

The University of Tennessee Health Science Center

COMPLIANCE WITH FEDERAL AND STATE REGULATIONS FOR CONTROLLED SUBSTANCES AND LEGEND DRUGS*

Effective Date: September 1, 1979

Revised Date: June 1994

DEFINITIONS:

Controlled Substances are those substances specifically named on the official regulatory list published separately by the Drug Enforcement Administration (DEA) and the Tennessee Department of Mental Health and Mental Retardation. The classification system for both federal and state agencies consists of six schedules. All controlled substances fall within one of six schedules. The two lists are essentially identical. (Copies may be obtained from the Department of Pharmacy Services, University of Tennessee William F. Bowld Hospital. (WFBH 448-4136)

Legend Drugs are any prescription drug.

WHO MUST COMPLY:

All students, faculty, and staff of UTHSC who are NOT alicensed physician, dentist, or veterinarian for a recognized research purpose, teaching instruction or lawfully administrating, dispensing, or prescribing a legend drug or controlled substance in the course of his or her professional practice to an ultimate user for a recognized medical purpose.

USAGES FOR WHICH COMPLIANCE IS NECESSARY:

This policy and procedure applies to all controlled substances and legend drugs used in either RESEARCH OR INSTRUCTIONAL USE. All forms mentioned may be obtained from the Department of Pharmacy Services.

RESEARCH USE OF CONTROLLED SUBSTANCES

Each investigator not clinically licensed (See definition above - "Who must comply") must obtain approval at the federal, state, and institutional level before the acquisition of the controlled substance can be made.

Step 1 - Obtaining Federal Approval

File a DEA-225 application to the United States Department of Justice, Drug Enforcement Administration (DEA), P.O. Box 28083 Central Station, Washington, D.C. 20005 for the approval for the acquisition and use of controlled substances. The federal application (DEA-225) can be obtained directly from the agency or from the Department of Pharmacy Services, University of Tennessee William F. Bowld Hospital (WFBH 448-4136). Please allow one month for DEA approval.

Step 2 - Obtaining Institutional UTHSC Approval

Investigators whose research protocol involves the use of controlled substances on either animals or human subjects and who have obtained approval from the UTHSC Institutional Review Board (IRB) for the protection of human subjects constitutes instructional approval for the acquisition of the controlled substance specified in the protocol.

Investigators whose research protocol involves controlled substances in a medium other than animals or human subjects must submit to his or her departmental chairman for approval, an institutional application containing the following information: (a) the name, campus telephone number and address of the person requesting the acquisition; (b) name of the departmental chairman with his or her approval signature and date; (c) the nature of the proposed project; (d) the qualifications of the applicant to engage in such a project; (e) the proposed quantity of each drug involved; (f) the measures proposed to provide for security and proper record keeping of the drug.

Step 3 - Obtaining Additional Department or Collegiate Guidelines, if any

The investigator should check with the department administrator to see if there are any specific additional guidelines at the department or collegiate level not contained in this policy concerning acquisition, use, and inventory (record keeping) for controlled substances.

Step 4 - Ordering Controlled Substance

A. "Filing an Approved Requisition to the Department of Pharmacy Services"

For controlled substances, the investigator will forward to the Department of Pharmacy Services, University of Tennessee William F. Bowld Hospital (WFBH), a copy of a document certifying approval by either the Animal Care Committee, IRB, or institutional application. In addition for Schedule II Controlled Substance, the research investigator shall forward to the Department of Pharmacy Service, (WFBH), a signed Schedule II Controlled Substance order form and the order form must be accompanied by a signed and appropriately completed outside requisition with name, strength, and quantity of controlled substance requested.

NOTE: The research investigator may complete the Schedule II controlled Substance order form or have the Pharmacy Department complete the signed Schedule II Controlled Substance order form if the investigator is not familiar with the proper format.

For Schedule III, IV, and V controlled substances the investigator shall forward to the Department of Pharmacy, WFBH, a signed and appropriately completed outside requisition, and a copy of DEA license. On the requisition will be listed the controlled substances requested and the research investigator's Drug Enforcement Administration number.

B. "Processing of Requisition"

The Department of Pharmacy Services will verify the completeness of the controlled substance order forms and the outside requisition and will approve the purchase of the controlled substance(s). Upon approval, the completed form will be forwarded to the UTHSC Purchasing Office. All Schedule II through V substances ordered through this procedure will be delivered directly to the investigator as indicated in the outside requisition.

Step 5 - Security

A. All drugs must be in-date and properly labeled.

B. All drugs must be stored under an appropriate environment consistent to maintain drug stability.

C. Access to all drugs must be restricted to authorized personnel only.

D. Controlled substances must be stored in a securely locked, substantially constructed metal cabinet or another structure which provides the equivalent or better physical security.

Step 6 - Inventory and Maintenance of Records

A. The investigator must maintain for a period of two years, all invoices for receipt of controlled substances. For Schedule II Controlled Substances, the quantity and date of receipt of the Schedule II Controlled Substances must be indicated on the Investigator's copy of the controlled substances order form.

B. The investigator must take an inventory every two years of all stock of controlled substances on hand.

C. The investigator is required to maintain a record of the use of controlled substances for a period of two years. A controlled drug must be able to be traced from the time of receipt to the time of use.

D. Perpetual inventory sheets will be supplied by the Department of Pharmacy Services for the use by the investigator in the maintenance of records.

E. The Director of Pharmacy Services or his designee will maintain the right to inspect for proper record maintenance.

INSTRUCTIONAL USE OF CONTROLLED SUBSTANCES

Registration of UTHSC is maintained by the Department of Pharmacy Services, WFBH for ordering of controlled substances for Teaching Instructional Purposes. The Department of Pharmacy Services is responsible for final approval of departmental requisitions and both the Department of Pharmacy Services and the requisitioning department are responsible for record-keeping for all controlled substances in this classification. All UTHSC personnel not clinically licensed (See definition above - "Who Must Comply") must obtain UTHSC institutional approval and be approved through the Department of Pharmacy Services WFBH before the acquisition or use of the controlled substances can be made. UTHSC maintains its own DEA license for the use of controlled substances II through V (therefore UTHSC personnel do not have to obtain an individual license when the use of the controlled substance is for an instructional purpose).

Step 1 - Obtaining Institutional Approval

The instructor must submit to his or her department chair for their approval an application containing the following information: (a) the name, campus telephone number and address of the person requesting the controlled substance; (b) name of the department chair with his or her approval signature and date; (c) the title and course number in which the controlled substances will be used for instruction; (d) the proposed quantity of each drug involved; (e) the measures proposed to provide for security and proper record-keeping of the drugs; (f) specific provisions for the safe administration or dispensing of drugs.

Step 2 - Ordering Controlled Substances

A. "Filing an Approved Requisition to the Department of Pharmacy Services."

For Schedule II through V controlled substances the department chair will forward to the Department of Pharmacy Services, WFBH, a copy of the approved institutional application, a signed transfer voucher with the correct account number, a name of the account being debited, and name, strength and quantity of controlled substance(s) requested.

B. "Transfer of Funds"

The Department of Pharmacy Services will enter the correct acquisition cost and service fee on a transfer voucher and process the transfer voucher once the controlled substance order has been filled. A copy of the completed transfer voucher will be returned to the requisitioning department.

C. "Receipt of Controlled Substances"

Once the controlled substances have been received in the Department of Pharmacy Services at the WFBH, the requisitioning department will be notified. To obtain the controlled substances from the Department of Pharmacy Services a signed authorization accepting responsibility for the disposition of the controlled substances must be presented from the appropriate departmental chairman and the voucher must be signed by the individual who receives the controlled substances.

Step 3 - Security

- A. All drugs must be in-date and properly labeled.
- B. All drugs must be stored under an appropriate environment consistent to maintain drug stability.
- C. Access to all drugs must be restricted to authorized personnel only.
- D. Controlled substances must be stored in a securely locked, substantially constructed metal cabinet or another structure which provides the equivalent or better physical security.

Step 4 - Inventory and Maintenance of Records

- A. The department chair or his or her designee must take an inventory every two years of all stocks of instructional controlled substances in their areas. A copy of the inventory must be forwarded to the Department of Pharmacy Services.
- B. Perpetual inventory sheets will be supplied by the Department of Pharmacy Services for use by the departmental chairmen or their designees for the maintenance of records. A controlled substance must be able to be traced from the time of receipt to the time of use.
- C. The department chair or his or her designee will be responsible for maintaining records for disposition of controlled substances.
- D. The Director of Pharmacy Services or his designee will maintain the right to inspect for proper record maintenance.

RESEARCH USE OF LEGEND DRUGS

Each investigator not clinically licensed (see definition above- "Who Must Comply") must obtain institutional (UTHSC) approval before the acquisition of the legend drug can be made.

Step 1 - Obtaining Institutional Approval

Investigators whose research protocol involves the use of legend drugs on either animals or human subjects and who have obtained approval from the UTHSC Animal Care Committee or the UTHSC Institutional Review Board (IRB) for the protection of human

subjects constitutes institutional approval for the acquisition of the legend drugs(s) specified in the protocol.

Investigators whose research protocol involves the use of legend drugs on either animals or human subjects must submit to his or her department chair for approval an institutional application containing the following information: (a) the name, campus telephone number and address of the person requesting the acquisition; (b) name of the department chair with his or her approval signature and date; (c) the nature of the proposed project; (d) the qualifications of the applicant to engage in such a project; (e) the proposed quantity of each drug involved; (f) the measures proposed to provide for security and proper record keeping of the drugs.

Step 2 - Obtaining Additional Department or Collegiate Guidelines, if any

The investigator should check with the department administrator to see if there are any specific additional guidelines at the department or collegiate level not contained in this policy concerning acquisition, use, and inventory (record keeping) for legend drugs.

Step 3 - Ordering Legend Drugs

A. "Filing an Approved Requisition to the Department of Pharmacy Services"

For legend drugs the investigator will forward to the Department of Pharmacy Services, University of Tennessee William F. Bowld Hospital (WFBH), a copy of a document certifying approval by either the Animal Care Committee, IRB, or institutional application; a signed transfer voucher with the correct account number, name of the account being debited, and name, strength, and quantity of the legend drugs requested.

B. "Transfer of Funds"

The Department of Pharmacy Services will enter the correct acquisition cost and service fee on the transfer voucher once the order for legend drugs has been filled. A copy of the completed transfer voucher will be returned to the requisitioning department.

C. "Receipt of Legend Drugs"

Once the legend drugs have been received in the Department of Pharmacy Services at the WFBH the requisitioning department will be notified. To obtain the legend drugs from the Department of Pharmacy Services, a signed authorization accepting responsibility for the disposition of the legend drugs must be presented from the appropriate investigator and the transfer voucher must be signed by the individual who receives the legend drugs.

Step 4 - Security

A. All legend drugs must be kept in a secure area. A locked cabinet is preferred.

B. All drugs must be in-date and properly labeled.

C. All drugs must be stored under an appropriate environment consistent to maintain drug stability.

D. Access to all drugs must be restricted to authorized personnel only.

Step 5 - Inventory and Maintenance Records

A. The researcher or designee will be responsible for maintaining records showing the receipt, administration, dispensing and destruction of all legend drugs. These records must be maintained for two years.

B. Perpetual inventory sheets will be supplied by the Department of Pharmacy Services for use by the investigator in the maintenance of records.

C. The Department of Pharmacy Services or his designee will maintain the right to inspect for proper record maintenance.

INSTRUCTIONAL USE OF LEGEND DRUGS

Registration for UTHSC is maintained by the Department of Pharmacy Services, WFBH for ordering of legend drugs for Teaching Instructional Purposes. The Department of Pharmacy is responsible for final approval of departmental requisitions and both the Department of Pharmacy Services and the requisitioning department are responsible for record-keeping for all legend drugs in this classification. All UTHSC personnel not clinically licensed (see definition above - "Who Must Comply") must obtain UTHSC institutional approval and be approved through the Department of Pharmacy Services WFBH before the acquisition or use of the legend drug can be made.

Step 1 - Obtaining Institutional Approval

The instructor must submit to his or her department chair for his approval an institutional (UTHSC) application containing the following information: (a) the name, campus telephone number and address of the person requesting the legend drug; (b) name of the department chair with his or her approval signature and date; (c) the title and course number in which the legend drug(s) will be used for instruction; (d) the proposed quantity of each drug involved; (e) the measures proposed to provide for security and proper record keeping of the drugs; (f) specific provisions for the safe administration or dispensing of drugs.

Step 2 - Ordering Legend Drug

A. For legend drugs the departmental chairman will forward to the Department of Pharmacy Services, University of Tennessee William F. Bowld Hospital (WFBH), a copy of the approved institutional application, a signed transfer voucher with the correct account number, and the name of the account being debited. In addition, on the transfer voucher will be listed the quantity of legend drugs requested.

B. "Transfer of Funds"

The Department of Pharmacy Services will enter the correct acquisition cost and service fee on a transfer voucher and process the transfer voucher once the legend drug order has been filled. A copy of the completed transfer voucher will be returned to the requisitioning department.

C. "Receipt of Legend Drug(s)"

Once the legend drug(s) has been received in the Department of Pharmacy Services at the WFBH the requisitioning department will be notified. To obtain the legend drug from the Department of Pharmacy Services, a signed authorization accepting responsibility for the disposition of the legend drug must be presented from the appropriate departmental chairman and the voucher must be signed by the individual who receives the legend drug.

Step 3 - Security

A. All legend drugs must be kept in a secure area. A locked cabinet is preferred.

B. All drugs must be in-date and properly labeled.

C. All drugs must be stored under an appropriate environment consistent to maintain drug stability.

D. Access to all drugs must be restricted to authorized personnel only.

Step 4 - Inventory and Maintenance of Records

A. The department chair or his designee will be responsible for maintaining records showing the receipt, administration, dispensing and destruction of legend drugs received. These records must be maintained for two years.

B. Perpetual inventory sheets will be supplied by the Department of Pharmacy Services for use by department chair or his/her designee for the maintenance of records.

C. The Director of Pharmacy Services or his designee will maintain the right to inspect for proper record maintenance.

*Controlled Substance Act of 1970 (21CFR-1301.21); Tennessee Code Annotated 52-1446, 33-104, 52-1410-423; Public Chapter Number 717 Tennessee Legend Drug and Controlled Substance Research Act of 1984, and Amended Tennessee Code Annotated, Section 53-11-412, and Title 53.

Investigational new drug (IND) approval must be obtained from FDA. INDs operate under a separate set of guidelines and procedures. For further information, contact the Institutional Review Board (IRB) for the protection of human subjects (448-5781).