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INTRODUCTION:

Any party (the “Dispensing Party”), including the Investigational Drug Service and designated staff (“IDS”), the GWUH pharmacy department and designated staff (“GWUHP”), or the Principal Investigator (“PI”), shall dispense Investigational Drugs within the Medical Faculty Associates (“MFA”), The George Washington University Medical Center (“GWUMC”) and The George Washington University Hospital (“GWUH”) (the “GWU Research Community”) for both inpatient and outpatients studies in accordance with this Investigational Drug Policy and Procedure Manual. The IDS, GWUH, GWUHP or the MFA may require the Dispensing Party to comply with additional policies and procedures. However, any Dispensing Party within the GWU Research Community, as a minimum standard practice, must comply with this Investigational Drug Policy and Procedure Manual.

The IDS is available as the coordinating and control center for the Investigational Drug. As the coordinating and control center, the IDS assumes the responsibility for maintaining records of the drugs delivered to the IDS, inventory of the drug, dispensing of drugs to research subjects, and the return to the sponsor or disposition of unused product.

If the IDS or the GWUHP is not coordinating the control of the research drug, as outlined in the above paragraph, then the PI is responsible for the control of the drug. Both the PI and IDS must dispense Investigational Drugs as specified by the sponsor and in accordance with this Investigation Drug Policy and Procedure Manual.

While the IDS staff makes every effort to be directly involved with the dispensing of Investigational Drugs for inpatient studies, the IDS relies on the assistance of the GWUHP when the IDS Staff is not available to dispense Investigational Drugs for inpatient protocols. From time to time, the scope of involvement of the IDS may change based on organizational changes and/or re-prioritization of institutional commitments. Examples of limitations of IDS involvement include, but are not limited to, exclusion of oversight responsibility for oncology studies and/or involvement with studies where physicians serving as PIs are not employees of the MFA.

Similarly, from time to time, certain sponsors of research may insist that the documentation and accountability of Investigational Drugs be recorded on the forms specified by the sponsor. In those instances, the Dispensing Party shall review those sponsor’s forms to determine comparability with the requirements of
these policies and procedures. If acceptable, the Dispensing Party may elect to
document Investigational Drug accountability activities using the sponsor’s forms.

This *Investigation Drug Policy and Procedure Manual* acknowledges that the IDS
may be one member of the team of individuals and departments responsible for
the appropriate and ethical conduct of research with the goal of protecting
research participants. As such, the IDS recognizes that verification of certain
activities outside the domain and jurisdiction of the IDS (such as obtaining
appropriate informed consent prior to initiating any research related activities)
may have to be accepted as “completed” when those responsible for such
activities simply say so. However, the IDS may play a more active role in
supplementing the institution’s ongoing quality improvement activities as they are
and will be defined.

For the purposes of this *Investigation Drug Policy and Procedure Manual*, the
term “Investigational Drug” refers to any Investigational Drug, medication
(approved or not), or test article used in a research study.
SECTION 1 RECEIPT, STORAGE, DISPENSING AND RECORDS OF INVESTIGATIONAL DRUGS

POLICY: Within the GWU Research Community all Investigational Drugs shall be received, stored and dispensed in accordance with this Section 2.

PROCEDURE:

1. The Dispensing Party shall be responsible for preparing and maintaining appropriate files (paper as well as electronic, to track status, etc.) for each IRB-approved study involving Investigational Drugs.

2. The Dispensing Party shall maintain all necessary information (active/updated protocol, investigator's brochure, Investigational Drug information, shipping receipts/invoices, etc.) for all IRB-approved protocols by the Dispensing Party.

3. All drug accountability logs pertinent to the study and information relating to the storage, preparation and dispensing of Investigational Drugs shall also be the responsibility of the Dispensing Party and shall be maintained by the Dispensing Party unless otherwise noted.

4. Copies of appropriate Investigational Drug information (storage, preparation, dispensing, etc.) together with copies of protocols and updated Investigational Drug brochures/fact-sheets shall also be maintained in the GWUHP for those studies involving administration of Investigational Drugs to inpatient research subjects. In addition, the PI shall be responsible for complying with all GWUHP policies and procedures for inpatient studies.

5. The Dispensing Party shall receive and store all Investigational Drugs in compliance with applicable regulations and in accordance with the manufacturer’s/sponsor’s specifications to insure adequate controls and safeguards regarding appropriate storage conditions.

   A. A separate Master Investigational Drug Accountability Log (Appendix 1) shall be used for each study to account for all Investigational Drugs received and returned by the Dispensing Party.

   B. The Dispensing Party shall document receipt of all Investigational Drugs by recording date and time of receipt on documentation accompanying the shipment of Investigational Drug. This documentation shall be maintained by the Dispensing Party together with other pertinent information for the duration of the study. If no such
documentation is shipped with the Investigational Drug, the Dispensing Party shall document date and time of receipt on the Master Investigational Drug Accountability Log (Appendix 1.)

C. The Dispensing Party shall ensure appropriate storage of all Investigational Drugs.
   
   i. All Investigational Drugs for active inpatient studies will be stored in the GWUHP in accordance with the policies and procedures of the GWUHP.
   
   ii. All Investigational Drugs will be stored under the environmental conditions stated in the study protocol.
   
   iii. A section of the GWUHP refrigerator shall be dedicated for Investigational Drug storage.
   
   iv. The Dispensing Party shall document appropriate storage conditions by maintaining appropriate temperature control logs for refrigerated and room temperatures.

D. All Investigational Drugs for outpatient studies will be stored in an appropriately secured, limited access area.
   
   i. The Dispensing Party ensures that storage, dispensing, accountability and security comply with federal and state laws and regulations and with GWU policy.
   
   ii. Access to the cabinets and refrigerator storing Investigational Drugs is restricted by a secure locking system which limits access to the Dispensing Party or designated staff only.

5. The Dispensing Party will confirm that protocols have been appropriately reviewed and approved by the IRB by noting the IRB protocol number (only following verification that the IRB had reviewed and approved the protocol) on the Master Investigational Drug Accountability Log (Appendix 1).

6. For each and every IRB-approved research involving Investigational Drugs enrolling inpatients or outpatients, the Dispensing Party shall account for the receipt, dispensing, and return (or destruction) of Investigational Drugs through timely and appropriate documentation for each research subject.

   A. Upon notification by authorized study personnel, the Dispensing Party shall dispense the Investigational Drug.
B. Accountability of dispensed Investigational Drugs shall be recorded on Study Drug Preparation/Dispensing Log (Appendix 2).

C. For Investigational Drugs used in an inpatient setting, GWUHP shall enter the order for the Investigational Drug into the GWUHP order entry system as a non-formulary item and at no charge to the research participant.

D. All discontinued Investigational Drugs or dispensed Investigational Drugs not administered to the research participant shall be immediately returned to the Dispensing Party.

E. Returned Investigational Drugs shall be documented on the Study Drug Preparation/Dispensing Log (Appendix 2).

F. Destruction of Investigational Drugs shall be documented on the Dispensing Party’s Record of Destruction of Investigational Drug Form (Appendix 3, See Section 4).
SECTION 2 LABELING OF INVESTIGATIONAL DRUGS

POLICY: The Dispensing Party shall dispense Investigational Drugs with the appropriate labeling.

PROCEDURE:

1. All Investigational Drugs dispensed within the GWU Research Community shall bear the label "Investigational Drug: Limited by Federal Law to Investigational Use."

2. Additional labeling for inpatient Investigational Drugs shall be in compliance with GWUHP policies.
   A. Any other information pertinent to administration of the Investigational Drug may also be included on the label (i.e. pump flow rate, expiration, date/time).

3. Additional labeling for outpatient Investigational Drugs shall include: patient name or initials, subject study identification number, date, prescription number, study drug name, directions for use, quantity, and name of PI and initials of dispensing technician and/or pharmacist.

4. Under no circumstances shall any Investigational Drug bearing the label "Investigational Drug: Limited by Federal Law to Investigational Use" be used as regular pharmacy stock or for any other purpose without prior approval from the PI and sponsor if additional authorization is required by the sponsor.
   A. Marketed and FDA-approved drugs bearing the "Investigational Drug: Limited by Federal Law to Investigational Use" label supplied by a pharmaceutical company or sponsor for use in an investigational study shall be used in that specific study only and for no other purpose.
   B. In the event that an Investigational Drug is used for non-investigational purposes, a memo shall be drafted describing the event, reason for use, individuals involved, approximate dates and action taken by the Dispensing Party.
      i. This information will be shared with the PI, study coordinator, appropriate sponsor personnel, the individuals involved and their supervisors.
      ii. A copy of the memo will be placed in the study binder and/or file.
iii. A copy of the memo shall be submitted to the IRB.
SECTION 3 ORDERING FROM AND RETURN TO SPONSOR OF INVESTIGATIONAL DRUGS; TRANSFER OR APPROPRIATE DESTRUCTION/DISPOSAL OF INVESTIGATIONAL DRUGS

POLICY: The Dispensing Party shall be responsible for: ordering Investigational Drugs from sponsor; returning to sponsor or sponsor’s designee unused Investigational Drugs; and transfer or appropriate destruction/disposal of Investigational Drugs.

PROCEDURE:

1. The Dispensing Party may be responsible for the ordering of additional study drug and/or supplies according to study protocol.

   A. The PI, coordinator or sponsor may delegate this responsibility to the Dispensing Party.

   B. Ordering shall proceed according to study protocol when the minimum level of Investigational Drug is reached.

2. The Dispensing Party shall return, transfer or destroy all unused Investigational Drugs according to specific instructions provided by the sponsor and/or protocol in accordance with applicable regulations.

   A. Return, transfer or destruction of the unused Investigational Drugs shall be documented in the Master Investigational Drug Accountability Log (Appendix 1). For transfer of Investigational Drugs, documentation shall note reason for transfer and recipient.

   B. The Record of Destruction of Investigational Drug Form shall be used (Appendix 3) to document the destruction of Investigational Drugs.
SECTION 4 OBTAINING IRB APPROVAL PRIOR TO USAGE OF ANY INVESTIGATIONAL DRUG.

POLICY: Except under special circumstances, approval from the IRB must be obtained prior to usage of any Investigational Drug.

PROCEDURE:

1. The PI shall be responsible for obtaining approval from the IRB.

2. Prior to the dispensing of any Investigational Drug, the PI shall inform the Dispensing Party that IRB approval has been obtained.
SECTION 5 EMERGENCY USE OF INVESTIGATIONAL DRUGS

POLICY: Patients may be administered Investigational Drugs without prior approval from the IRB under special or emergency circumstances.

PROCEDURE:

1. The PI, if not the Dispensing Party, shall be responsible for obtaining adequate documentation from the patient and communication of consent to the IRB.

2. The PI shall be responsible for obtaining and transferring (to the Dispensing Party) the supply of Investigational Drugs to be used in special or emergency circumstances.

3. The Dispensing Party shall store, account for and dispense all emergency supplies of Investigational Drugs.
SECTION 6 PROVIDING CLINICAL INFORMATION REGARDING INVESTIGATIONAL DRUGS

POLICY: The Dispensing Party will assume the responsibility of providing pertinent clinical information to pharmacists, nurses or whoever under the protocol is involved with the receipt, storage, dispensing, and administration of Investigational Drugs.

PROCEDURE:

1. The Dispensing Party shall prepare an Investigational Drug Data Sheet (Appendix 4) for each study.

   A. For all inpatient studies, this information shall be provided to all GWUH pharmacists; a copy will be posted in the GWUHP on the IDS bulletin board; and a copy will be maintained with other pertinent study information in the GWUHP. For inpatient studies, the Dispensing Party shall comply with any additional GWUH policies and procedures.

   B. For outpatient studies, the Dispensing Party shall develop similar information that shall be maintained by the Dispensing Party.

2. For all inpatient studies, the Dispensing Party will disseminate information to the GWUH Pharmacists through routine communications including periodic in-service training and as required by GWUHP policies and procedures.

   A. Prior to or at initiation of any new inpatient studies, the Dispensing Party shall conduct an in-service for all GWUHP staff.

   B. At the request of the Nursing Department, or as determined by the Dispensing Party, similar in-service activities may be conducted with nursing/research staff.
SECTION 7 QUALITY IMPROVEMENT AUDITS AND QUALITY ASSURANCE

POLICY: OHRCTT shall conduct periodic quality improvement audits and maintain quality assurance for all Investigational Drugs.

PROCEDURE:

1. The OHRCTT shall monitor dispensing of Investigational Drugs within the GWU Research Community.
   A. Accountability forms shall be reviewed for completeness and accuracy.
   B. Any Investigational Drug used in the GWUHP not signed out or signed out improperly shall be brought to the immediate attention of the OHRCTT.
   C. The OHRCTT shall re-educate any Dispensing Party who repeatedly provides incorrect or inadequate documentation of a dispensed Investigational Drug.

2. The Dispensing Party shall conduct a monthly inventory of all Investigational Drugs.
   A. The Dispensing Party shall perform a physical inventory of all the Investigational Drugs within the Dispensing Party’s control.
   B. The inventory count shall be entered on the Master Investigational Drug Accountability Log (Appendix 1).
      i. The inventory shall be documented in ink on the next available line and shall contain the actual physical count, lot number(s), date, and initials of person performing the inventory.
      ii. The Dispensing Party shall monitor and counter-sign any inventory counts performed by designated staff.
         a. All discrepancies shall be immediately brought to the attention of the Dispensing Party for immediate resolution.

3. The Dispensing Party shall verify, upon each monitoring visit by a sponsor/representative, the accuracy of both dispensing and return of all Investigational Drugs.
i. Verification shall be documented by notification by signature of the Dispensing Party and sponsor representative as noted above (2.B.)
SECTION 8 IDS COMMUNICATION WITH THE IRB

POLICY: The IDS shall maintain communication between the IRB, PI or coordinator, and GWUHP regarding the status of protocols utilizing Investigational Drugs.

PROCEDURE:

1. The IDS pharmacist may act as a member of the medical IRB.

   A. When reviewing protocols for approval, particular attention shall be paid to the following:

      i. Drug related portions of the protocol;

      ii. Consent form to check accuracy of information; and

      iii. Study viability and resource utilization.

4. The IDS shall provide the IRB with a list of all protocols for which the IDS provides services upon request.
SECTION 9 RESEARCH PHARMACIST SUMMARY OF INVESTIGATIONAL DRUG USE

POLICY: Every Dispensing Party shall prepare an annual or semiannual descriptive summary of Investigational Drug use that shall be available at the time of audit.

PROCEDURE:

1. The summary shall include the number of active studies in progress and a list of all studies during the previous period.

2. This summary shall be available for review upon request.

3. No patient information from which study subjects can be identified shall be contained in this summary.
SECTION 10 BLINDING OF INVESTIGATIONAL DRUGS

POLICY: The Dispensing Party shall facilitate maintaining appropriate blinding of Investigational Drugs.

PROCEDURE:

1. The Dispensing Party shall manage access to treatment assignment records in blinded studies.
   
   A. No unauthorized study personnel shall be allowed access to unblinded records.
   
   B. The Dispensing Party shall limit contact with any blinded study personnel and study subjects in order to maintain the blind.
   
   C. Any unblinding of blinded Investigational Drugs will be managed by the Dispensing Party.
      
      i. If unblinding is deemed necessary, the Dispensing Party, after receiving authorization from the PI, if not the Dispensing Party, and sponsor if additional authorization is required by the sponsor, may assist in unblinding study treatment.
      
      ii. If unblinding is required during off-hours, the PI shall notify the Dispensing Party or their staff and may request entrance to the Dispensing Party’s office to retrieve unblinding materials.
SECTION 11 PERIODIC REVIEW AND APPROVAL OF POLICIES AND PROCEDURES

POLICY: This Policy and Procedures Manual governing the distribution of Investigational Drugs within the GWU Research Community shall be reviewed and approved periodically, not to exceed a period of twelve (12) months, to insure compliance with existing regulatory and institutional guidelines.

PROCEDURE:

This procedure describes the process by which the GWU Research Community generates, develops, and adopts new and revised Investigation Drug Policy and Procedure Manual.

Step 1: Proposals: Draft IDS Policies and Procedures

Proposals to generate new or revisions to existing, Investigational Drug Policy and Procedures may be initiated by the OHRCTT. OHRCTT may ask external and/or internal experts to review the proposals. Reviewers will be asked to submit written comments within ten (10) working days. The OHRCTT, or appropriate designee, will incorporate approved proposals into the Draft Investigational Drug Policies and Procedures for further review.

At all stages of review and until final approval, the phrase “Draft Investigational Drug Policy and Procedures (Month Year)” will appear on every page of the document. Version control for all forms will be documented by inclusion of “YYMMDDIDPolicy”.

Step 2: Review

The Draft Investigational Drug Policy and Procedures will be reviewed by appropriate individuals whose departments/personnel may be affected by the implementation of the Policy and Procedure. All reviewers will be asked to submit written comments within five (5) working days. The OHRCTT will incorporate approved changes into the Draft Investigational Drug Policies and Procedures for further review.

Step 3: Final Administrative Review and Approval

The Draft Investigational Drug Policy and Procedures, incorporating the modifications made in Step 1 and Step 2, will be reviewed by appropriate representatives from the GWU Research Community. All reviewers will be asked to submit written comments within five (5) working days. Following appropriate incorporation of comments, the Research Pharmacist and appropriate
representatives from MFA and GWU shall sign-off authorizing final approval of the *Investigational Drug Policy and Procedures*.

**Step 4: Periodic Review**

The *Investigational Drug Policy and Procedure* shall be reviewed every year. Steps 1 and 2 will take place in the Fall, and Step 3 will take place in January of each new year. If impelled by issues or events that impact human subject protection in clinical research, the IDS may initiate a special review.
APPENDIX 1: MASTER INVESTIGATIONAL DRUG ACCOUNTABILITY LOG

**Protocol Title:**

**Sponsor:**

**GWU IRB #:**

**Protocol Number:**

<table>
<thead>
<tr>
<th>Date</th>
<th>Drug</th>
<th>Lot Number</th>
<th>Expiration Date</th>
<th>Quantity Received or Returned/Destroyed*</th>
<th>Comments</th>
<th>Initials</th>
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* If Investigational Drug supply is destroyed, please complete Record of Destruction of Investigational Drug (**Appendix 3**)
APPENDIX 2: STUDY DRUG PREPARATION/DISPENSING LOG

<table>
<thead>
<tr>
<th>Date</th>
<th>Time (2400)</th>
<th>Drug</th>
<th>Lot #</th>
<th>Dose Volume</th>
<th>Dispensed/Returned</th>
<th>Balance</th>
<th>RPh Initials</th>
<th>Comments</th>
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* If Investigational Drug supply is destroyed, please complete Record of Destruction of Investigational Drug (Appendix 3)

This form is (PLEASE CHECK ONE): ☐ From GWUHP ☐ From IDS
Version: 031001IDS
APPENDIX 3: RECORD OF DESTRUCTION OF INVESTIGATIONAL DRUG

Date of Destruction: __________________________________________________________

Protocol Title: ____________________________________________________________________________________________

__________________________________________________________________________________________

Protocol Number: __________________________________________________________

Sponsor: __________________________________________________________ GWU IRB#: ____________________

Principal Investigator: __________________________________________________________

Method of Destruction: __________________________________________________________

________________________________________________________________________________________

Drug Name: __________________________ Quantity: __________________________

Strength, Dose Form(s): __________________________________________________________________________________________

Lot Number(s): __________________________________________________________________________

________________________________________________________________________________________

Name of Research Pharmacist/ PI if Dispensing Party: __________________________

Signature of Research Pharmacist/PI if Dispensing Party: __________________________

Name and Title of Witness: __________________________

Signature of Witness: __________________________

Version: 031001IDS
APPENDIX 4: INVESTIGATIONAL DRUG DATA SHEET

Principal Investigator/Department: _________________________________________________

PI Phone:_____________________ Pager: ______________ Other: ____________________

Sub/Co-Investigators: ___________________________________________________________
____________________________________________________________________________
____________________________________________________________________________

Protocol Title & #: ______________________________________________________________
____________________________________________________________________________

Sponsor: ______________________________________   GWU IRB #: ___________________

IND # : __________________________   ________(If not noted, check to see if one is required.)

1. Drug name (generic, trade, and name to be used in labeling):

2. Therapeutic class, brief pharmacology and pharmacokinetics:

3. Indications for use in the study:

4. Other indications (non-study related, if any):

5. Dosage(s)/strength(s) used in study:

6. Route of administration in this study:
7. Storage requirements (refrigeration, room temperature, etc.)


9. If intravenously administered, are there any compatibility, infusion (rate, volume, etc.), toxicity concerns? Explain in detail.

10. Expected therapeutic effects:

11. Anticipated adverse effects:

12. Based on teratogenicity, carcinogenicity, mutagenicity, reproductive and other toxicity studies, are there any special handling/preparation requirements? Describe in detail.

13. Other information:
GLOSSARY

Note: The Terms of the Glossary are in alphabetical order; those in **bold** are defined in this Glossary.

**Approved drug** is a drug or biological that has been approved by the FDA for marketing for specific uses.

**Authorized Designee(s) or Study Coordinator(s)** are individual(s) within a category of individuals which, at the time of the review of the protocol, may be authorized by the OHR to obtain informed consent and initiate treatment at the request of the principal investigator.

**Dispensing Party** shall be limited to the PI, the IDS or the GWUHP staff.

**IDS Pharmacist**, also designated “research pharmacist,” is responsible for upholding the **Policies and Procedures** as described herein as well as the supervision of any support staff (Research Technician and/or GWUH pharmacists).

**IDS Staff** includes the IDS pharmacist and any IDS-appointed support staff (Research Technician).

**Informed Consent** is a process by which a subject voluntarily gives his or her permission to participate in a particular trial after having been informed of all aspects of the trial that are relevant to the decision to participate. In most cases, informed consent is documented by means of a written, signed and dated Informed Consent form.

**Institutional Review Board (IRB)** is the committee that conducts oversight for all research involving human subjects at GWU. This committee is federally-mandated to ensure that research is conducted in accordance with the federal regulations, and that the rights of human subjects are protected for all ongoing investigations. Currently there are two separate IRBs at GWU, the Non-Medical Review Board and the Medical Review Board. All clinical research projects at GWU, regardless of funding status, must be reviewed and approved by the IRB prior to enrolling any subjects.

**Investigational Drug** is any drug, chemical, or biological product that is being used in the context of a clinical investigation. An Investigational Drug may be approved by FDA or not yet marketed. An Investigational Drug may be one of the following:

- A drug or biologic product that has not been approved for marketing by FDA;
- A marketed drug being investigated for a new indication for use or other labeling change;
- A marketed drug undergoing a post-marketing (phase 4) investigation;
- A new dosage form or route of administration of a marketed drug.
- A new formulation of a marketed drug.

**IRB Number** is the number assigned by the IRB to each study protocol submitted for approval.

**Marketed drug** is a drug or biologic product that has been approved by the FDA for commercial marketing in the United States.

**Office of Health Research, Compliance and Technology Transfer (OHRCTT)** is responsible for the compliance oversight and support of the health research programs at The George Washington University. The Associate and Assistant Vice Presidents, Office of Health Research, Compliance and Technology Transfer coordinate the administrative activities and organizations related to compliance at the University.

**Office of Human Research (OHR)** operates within the Office of Health Research, Compliance, and Technology Transfer and is the university’s agency for compliance with federal regulations regarding the protection of human research subjects or analysis of data gathered from human subjects, regardless of funding status, that must be reviewed by the OHR prior to the implementation of any research activity.

**Principal/Primary Investigator (PI)** is that faculty or staff member of the GWU-MFA who is responsible for overseeing the conduct of a protocol as approved by the OHR. Certain specific responsibilities are as follows:

1. Supervising the use of Investigational Drugs (authorized co-investigators share this responsibility).
2. Obtaining **Informed Consent** prior to administering any investigational product.
3. Maintaining properly case report forms and all other study records required by the sponsor, GWUMC and the FDA.
**Sub/Co-Investigator(s):** one or more faculty or staff of the GWU-MFA or GWUH Medical Staff who have been approved to participate in the conduct of the protocol under the overall direction of the Principal Investigator (PI).