Pharmacy Coordinated Investigational Drug Service

Inpatient Department

POLICY:

All investigational drugs in use at West Virginia University Hospitals, Inc. 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 much 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 (ie: 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 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. 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. 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.

9. 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

10. The Pharmacy will be responsible for distributing copies of the Drug Data sheet with each dose of an investigational drug that is dispensed.

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

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

13. 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.

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

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

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

Carol Woodward
Director of Pharmacy

Pharmacy Coordinated

Investigational Drug Service

Outpatient Departments

POLICY:

All investigational drugs in use at the Cancer Center are received, distributed, and controlled by the West Virginia University Hospitals Department of Pharmaceutical Services and are used only under the direct supervision of the authorized principal investigator(s). Investigational drugs in use at the physician office center may be received, distributed, and controlled by the authorized principal investigator only after approval by the Investigational Drug Pharmacist.

PROCEDURE:

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

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 FDA approved protocol, and

B. use the product in patients under his/her supervision or under the supervision of physicians who are directly responsible 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 <u>emergency use</u> 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 the 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 (ie: 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 prescribing 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 approved the protocol for that use. Questions can be addressed to the Secretary of the IRB.

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

5. The principal investigator must be a member of the Physican Office Center and/or Cancer Center 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. Investigational drug supplies may be stored in the pharmacy department or the Physician Office Center/Cancer Center. The investigational drug pharmacist shall be responsible for the approval of proper storage of investigational drug supplies in the Physician Office Center/Cancer Center prior to study initiation.

7. The Pharmacy and/or principal investigator shall maintain a perpetual inventory of all investigational drugs. Data recorded will include amount received, dispensed, returned, date, patient information, and amount currently on hand. Study drug maintained by the principal investigator will be inspected by the investigational drug pharmacist on a quarterly basis.

8. For drugs stocked in the pharmacy, the investigational drug pharmacist will reorder study drug as needed. Drugs not stocked in the pharmacy must be reordered by the principal investigator or his/her designee.

9. Investigational drugs that are dispensed by the Pharmacy will be integrated with the inpatient and outpatient drug distribution system with respect to packaging, labeling, order review, profile maintenance, delivery, and so forth. Investigational drugs that are dispensed by the principal investigator must adhere to the appropriate labelling and packaging laws. The investigational drug pharmacist must give prior approval of labels and packaging. 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 label will also include the protocol name.

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 as outlined in the Protocol Summary and Procedures prepared by the pharmacy must have been reviewed by pharmacy administration.

D. 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, for investigational drugs dispensed by the pharmacy, 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 specific to the protocol

E. Expected therapeutic effect

F. Expected and potential untoward effects

G. Contraindications

H. Storage requirements

I. Instructions for dosage administration

J. Names of the 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 by the pharmacy.

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

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

14. Pharmacy files on investigational drugs will be maintained by study name.

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

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

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 inservices will be scheduled for a clinical trial. Each pharmacist will sign and date the training log after attending an inservice.
D. Pharmacists who are unable to attend an inservice, 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.

Carol Woodward

Director of Pharmacy