time for monitors, auditors, and inspectors. Access can be requested by emailing invdrugs@ohsu.edu during RPS hours of operation.
2. Pharmacy Access
    a. Research medications are stored will be secured by locked badge entry doors. Badge entry access is restricted to Pharmacy staff. Access to the Pharmacy is monitored and controlled by Pharmacy staff.
    b. After normal business hours the Pharmacy is locked with additional key access bolts. The key to these locks is only provided to Pharmacists.
    c. The narcotic cabinet is secured by a digital lock. Access is only given to Pharmacists.
3. Scope of Service
    a. Management of research medications is the responsibility of the OHSU Pharmacy. The definition of a research medication is outline in Policy Investigational Medication Dispensed to Research Subjects.
4. Study Start-up
    a. Pre Site Initiation Visit (PSIV) and Site Initiation Visit (SIV):
        i. An RPS staff member will be available to the PI, study team, or sponsor for pre-site and site initiation visits via email or pre-arranged phone meeting.
            1. PSIV: RPS SOPs and pictures will be sent to study team or sponsor via email, in lieu of a pharmacy tour. All follow-up questions should be emailed to invdrugs@ohsu.edu or asked at the SIV.
            2. SIV:

a. A meeting with the Lead Pharmacist will be scheduled as a teleconference.
b. RPS SOPs and pictures will be sent to study team or sponsor via email, in lieu of a pharmacy tour. All follow-up questions should be emailed to invdrugs@ohsu.edu.

b. eCRIS Review:
   i. RPS is notified of studies requiring RPS services via an electronic notification through eCRIS. An RPS Pharmacist will review the study materials to determine the feasibility of conducting the study utilizing RPS. Feasibility assessment will include analysis of drug quantity, storage requirements, additional supplies needed, randomization details, preparation requirements and complexity, location of dispense, timing of doses, and unique drug specific information.
   ii. RPS will review the eCRIS budget for appropriateness of RPS fees and approve the budget or request changes.
c. Electronic Orders:
   i. All research orders are required to be electronic and ordered through Epic. The protocol, pharmacy manual, and other supporting materials will be used to create electronic orders and order sets.
      1. IP orders for oncology research require a Beacon plan. More information regarding this process can be found on the Beacon Protocol Bridge site located at https://bridge.ohsu.edu/health/pharmacy/beacon-protocol/SitePages/Home.aspx
      2. IP administered in the CTRC require an infusion plan requested by the study coordinator. More information regarding this process can be found on the Beacon Protocol Bridge site located at https://bridge.ohsu.edu/health/pharmacy/beacon-protocol/SitePages/Home.aspx
      3. Research Medication files that do not require a Beacon plan or infusion plan will be built into a Smart Set by Epic Research.
   ii. RPS Pharmacists will create an Epic build request to be submitted to Pharmacy Informatics. Pharmacy Informatics will build an Epic drug file using the information provided by Research Pharmacy. These drug files will be built into the Beacon plan, infusion plan, or Smart Set by Pharmacy Informatics. Research medications are pre-built in the Epic and use “INV” and medication name as identifiers. Both identifiers print on the dispensing labels.
   iii. Infusion reaction orders will be built following the OHSU Treatment Algorithm for Acute Infusion Reaction Adults or Treatment Algorithm for Acute Infusion Reaction Pediatrics. Exceptions to these policies must be reviewed by the PI, RPS and nursing.
d. Interactive Voice Response System (IVRS)/Interactive Web Response System (IWRS):
   i. If the study utilizes IVRS/IWRS for shipment confirmations, all Research Pharmacy staff will be provided access by the sponsor.
   ii. Patient enrollment, randomization, and kit assignments in IVRS/IWRS will be performed by the study coordinator and the information will be forwarded to RPS unless Research Pharmacy are the only unblinded OHSU staff. In this case, RPS will request the randomization.

5. Electronic Pharmacy Binder
   a. RPS Pharmacists will use the information provided in the protocol and other supporting materials to create an electronic Pharmacy binder in Vestigo™ which will include the following elements:
      i. Protocol Information: The protocol name, basic study design, protocol number, eIRB number, IRB status, and IRB expiration.

ii. Pharmacy instructions: A brief description of the research medication, the study dosing, and study specific instructions including receipt, storage, maintenance, dispensing, and return/destruction of the research medication.
iii. Epic Catalog: Information regarding the dosing, preparation and administration of the research medication.
iv. The following documents will be scanned and uploaded to Vestigo™ and will be available for monitor review:
    1. Shipping Document and Disposition Forms
    2. Medication Expiration and Extensions
    3. Patient Specific Worksheets
    4. Production Labels
    5. Sponsor and Study Team Correspondence (As deemed appropriate by RPS staff, i.e. if correspondence is pertinent to study procedures)
v. Pharmacy Protocol Training as described below in section 6.b.iii.

b. Copies of the protocol and investigator's brochure will not be maintained in the electronic Pharmacy binder. An electronic copy of these documents is available on the OHSU electronic IRB (eIRB). Documents (ie. pharmacy manual) not included on eIRB will be stored on the RPS network folder (x: drive). All protocol material reviewed and approved by the IRB or provided by a study sponsor is to remain confidential. The material may not be released, except to the sponsor, FDA, and associated regulatory agencies, or used for any reason except for the purposes of conducting studies at OHSU.
c. Amendments and New Study Documents: The study team is responsible for notifying RPS of any protocol amendments and new study documents related to the study medication. RPS will review these documents and make any necessary updates to the dispensing guidelines.

6. Protocol Training
    a. Delegation of Authority
        i. For each study only one RPS Pharmacist will be required on the main study delegation of authority by the PI. All other RPS staff will be delegated responsibilities and duties under the authority of the primary RPS Pharmacist. A list of all RPS personnel and their dates of employment in RPS will be maintained and be made available for review.
    b. Pharmacy Training
        i. All Pharmacy staff that perform study specific tasks will be trained by the RPS Pharmacist listed on the Delegation of Authority Log for the study prior to performing study tasks.
        ii. The delegated RPS Pharmacist will develop a procedure based on protocol documents which aid in the appropriate preparation and dispensing of research medications. This procedure and any other supporting documentation, as determined by the RPS Pharmacist, will serve as training for Pharmacy staff working in RPS.
            1. Training materials will be available to additional staff prior to the need to participate in study related activity.
            2. Each RPS staff member will acknowledge training in the Vestigo™ after training materials are reviewed. Training instruction for sterile compounding will be located on the production label that contains preparation instructions. Individuals performing sterile compounding will read and acknowledge training by initialing the production label under the preparation instructions. Vestigo™ training acknowledgement is not required.

iii. New protocol training will be documented in response to protocol amendments. Protocol amendments will be reviewed by an RPS Pharmacist and changes will be made to Pharmacy procedures as necessary. A summary of Pharmacy related changes will be electronically shared with all other RPS staff previously trained on the study. Documentation of training for new amendments will be maintained in Vestigo™.
    1. A copy of the Vestigo™ training log can be downloaded from Vestigo™.
    2. Documentation of training on documents that supplement the protocol (i.e. Pharmacy Manual) will not be created.
iv. Training logs should be downloaded from Vestigo™.
v. Form FDA 1572
    1. Pharmacy personnel will not be listed on study Form FDA 1572s.
    2. A list of RPS personnel, including CVs and licenses, will be maintained and will be readily available upon request.

7. Research Medication Procurement and Ordering
    a. For NCI studies, upon receiving notice of patient enrollment, research medications may be ordered from NCI by an RPS Pharmacist with ordering credentials. It is the responsibility of the study team to notify Pharmacy of patient enrollment.
    b. If initial or recurring drug supply is not sent automatically, RPS must be provided the procedure for ordering by the study team or sponsor.
    c. Inventory is ordered in a quantity to maintain a minimum of one-month drug supply or as space allows. Minimum par and reorder points are set in Vestigo™ and are based on patient enrollment. Instructions for reordering can be found in Vestigo™.
    d. Commercial products used for research studies will be procured through Cardinal using wholesale acquisition pricing.
    e. Shipping address:
        i. Shipments will be sent to the following address:
            1. Research Pharmacy Services
                a. Center for Health and Healing Building 2 (CHH2)
                b. 3303 S Bond Ave Suite 12270
                c. Portland, OR 97239
        ii. OHSU Logistics is the contracted direct courier for OHSU research medications, and guarantees secure and timely delivery of all research medications from the loading dock to RPS. Each shipment will remain intact and unopened until it has reached RPS, where it is unpacked, inventoried and appropriately stored according to specified storage conditions.
        iii. Substances with a CI classification must be ordered by the Principle Investigator with a valid CI DEA license. RPS will provided secure drug storage and accountability of the inventory.
8. Receipt of Research Medication
    a. Receipt of inventory is handled on the same day of arrival to RPS.
    b. Receipt of research medication is documented in Vestigo™. Inventory information will include the following:
        i. Product name, strength, description, lot/batch number, and expiration date if known
        ii. Quantity received utilizing appropriate units (bottle, vial, tablets, capsules)
        iii. Location to be stored within Control Pharmacy
        iv. Ordering investigator if applicable
        v. Date received as noted on the shipping invoice

vi. Patient/subject assignment if known

c. Shipment checklist:
   i. Two RPS staff members will complete and initial the shipment checklist to verify that the shipment content matches the shipment invoice and the product is received in good condition. Receipt is documented correctly in Vestigo™, and the inventory is stored in the correct location.
d. The date and time of receipt will be written on the shipment checklist.
e. Expiration date or retest notifications will serve as source documents for updates to the inventory expiration dating. These documents will be uploaded and maintained in Vestigo™.
f. Shipment invoice instructions will be followed to acknowledge receipt of the shipment.
g. All shipment receipts and the RPS shipment checklist will be scanned and maintained in Vestigo™. The paper copy will be disposed of as confidential information.
h. For shipments containing a temperature monitoring device, the temperature is read, recorded, and the temperature monitoring device is destroyed unless the shipment contains return instructions and packing supplies needed to return the device.
i. Any product that is received with a noted temperature excursion or if deviations from the shipping receipt are identified, the product will be quarantined until further instructions are received from the study team or study sponsor (see Inventory Quarantine below). Additional instructions and final medication disposition will be documented in Vestigo™.
j. Inventory that is maintained in the 4C pharmacy satellite will be received at RPS and transferred to the satellite pharmacy by RPS staff on the same day or next business day. This transfer is documented in Vestigo™.
k. Transfer of research medications between protocols may occur only under specific circumstances after approval from the sponsor. Transfer of NCI products between studies will follow NCI guidelines.

9. Inventory Storage and Maintenance
   a. Research medications will be stored under appropriate temperature conditions and in a secure location. The medication for each study is stored in a separate bin labeled with the IRB number or study IND number. Research medications will be stored separately from any standard of care medications.
   b. Temperature is continuously monitored on all refrigerators, freezers, and drug storage areas containing research medications.
      i. For temperature readings outside of Research Pharmacy standard ranges, protocol information will be used to determine if a temperature deviation occurred. Temperature deviations will be managed according to Research Pharmacy Services Temperature Monitoring policy
      ii. For medications purchased from the OHSU commercial supplier (i.e. Cardinal), the Refrigerator and Freezer Temperature monitoring and Management policy will be followed.
      iii. Temperature logs, calibration certificates, and notes to file (NTF) regarding temperature events will be uploaded to Vestigo™ as a PDF document for the sponsor/monitor to view/download. The logs will not be printed or signed by Research Pharmacy. Temperature logs do not contain protocol specific information. This information will not be added to the document. The temperature report will contain he name of the RPS staff member that initiated the report. This will serve as proof that the document originated from RPS.
      iv. Only completed month temperature logs will be uploaded to Vestigo™. Current month temperature logs should be requested via email to invdrugs@ohsu.edu.

c. Expirations:
    i. All research medication expirations are audited every month. This task will be documented in Simplifi.
    ii. The following procedure will be followed in the event that expiration dating is not provided on the medication packaging:
        1. RPS Pharmacy staff will contact the sponsor to determine if the batch/lot has a known expiration or if the sponsor will maintain expiration reports and notify RPS of expired medications.
            a. A two week retest date will be assigned to the inventory received. This will trigger further follow-up if the sponsor has not supplied expiration information in that time frame.
        2. Research medications supplied by the NCI Pharmaceutical Management Branch (PMB) with unknown expirations will remain unknown until an expiration memo is released from the PMB.
        3. All expiration memos will be stored in Vestigo™ under Protocol Documents.
        4. All expiration memo information will be added to the Vestigo™ inventory tab information.
        5. Current study inventory will also be searched when receiving inventory to identify if the received lot matches current or previous inventory that has expiration information.
    iii. The sponsor and study team will be notified of approaching research medication expirations and be asked to inquire about drug disposition of expired medication.
    iv. Research medications that have reached their expiration date will be quarantined awaiting disposition as described in inventory quarantine section.

10. Inventory Quarantine
    a. Drug may be removed from active inventory for the following reasons:
        i. Shipment temperature excursions.
        ii. Discrepancies between the physical container and packing list.
        iii. Temperature excursions or malfunctions during medication storage.
        iv. Medication expiration or approaching expiration date less than 30 days.
        v. Insufficient quantity to fulfill a prescription order prior to drug expiration.
        vi. Notification of medication recall.
    b. Quarantined medication will be separated from active inventory and will be bagged and labeled as “Quarantine” and wrapped in taper evident tape. Medication(s) will be listed as quarantined in Vestigo™. RPS staff will notify study sponsor, study monitor(s), study coordinator(s) and the PI, as applicable, of the quarantine.
    c. Medication(s) will not be release from quarantine until RPS is granted written consent from the sponsor or responsible authority. When the medication is released from quarantine, RPS staff will remove the quarantined product from the quarantined bag, return it to active inventory in Vestigo™, and scan documentation of the release in Vestigo™.
    d. When inventory is obtained commercially (i.e. not provided by the sponsor) instructions from the manufacturer, including the package insert, will be considered viable sources of information to discern usability of inventory.
    e. Quarantined research medications will not be returned to the sponsor, stored outside required conditions, or destroyed until written permission is granted by the PI, sponsor, or responsible

authority. Once permission is obtained, RPS will dispose of the research medication per instructions. Proper disposition could include, but is not limited to, return to sponsor or destruction per the RPS Services Drug Disposal and Destruction policy. Vestigo™ Certificate of Destruction may be requested from invdrugs@ohsu.edu.

11. Research Medication Accountability
    a. Inventory records of IP at OHSU are maintained in Vestigo™. RPS personnel are responsible for documenting the receipt, maintenance, return, and disposition of all IP.
    b. Accountability will apply solely for drugs considered investigational. Commercial drugs which are used within research studies, and are not provided by the sponsor or otherwise obtained by RPS for use in the study, are not considered investigational drugs for the purposes of record keeping. Lot numbers of these commercial agents, will not be maintained by IDS or provided to sponsors. Requested information that is found elsewhere (i.e. electronic medical record) will not be duplicated on logs.
    c. Inventory records will contain protocol name and number, ordering provider or PI, CTEP number if applicable, drug name, dosage form, strength, package size, manufacturer, lot number, expiration date if known, storage location, inventory activity, patient identification, and date of service.
    d. All NCI studies will track inventory by the ordering provider.
        i. If a cycle count is documented in Vestigo™, it is considered a separate page of the control record and references the name/CTEP number of the PI.
    e. Inventory for research medications requiring compounding/preparation while RPS is closed will be transferred to a Satellite Pharmacy/location. Drug stored, compounded, and dispensed by the Satellite Pharmacy will be recorded in Vestigo™ as transferred to and dispensed from a Satellite Pharmacy.
12. Order Entry
    a. Research medications cannot be dispensed or administered without a signed IRB approved informed consent form. A copy of the signed consent form must be scanned into the Integrated Health Record per the OHSU Research Documentation policy. The research subject enrollment, status changes, and visit dates must be tracked in eCRIS per the OHSU Research Documentation policy.
    b. The study team will provide RPS with the patient's study number. The study team will also provide documentation of cohort assignment to RPS when required. The study team will assign a research diagnosis code to all research medication orders.
    c. Orders or prescriptions must be transmitted electronically to RPS. Electronic orders are placed in Epic or Willow and released by study personnel or nursing to the Research Pharmacy using protocol specific Beacon Plans, Infusion Plans, or Smart Sets.
        i. All dispensing and administering of research medications to research subjects will be pursuant to an order from the PI or a sub-investigator on the research study with the appropriate current license to prescribe the medication.
        ii. Orders will only be released after the patient has been evaluated by the study team and is determined to qualify for treatment according to protocol guidelines. New outpatient orders should be generated for each dispense to ensure dosing, directions for use, and quantities are current.
        iii. Willow (Outpatient) orders will list pick up time, pick up location, and appropriate study team contact information in the notes to Pharmacy.
        iv. Orders must include all information required by state and federal regulations.
        v. Orders will also include the study IRB number.

d. Abbreviations listed on the "OHSU Unacceptable Abbreviations" list may not be used.
e. All new patients on the study are entered into Vestigo™. Patient information will include the following: first and last name, medical record number, gender, date of birth, patient study number, investigator/physician, and study assignment (arm).
    i. Alerts will be added, by the RPS Pharmacist, to the patient's profile for information deemed necessary to process prescriptions. Patients will be deactivated in Vestigo™ once the RPS Pharmacist has received communication in writing that the patient is no longer eligible or treatment has been completed.

13. Order Verification
    a. Research medication orders and prescriptions will not be verified in Epic/Willow or prepared until the research staff has ensured all criteria are met for treatment per the study protocol. The RPS Pharmacist will consult the study protocol and discuss with the prescriber prior to verifying the dose if clarification on criteria or patient dose is required. If deemed appropriate by the RPS Pharmacist, pre-production/advanced preparation workflow may occur for research medication orders that require preparation prior to patient arrival.
        i. OHSU research personnel will maintain an up-to-date list of NCI-registered investigators to be referenced by the Research Pharmacy Staff prior to filling any order of NCI-supplied agents. The Research Pharmacy will be notified when changes are made to the list.
    b. Injectable medications will have the concentration pre-built in Epic so that the dose volume is calculated automatically within Epic and printed on the label. If more advanced calculations are required for dosage preparation, a dosing worksheet may be utilized to document those calculations. If used, completed dosing worksheets will be stored in the Vestigo™.
    c. A set of labels is generated from Epic for each research medication ordered. A set consists of one dispensing label and one production label. The dispensing label is attached to the final product. The production label is maintained in Vestigo™
    d. The standard formula used to calculate BSA is Mosteller.
    e. A record of the ordering provider, ordered dose, verifying Pharmacist, and administration of research medications is maintained in Epic/Willow. A record of the medication, dose, dispense date, dispense quantity, filling Pharmacy Technician or Pharmacist, and verifying Pharmacist is maintained in Vestigo™.
14. Preparation
    a. Lot numbers for ancillary supplies used in the preparation of the product will not be documented.
    b. Research medications will be prepared by a Pharmacy Technician according to the instructions in the study protocol and any other supporting documents (e.g. Pharmacy manual) supplied by the study sponsor. Preparations will be checked by a Pharmacist prior to being dispensed.
    c. Research medications may be prepared in RPS or a Satellite Pharmacy. The location of preparation will be documented.
    d. Research medications will be dispensed in the most ready-to-administer dosage form available in quantities consistent with patient needs, either in manufacturer-labeled packaging or as repackaged medications labeled by RPS.
    e. A copy of the IVRS/IWRS assignment numbers must be given to RPS prior to dispensing the research medication. Two staff members will initial the IVRS/IWRS assignment to verify that the product is correct.
    f. Compounding of research medications will follow the Research Pharmacy Services Compounding Procedure.

15. Labeling
    a. Research medications will be appropriately labeled upon dispensing as per sponsor requirements and applicable State and Federal regulations and guidelines. Research medication containers and packaging must include the following language: “Caution: New Drug Limited by Federal or United states Law to Investigational Use”.
    b. All research medications will be labeled with an institutional label with the patient’s name, drug name, strength, directions, quantity, and PI or treating physician’s name. Auxiliary labels will also be placed on the labels as appropriate.
    c. Dispensing labels for research medications prepared by injectable route will include:
        i. Total volume in the bag or syringe
        ii. Preparation date and time
        iii. Stability of prepared product
        iv. Verifying Pharmacist’s initials
    d. Production labels for research medications prepared by injectable route will include:
        i. Total volume in the bag or syringe
        ii. Preparation month, day, and time
        iii. Preparer’s initials
        iv. Verifying Pharmacist’s initials
        v. Unblinded placebo preparation labels will document the use of placebo
    e. Dispensing labels for research medications intended for take-home use will include:
        i. Medication expiration:
            1. Manufacturer/sponsor packaging: expiration date on packaging or “unknown” if the expiration date is unavailable.
            2. Research medications transferred to amber bottles: expiration date per original packaging or 1 year from repackaging, per pharmacist discretion.
        ii. Verifying Pharmacist’s initials
        iii. Auxiliary labels as appropriate
16. Randomization and Blinding
    a. RPS is responsible for the integrity of blinded studies involving medications. The RPS Pharmacist is responsible for observing protocol requirements for randomization, maintaining confidentiality of records, and unblinding per protocol when these responsibilities are delegated to RPS.
    b. Reasons for premature unblinding will be clearly documented by all RPS staff with a note to file. This will be scanned and saved in Vestigo™.
    c. In cases of emergency unblinding where written permission cannot be obtained, verbal permission from the PI or sponsor will suffice and be documented by receiving Pharmacist in addition to subsequent written documentation after the unblinding has occurred. In cases where RPS is blinded to the treatment, the sponsor must be contacted and procedures specified in the protocol and/or Pharmacy manual must be followed.
    d. Once the study has been closed, either in writing from PI or study sponsor, or via IRB closure notification, randomization documentation will be supplied to the study team if requested in writing from the PI, study coordinator, or study sponsor.
17. Patient Counseling
    a. All patients will be provided with an IRB approved informed consent form by the study team. This document contains a description of the medication and expected adverse effects as required by the study protocol and by law. Subjects cannot begin study medication prior to reviewing and signing the

consent with study trained personnel. This signed consent is filed in the regulatory binder maintained by the study coordinator and in the patient's medication record.

b. All patients who pick up research medication directly from RPS will be offered counseling. The Pharmacist who provides counseling or accepts the request from the patient not to be counseled, shall document the interaction on the RPS Documentation of Patient Counseling Log.

18. Transportation of Research Medications
    a. In order to maintain a chain of custody record for research medications, signatures are collected to document staff involved in transport of the research medication to the patient or their representative. The disposition of all prescriptions will be documented on the Research Pharmacy Delivery/Dispensing Log and Documentation of Patient Counseling Log.
    b. Research Pharmacy Services will prepare inventory for transport for the following reasons:
        i. Prescription is filled pursuant to a prescription order and requires transport to an alternate location for dispensing.
        ii. Potential new subject to be enrolled in a study and research medication must be available at an alternate location for dispensing.
    c. Inventory is transported between the following OHSU locations:
        i. Waterfront Locations:
            1. Research Pharmacy Services
                a. 3303 S Bond Ave Suite 12270
                b. Portland, OR 97239
            2. OHSU Logistics Warehouse
                a. 3930 S Macadam Ave
                b. Portland, OR 97239
        ii. Main Campus locations:
            1. Oregon Health & Science University Research Pharmacy Services/Inpatient Pharmacy
                a. 3181 SW Sam Jackson Park Road, 4th floor (4C) main hospital
                b. Mail Code: CR 9-4
                c. Portland, Oregon 97239
            2. Oregon Health and Science University Pavilion Pharmacy
                a. 3181 SW Sam Jackson Park Road
                b. Portland, OR 97239
        iii. Community Locations:
            1. Beaverton Location*
                a. 15700 SW Greystone Ct.
                b. Beaverton OR 97006
            2. Tualatin Location**
                a. 19300 SW 65th Ave., Suite 140
                b. Tualatin, OR 97063
            3. Gresham Location**
                a. 24988 SE Stark St., Building 3, Suite 140
                b. Gresham, OR 97030
            4. NW Portland Office**
                a. 1130 NW 22nd Ave., Building 3, Suite 100
                b. Portland, OR 97210
            5. East Portland**

a. 10000 SE Main St., Suite 350
b. Portland, OR 97216

6. *Denotes location of licensed Infusion Pharmacy, staffed by licensed Pharmacists
7. **Denotes location of licensed drug rooms, staffed by licensed Pharmacy Technicians and supervised remotely via video camera by licensed Pharmacists

d. Refer to Policy titled Shipping, Transporting and Delivering Medications for full transportation policy.

19. Mailing
    a. If a prescription must be mailed to a subject, the following steps will be followed:
        i. The prescriber or designated research team member will obtain prospective, written approval from the sponsor to ship research medication to a subject. The study coordinator will file the shipping form with the sponsor written approval and other essential documents for the study in the regulatory binder.
        ii. Research Pharmacy will package the research medication so the contents cannot become damaged or dislodged during shipment. The package will be given to the prescriber or study coordinator for shipping and tracking.
20. Dispensed Medications and Patient Returns
    a. All dispensed medications will be documented in Vestigo™. Unused product from the dispensed kit will be disposed of according to the RPS Services Drug Disposal and Destruction policy
    b. Patient returns of research medications will be disposed of after documentation is complete. Patient returns will be disposed of according to the RPS Services Drug Disposal and Destruction policy
    c. Dispensed medications and patient returns will not be retained for monitor reconciliation.
    d. Drug returns will be counted and verified by two study personnel. Any discrepancy between the individual counts will be reconciled prior to drug destruction. Patient medication returns will be recorded in Vestigo™ under the appropriate protocol and date of dispense. The date returned to the Pharmacy and the amount returned (including empty bottles) will be documented in Vestigo™. The following terminology will be used to document amount returned:
        i. Empty container: 1 – E
        ii. Full/unopened container: 1 – F
        iii. Partial container: 1 - # of units returned
        iv. Partial container of liquid or semi-solid: 1 – P (volume will not be estimated)
    e. All used vials from parenteral compounding will be destroyed immediately after preparation. Assignment of the vial in Vestigo™ will serve as documentation of destruction.
    f. Sponsor specific destruction forms are not utilized to document medication destruction.
    g. Certificates of destruction are available from Vestigo™ by email request to invdrugs@ohsu.edu.
21. Unused Investigational Drugs
    a. Any expired or quarantined investigational products accumulated as a result of site participation in a sponsor's study will be segregated from regular inventory and sealed in a bag with tamper evident tape. Monitors are contacted by the Investigational Pharmacy to schedule a remote monitoring visit within 90 days to reconcile these products so that these items may be shipped back to the sponsor at the sponsor's expense, or disposed of on site. Photos of the expired IP may be emailed to the monitor to help expedite remote approval of destruction or return. At the end of the 90 day period, if the monitor has not scheduled a remote visit or made other arrangements, all expired or quarantined products are disposed of on site and destruction is documented in Vestigo™.
    b. Sponsor specific destruction forms are not utilized to document medication destruction.
    c. Certificates of destruction are available from Vestigo™ by email request to invdrugs@ohsu.edu.

d. All research medications will be disposed of according to the RPS Services Drug Disposal and Destruction policy

22. Protocol Deviations
    a. A deviation from the protocol with regard to drug receipt, drug storage, drug dispensing, drug accountability, drug preparation or any other issue that pertains to the responsibilities of RPS with regard to research medications will be immediately reported to the sponsor and, as applicable, the PI and research coordinator. The IRB will be notified, if necessary, per IRB policy. Deviations will also be documented in a note to file. Notes to file will remain Vestigo™. Copies will be distributed as required.
    b. A Patient Safety Incident (PSI) report will be completed for all protocol deviations.
23. Study Closure
    a. Upon written notification of study closure from the PI, study coordinator, or sponsor, RPS personnel will complete any and all documentation regarding final inventory of research medications used during the protocol. Protocols will be closed in Vestigo™.
    b. Research medications will be removed from active protocol storage and will be returned to the sponsor or destroyed per written instruction from the PI, study coordinator, or study sponsor.
24. Archiving
    a. RPS study documentation will be archived after the study closure process.
        i. RPS will maintain Pharmacy-related documents for electronic retention. These documents include as applicable, but are not limited to: enrollment records, randomization records, shipping invoices, product return records, and dose calculation records. The records are maintained in Vestigo™ indefinitely.
        ii. Pharmacy-specific procedure and prescription or medication order records will be maintained in Vestigo™.

RELATED DOCUMENTS:

- Investigational Medication Dispensed to Research Subjects
- Research Pharmacy Services Drug Disposal and Destruction
- Research Pharmacy Services Temperature Monitoring
- Medication Management: Procurement, Distribution, Preparation, Labeling, Beyond Use Dating, Security, Storage
- Refrigerator and Freezer Temperature Monitoring and Management
- Research Documentation in the Integrated Health Record (IHR)
- Compounding, Home Infusion, and Ambulatory Pharmacy Services: Non-Sterile Compounding (USP 795) Hazardous Medications
- Shipping, Transporting and Delivering Medications
- Treatment Algorithm for Acute Infusion Reaction Adults (HC-PAT-133-GUD)
- Treatment Algorithm for Acute Infusion Reaction Pediatrics (HC-PAT-132-GUD)

EXTERNAL LINKS/RELEVANT REFERENCES:

- American Society of Health-System Pharmacists. ASHP Guidelines on Clinical Drug Research. Am J Health Syst. Pharm. 1998; 55:369-376.

- American Society of Health-System Pharmacists. ASHP guidelines for the management of investigational drug products. Am J Health-Syst Pharm. 2018; 75:561–73.
- Food and Drug Administration. 21 CFR Chapter 1 – Subchapter D - Drugs for Human Use. Washington, DC: US Department of Health and Human Services. Accessed 2022 at https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/
  - Definition at 21CFR312.3 (Investigational New Drug Application) and 21CFR310.3 (New Drugs)
- Food and Drug Administration. International Conference on Harmonization; Good Clinical Practice: Consolidated Guideline; Notice of Availability. Washington, DC: US Department of Health and Human Services, 1997; Federal Register, Volume 62, Number 90.
- National Institutes of Health. Glossary of Clinical Trials Terms. National Library of Medicine. Accessed August, 2022 at https://www.clinicaltrials.gov/ct2/about-studies/glossary.
- NIAHO Standards
- Research Drug Service Order Forms
- Code of Federal Regulations: 21CFR312.3 and 21CFR310.3
- Oregon Board of Pharmacy OAR 855-041-6260 – Investigational Drugs

APPROVING COMMITTEE(S):

Pharmacy Performance Improvement and Regulatory Compliance Committee

REVISION HISTORY (Revision history can be listed in the table below and/or in MCN)

Revision History Table

Document Number and Revision Level	Final Approval by	Brief description of change/revision
HC-PHR-256-POL Rev. 060220	Chief Pharmacy Officer	• New policy template • Remote access to Vestigo™ is available at any time for monitors, auditors, and inspectors. Access can be requested by emailing invdrugs@ohsu.edu during RPS hours of operation. • The protocol, pharmacy manual, and other supporting materials will be used to create electronic orders and order sets. • Infusion reaction orders will be built following the OHSU Treatment Algorithm for Acute Infusion Reaction

		Adults (HC-PAT-133-GUD) or Treatment Algorithm for Acute Infusion Reaction Pediatrics (HC-PAT-132-GUD). Exceptions to these policies must be reviewed by the PI, RPS and nursing. • Training materials will be available to additional staff prior to the need to participate in study related activity. • Training logs must be requested by emailing invdrugs@ohsu.edu during RPS hours of operation. Training logs cannot be seen by monitors in Vestigo™. • Accountability will apply solely for drugs considered investigational. Commercial drugs which are used within research studies, and are not provided by the sponsor or otherwise obtained by IDS for use in the study, are not considered investigational drugs for the purposes of record keeping. Lot numbers of these commercial agents, will not be maintained by IDS or provided to sponsors. Requested information that is found elsewhere (i.e. electronic medical record) will not be duplicated on logs. • Shipping Address for Waterfront locations updated • Refer to Policy Shipping, Transporting and Delivering

		Medications for full transportation policy • Related documents added
HC-PHR-256-POL Rev. 062921	Chief Pharmacy Officer	• Up for annual review, no content change
HC-PHR-256-POL Rev. 031622	Chief Pharmacy Officer	• All monitoring has been moved to remote, and the policy updated to reflect this. • All PSIVs and SIVs have been moved to remote, and the policy updated to reflect this. • Updated Outpatient order process • Minor operational updates made to align with remote monitoring processes. • Updated policy name • Minor formatting updates.