Pharmacy Coordinated
Investigational Drug Service

Inpatient Department

POLICY:

All investigational drugs in use at West Virginia University Healthcare are stored, distributed, and controlled by the Department of Pharmaceutical Services and are used only under the supervision of the authorized investigator(s).

PROCEDURE:

1. The Institutional Review Board (IRB) is responsible for initial approval and ongoing monitoring of all investigational protocols being used in the institution.

2. The physician initiating an investigational protocol must do the following to satisfy Institutional Review Board requirements:
   
   A. use the drug or biologic only in accordance with the plan of investigation as described in the approved protocol, and
   
   B. use the product in patients under his/her supervision or under the supervision of physicians who directly report to him/her,
   
   C. obtain proper informed consent from the patient or the patient's legal representative

3. The physician must notify the IRB, in writing, for emergency use of an investigational drug or biologic within five (5) working days of its use. This notification must include a detailed explanation of the reason for using the drug or biologic in this patient. The written notification must have as attachments the approved FDA protocol and a copy of the consent form signed by the patient or his representative, the physician, and appropriate witnesses. The notification must include the following in a narrative developed by the physician administering the drug:
A. the chemical and commercial name of the drug or biologic
B. the name of the company manufacturing the drug
C. the date and time the investigational drug was initially administered
D. the drug IND number
E. the name of the organization that supplied the drug (i.e.: NCI, drug company, etc.)
F. a discussion of the reason this investigational drug was employed as opposed to an approved drug or treatment regimen
G. the risks or side effects associated with the use of the investigational drug or biologic.
H. The narrative must be signed by the physician administering the drug.
I. Investigational drugs or biologics may be used only once under the FDA Emergency Use Provision. Any subsequent use must not take place until the Institutional Review Board has an approved protocol for that use. Questions can be addressed to the Secretary of the IRB.

4. The investigator is responsible for providing a copy of approved drug study protocols for inpatients with the approved consent form to the investigational drug pharmacist.

5. The principal investigator must be a member of the institution's professional staff and is responsible for the following:
   A. Submitting proper information and documentation to the IRB to obtain protocol approval.
   B. Obtaining the written, informed consent of the patient to participate in the study.
   C. Maintenance of the case report forms and all other records required in the study by the drug sponsor, institution, or FDA.
   D. Informing the Investigational Drug Pharmacist of study completion.

6. Only the Pharmacy shall be responsible for proper storage of investigational drug supplies.
7. The Pharmacy shall reorder study drug as necessary and maintain a perpetual inventory of all investigational drugs by utilizing an approved Accountability Record. Data will include amount received, dispensed, returned to sponsor, date, patient information, and amount currently on hand.

8. Receiving

The product is delivered directly to the Pharmacy and the order is checked against the packing slip. If there is a discrepancy between the order and packing slip, the supplier is notified. After verification that an order is correct, the investigational drug pharmacist files all shipping information with the study materials.

Receipt of a Schedule II drug shall be checked against the original DEA order form and signed and dated by the investigational drug pharmacist.

Damaged goods, goods that did not maintain proper temperature, shortages, short-dated items and delivery errors will be reported to the vendor and compensatory action will be taken to correct shortages and return any items that were received but not ordered.

9. All investigational drugs shall be dispensed by the Pharmacy and integrated with the inpatient and outpatient drug distribution system with respect to packaging, labeling, order review, profile maintenance, delivery, and so forth. The following special requirements exist:

A. The drug is dispensed only upon the written order of an authorized investigator.

B. The prescription label is distinguishable from other labels by the legend, "investigational drug". The protocol number and name will also be recorded on the label.

C. Before the Pharmacy will dispense the initial supply of drug:

1. The Pharmacy must have on file the study protocol and consent document.

2. The use of the investigational drug(s) as outlined in the Pharmacy Protocol Summary and Procedures must have been reviewed by pharmacy administration.

D. Investigational drugs require a double check process that mandates TWO (2) pharmacists independently check the investigational drug
study order with the protocol and verify the following components when applicable:

- Right Drug
- Right Kit or vial number
- Dose
- Concentration
- Infusion instructions
- Route of administration
- Volume of drug (in syringe or bag)
- Time of dose
- Expiration date and time
- Documentation in the drug accountability records.

E. If an investigational drug delivered to the nursing unit is not administered to the patient, the drug will be returned to the pharmacy for destruction.

10. The Pharmacy shall prepare an Investigational Drug Data Sheet which concisely summarizes for the Medical, Nursing, and Pharmacy Staffs information pertinent to use of the drug. The following information will be provided, at the minimum:

A. Drug designation and common synonym(s)
B. Available dosage forms and strengths
C. Usual dosage range, including dosage schedule and route of administration
D. Indications
E. Expected therapeutic effect
F. Expected and potential untoward effects
G. Contraindications
H. Storage requirements
I. Instructions for dosage administration
J. Names of principal investigator and study coordinator
11. The Pharmacy will be responsible for distributing copies of the Drug Data sheet with each dose of an investigational drug that is dispensed.

12. Patient education and monitoring of therapy shall be provided in a coordinated fashion by the Pharmacy and Nursing Staffs and the authorized investigator(s).

13. At the conclusion of the study, the Pharmacy will return unused drugs to the sponsor.

14. In the event that permission is granted for the destruction of any used or unused investigational drugs, the drugs will be sealed in a plastic bag and placed in the receptacle designated for incineration.

15. Upon completion of the study, Pharmacy records regarding drug disposition will be retained for at least two years, or longer if required by regulation.

16. Pharmacy files of investigational protocols will be maintained by protocol name.

17. When a patient is admitted with a supply of drugs from an investigational protocol that is independent of this hospital, a copy of the protocol must be obtained and added to the patient’s chart.

Carol Woodward
Director of Pharmacy
Pharmacy Coordinated
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Carol Woodward
Director of Pharmacy
Reporting Pharmacy Study Drug Errors

Policy

A dispensing error involving study drug in a clinical trial will be reported to the study coordinator, the physician, and the Institutional Review Board (IRB). If appropriate the error will also be reported through the Pharmacy Department Med Incident Pathway.

Procedure:

1. The study coordinator and the physician will be notified in the case of a dispensing error involving study drug in a clinical trial.
2. A Note to File (NTF) describing the incident will be prepared.
3. The NTF will be submitted to the study coordinator who in turn will submit it to the IRB.
4. If appropriate the pharmacist will also report the error through the Pharmacy Department Med Incident Pathway.

Carol Woodward
Director of Pharmacy
Pharmacist Training for Investigational Drug Studies

Policy

All pharmacists receive study-specific training for handling investigational drug studies in order to assure accuracy and compliance with the protocol.

Procedure

A. For sponsored clinical trials and trials involving an investigational drug, a study binder will be located in the IV Room. It will contain a Protocol Summary, Pharmacy Procedures, and all the required forms to record drug accountability.

B. The Protocol Summary and Pharmacy Procedures will also be posted on the pharmacy website.

C. Two pharmacy staff in-services will be scheduled for a clinical trial. Each pharmacist will sign and date the training log after attending an in-service.

D. Pharmacists who are unable to attend an in-service, will be asked to review the protocol summary, pharmacy procedures, and the study binder. After reviewing and completely understanding the study binder and summary and procedures, the pharmacist will sign and date the training log located in the study binder.

E. The Investigational Drug Pharmacist will follow-up with individuals who have not completed the training by the assigned deadline date.

Newsletter notification:
The _____(title)________study will begin _____(date)______________.
Inservices are scheduled _____(date and time)_____ and _____(date and time)______.
Pharmacists unable to attend, should review and completely understand the study binder, protocol summary, and pharmacy procedures, and then sign and date the training log located in the study binder (located in the IV Room).
If you have any questions, please ask___________.
The training log must be signed by _____(deadline date)______.

Carol Woodward
Director of Pharmacy
# Investigational Drug Refrigerator Temperature Excursion

## POLICY

In the event of an Investigational drug refrigerator temperature excursion, study drug will be moved to an alternate refrigerator, the study coordinator and/or the investigator will be notified, and the sponsor will be notified. Study drug will be quarantined until approval for use is received from the sponsor.

## PROCEDURE

1. In the event of a temperature excursion, the Investigational Drug Pharmacist or Pharmacy Administrator on Call will be notified.

2. The study drug will be moved to an alternate refrigerator. The time and date that the study drug was moved will be recorded.

3. Study drug will be quarantined until approval for use is received from the Sponsor.

4. The Study Coordinator and/or Investigator will be notified.

5. The Sponsor will be notified.

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Carol Woodward  
Director of Pharmacy
Point of Care Testing for Investigational Drug Equipment and State-Provided Vaccine Refrigerator

I. POLICY

Joint Commission regulations include a requirement for investigational drug storage. The Department of Pharmaceutical Services inspects, tests and maintains equipment including performing preventative maintenance, periodic inspection and performance testing of equipment and instruments.

II. PRINCIPLE

Temp Trak sensors used during the storage of pharmaceuticals used for clinical trials should be calibrated and standardized to prevent inaccurate indication of temperatures. Each Temp Trak sensor should be verified at initial use and annually thereafter to assure that no change has occurred.

III. SPECIMEN REQUIREMENTS: N/A

IV. MATERIALS AND EQUIPMENT:

a. NIST Traceable Standard Thermometer with certification for freezer
b. NIST Traceable Standard Thermometer with certification for refrigerator and room temperature storage
c. Temp Trak sensors/probes

V. QUALITY CONTROL: N/A

VI. PROCEDURE:

To verify Temp Trak probes:

a. Obtain the NIST Standard thermometer(s) from the Quality Coordinator in Peri-operative services
b. Place the appropriate NIST Standard thermometer’s probe next to the Temp Trak sensor probe
c. Allow adequate time for temperatures to equilibrate (app. 15 minutes)
d. Remove the cover off of the Temp Trak sensor. The sensor is located on the outside of the refrigerator/freezer
e. Carefully press the black reset button three times, waiting 5 seconds between each press
f. Document the NIST Standard thermometer reading
g. Log onto Temp Trak and access the appropriate sensor
h. Document the “actual” Temp Trak reading. This can be found by clicking the “Data Table” under Temp Trak Sensor History
i. Acceptable limit is within +/- 1º C of the NIST Standard thermometer for the refrigerated and room temperatures and +/- 2ºC for the freezer temperatures
j. Perform corrective actions if the acceptable difference is not met. Call Temp Trak Tech Support at 1-888-533-6900

VII. RECORDING RESULTS:

For Temp Trak probe verification see VII.08 Attachment

VIII. NOTES:

- NIST Standard Thermometers are used to verify refrigerated and room temperatures. Range is -50ºC to 70ºC. Certification for the thermometers may be obtained with this policy.
- NIST Standard Thermometer is used to verify freezer temperatures. Range is –99.9 to 199.9ºC
- If adequate time is not allowed for thermometers to equilibrate, false readings will result.
- The NIST Standard probe must be placed close to the Temp Trak probe for a more accurate reading.
- Low batteries on the NIST thermometers may cause erroneous results

IX. REFERENCE:

Temp Trak Reference Guide 2002-2006 Cooper Atkins
Return of Unused Investigational Drug from the Nursing Unit to the Pharmacy

Policy:

If an Investigational drug is dispensed to a Nursing Unit and subsequently not administered to the patient, the drug will be returned to the pharmacy for destruction.

Procedure:

1. If an Investigational drug is dispensed to a Nursing Unit and subsequently not administered to the patient, the drug will be returned to the pharmacy for destruction.
2. The return of the unused drug will be recorded on the Drug Accountability Record Form.
3. The unused drug will be destroyed per the SOP for Destruction of Drugs.
4. The destruction will be recorded on the Drug Accountability Record Form.

Carol Woodward
Director of Pharmacy