Use of Controlled Substances in Research Policy Manual

Introduction

Liberty University requires that Principal Investigators (PIs) conducting activities with Drug Enforcement Agency (DEA) controlled substances in basic and applied research settings be licensed with the Virginia Board of Pharmacy and registered with the DEA.

All individuals shall comply with state and federal regulations regarding the acquisition, record keeping, inventory, storage, use, and disposal of those substances.

Principal Investigators intending to use controlled substances in research must obtain a Virginia Board of Pharmacy Controlled Substance Registration and a DEA Registration prior to ordering or using controlled substances. An individual must be named and designated as providing research oversight on an approved LU Controlled Substance Research Protocol to serve as a Registrant for that protocol. Responsibilities associated with controlled substances are detailed and regularly enforced by both LU and the DEA. Those individuals not comfortable with assuming such responsibilities and with maintaining the required records are discouraged from applying for registration.

Delegation of the administrative and managerial oversight responsibilities to an authorized agent is permitted under a Power of Attorney (POA) delegation document; however, only the Registrant is permitted to dispense and dispose of controlled substances and the Registrant retains ultimate responsibility and accountability for recordkeeping. Responsibility is individually based. Individuals who are fined or individuals who have violated the law will not be reimbursed by LU or defended for criminal actions.

The Provost and Chief Academic Officer is the Institutional Official with ultimate responsibility for ensuring appropriate conduct of research at Liberty University. The Institutional Official is vested with the authority to suspend, revoke, or deny any researcher registration application submitted or registration issued through the state or federal processes, if necessary.

Questions about procurement, secure storage, use, disposal, required documentation, or regulatory questions regarding controlled substances in research should be directed to the Research Ethics Office at iacuc@liberty.edu. The Research Ethics Office offers controlled substances educations sessions for faculty, staff, and students.

General Definitions

Authorized Agent

Authorized Agents are not required to hold a DEA registration; however, they must be screened and vetted by the Registrant pursuant to 21 C.F.R. §1301.90 and granted POA. This individual must have the complete trust of the Registrant. By POA, a Registrant can give authorization to an Authorized Agent to order controlled substances, to assist in inventory oversight and recordkeeping, to access the storage of controlled substances, and the general management of controlled substances in the Registrant's absence. Registrants are not permitted to delegate

dispensing or disposal duties to Authorized Agents. To reduce the risk of drug diversion, a maximum of 2 individuals in a laboratory should be granted the status of an Authorized Agent. Regardless of POA authorization, the licensed researcher as Registrant remains ultimately responsible for the management of all controlled substances acquired under their DEA registration. Only the licensed researcher as Registrant and an Authorized Agent (if granted POA authority) should have access to the safe or locked cabinet where inventories of controlled substances are stored. Only Authorized Agents are permitted to know the licensed researcher's DEA registration number and are permitted to order controlled substances on their behalf.

Authorized Official
The individual(s) formally authorized to be an "approver" of DEA registration applications on behalf of the institution. The Authorized Officials for Liberty University are currently the Dean and Associate Dean of the Graduate School.

Authorized User
A University Member working under the direct supervision of a Registrant/researcher. In addition to the Registrant/researcher and Authorized Agents, the Authorized User may participate in using controlled substances during experiments or treatments. Authorized Users can perform these functions but only without keys or combination access to the safe or cabinet where bulk quantities of controlled substances are stored. Only Registrants are permitted to dispense limited quantities of controlled substances to Authorized Users for daily use (per 21 CFR §1301.90). Authorized Users do not require a DEA background check but must be screened by the Registrant (per 21 CFR §1301.90) and complete training prior to beginning work. Each Registrant/researcher is responsible for authorizing specific roles, and providing required training for proper handling of controlled substances.

Building
A structure with an official street address.

Bulk Form
A controlled substance as received from the manufacturer or supplier to be used in, capable of use in, or being used in, the manufacture of the same or other non-controlled substances in Finished Form. Per LU policy, Bulk Form substances may be dispensed to Authorized Users for a single day. Unused Bulk Form substance must be returned to the Registrant at the end of each day.

Controlled Substance
Any substance listed in the Controlled Substances Act, Code of Federal Regulations (21 CFR Parts 1300 - 1321) or the Virginia Drug Control Act, Title 54.1, Chapter 34 of the Code of Virginia. Controlled substances are identified in the schedules contained within the "Controlled Substance Inventory List" published by the DEA.

DEA Registrant ("Registrant")
The individual that holds a DEA registration(s) and is responsible for ordering, storing, using, and disposing of controlled substances. This individual is fully responsible to ensure compliance with controlled substance regulations at the location where the controlled substances are held.

Registrants may appoint a subordinate (i.e. power of attorney/authorized agent) to assist in managing controlled substances and related records; however, the Registrant is ultimately solely responsible for assuring proper recordkeeping, storage, and use of controlled substances. Deficiencies or discrepancies in recordkeeping are the responsibility of the Registrant.

DEA Research Protocol
A protocol to conduct research with Schedule I controlled substances in the form described in 21 CFR 1301.18. For Schedule II-V controlled substances, see LU Controlled Substances Protocol below.

Dispense
Prepare and distribute controlled substances to Authorized Users.

Disposal
Relinquishment of contaminated, expired, excess, residual (or waste) and unwanted controlled substances. Disposal must be conducted using DEA Form 41 through a DEA-authorized reverse distributor.

Drug Enforcement Administration (DEA)
The agency within the United States Department of Justice that enforces the controlled substances laws and regulations.

Expired and/or Unusable Substances
Controlled substances for which the expiration date has passed; or tablets, injections, liquid, or preparations compounded in error which contain controlled substances that can no longer be used for research due to contamination, etc.

Finished Form
A controlled substance altered from Bulk Form (diluted, compounded, etc.) which will be used for research (e.g., Bulk Form diluted 1:10 becomes Finished Form).

Institutional Official
The Provost and Chief Academic Officer at Liberty University.

Location
A room or designated area in a building where controlled substance inventory is stored.

LU Controlled Substance Research Protocol
An LU form meeting the requirements of a DEA protocol for use with research projects using Schedule II-V controlled substances.

Principal Investigator
The individual with final responsibility for the conduct of research or other activity described in a proposal or an award.

Recordkeeper

An individual assigned by the Registrant to assist with Registrant records. The Recordkeeper is not authorized to dispense substances, enter new substances into inventory, or dispose of substances. The Recordkeeper must only provide data entry services. The Registrant remains responsible for all actions and records of the Recordkeeper.

Registration
Formal grant of specific authority for controlled substances activities by the DEA and by the Virginia Board of Pharmacy. Often referred to as a license or certificate.

Research
A systematic investigation, including development, testing and evaluation designed to develop or contribute to generalizable knowledge.

Researcher
Any University Member that conducts research at LU.

Teaching Activity
Activities that include classroom demonstrations, laboratory exercises and research projects which are required for completion of a course at the undergraduate, graduate or professional level.

Transfer
To move a controlled substance from the inventory of one Registrant to another Registrant. Under LU policy, transfer of controlled substances between LU Registrants must be less than 5% of Registrant's annual total controlled substance inventory or usage unless written permission is obtained from the Roanoke DEA office to transfer more than 5%.

University Member
All LU full- and part-time faculty, classified employees, administrative staff, paid student assistants, students (under certain conditions as described in this policy), volunteers, fellows and trainees, visiting faculty and researchers, and those employees and visitors covered by sponsored program agreements or other contractual arrangements are considered University Members for purposes of this policy. Only full-time faculty members can be Registrants under this policy.

Usage Log
A document completed by each Registrant, Authorized Agent, and/or Authorized User tracking usage of controlled substances. Completed documents are maintained in the Registrant records.

Virginia Board of Pharmacy
The agency authorized by the Commonwealth of Virginia to implement and regulate Virginia Statutes and Board of Pharmacy Rules and to oversee the conduct and professional competency of Virginia Board of Pharmacy registrants.

Controlled Substance Definitions

Controlled substances are drugs or other chemicals that have the potential to be addictive or habit forming. The DEA has divided controlled substances into 5 schedules based on their potential to be habit forming and their usefulness in medicine as a drug. For a more comprehensive listing, see https://www.deadiversion.usdoj.gov/schedules/schedules.html. Schedule VI substances are those identified by the Code of Virginia, and this scheduling designation is not utilized by the DEA.

Schedule I
Drugs or other substances that have a high potential for abuse; no currently accepted medical use in treatment in the United States and have a lack of accepted safety for use even under medical supervision. Examples include: Heroin, Lysergic Acid Diethylamide (LSD), Marijuana (cannabis), 3,4-methylenedioxymethamphetamine (Ecstasy), Psilocybin (Magic Mushrooms) and Peyote.

Schedule II
Drugs or other substances that have a high potential for abuse; currently have an accepted medical use in treatment in the United States, and abuse may lead to severe psychological or physical dependence. Examples include: Oxycodone, Hydromorphone, Fentanyl, Morphine, Amphetamine, Methylphenidate, Cocaine and Methamphetamine.

Schedule III
Drugs or other substances that have a moderate potential for abuse (less than Schedule I or II); currently have an accepted medical use in treatment in the United States; abuse may lead to moderate or low physical and high psychological dependence. Examples include: Anabolic steroids, Ketamine, Combination pain medications with limited amounts of opioids (Hydrocodone combined with acetaminophen), and Buprenorphine.

Schedule IV
Drugs or other substances that have a low potential for abuse relative to those listed in Schedule III; currently have an accepted medical use in treatment in the United States; and have a limited risk of physical or psychological dependence (less than Schedule III). Examples include: Benzodiazepines, Zolpidem (Ambien), Eszopiclone (Lunesta), Tramadol, and Modafinil.

Schedule V
Drugs or other substances having the lowest potential for abuse among the controlled substances classified by the DEA; currently have an accepted medical use in treatment in the United States; and have a limited risk of physical or psychological dependence (less than Schedule IV). Examples include: Cough preparations containing small amounts of codeine, Diphenoxylate/atropine (Lomotil), and Pregabalin (Lyrica).

Schedule VI
Drugs or other substances recognized by Code of Virginia §54.1-3455 (Schedule VI)* containing any stimulant or depressant exempted from Schedules III, IV, V but designated by the Virginia Board of Pharmacy, or any drug not in Schedules I–V, which, because of potential toxicity must be prescribed by a licensed practitioner, or any drug not in Schedules I-V that is required by federal law to carry "Rx only" or other designated prescription labeling. Examples include: Amyl

nitrite and Nitrous oxide. *Note: This is specific to the Commonwealth of Virginia. The DEA does not utilize this scheduling designation.

Sample Forms

Using controlled substances requires specific documentation. Sample forms to authorize specific agents/users, maintain required inventory, and record use of controlled substances are available on the Controlled Substances page of the IACUC website. Use of these specific forms is not required but these templates do incorporate required elements from the applicable regulations. Any format used must meet the requirements of all applicable regulations. Individuals must determine a consistent documentation process to ensure best compliance practices. Documents may be maintained electronically so long as they can be printed and presented to DEA Investigators or institutional representatives, as requested.

Who Must Register

University Members who are full-time faculty members, and who store, administer or order controlled substances for LU Controlled Substance Research Protocols on which they are a contributing investigator must register with both the Virginia Board of Pharmacy and the Drug Enforcement Administration for the laboratory and specific address where controlled substances are stored. University Members must have oversight of the research to serve as the Registrant on a protocol.

Current Registrants Holding Clinical Practitioner Registrations

A Practitioner Registration from the DEA allows for the following coincident activities: research and instructional activities with those substances for which registration was granted. Therefore, a Practitioner may conduct clinical research under their Practitioner Registration. A Practitioner Registration may authorize research involving animals or chemical analysis if the registration includes the appropriate schedules and the intended activities fall within DEA-permitted scope. For activities outside of the Practitioner category, a separate Researcher Registration is required.

Registration and Inspection

It is the responsibility of each Registrant to obtain appropriate annual licenses and registrations, and to adhere to applicable state and federal regulatory requirements when working with controlled substances. Registrants shall not allow the registration to lapse until all controlled substances are spent, disposed of, or transferred to another Registrant. Registrants must obtain separate registrations for each address at which controlled substances will be used.

Virginia Board of Pharmacy Registration

Each individual desiring registration must complete a Virginia Board of Pharmacy Application for Controlled Substance Registration Certificate. Virginia Board of Pharmacy licensing is for a one (1) year period. There is an annual fee. The online forms are here: http://www.dhp.virginia.gov/Boards/Pharmacy/PractionerResources/FormsandApplications/

Virginia Board of Pharmacy applications must be sent to:

Commonwealth of Virginia Board of Pharmacy
9960 Mayland Drive, Suite 300
Henrico, VA 23233

A copy of the application also must be sent to iacuc@liberty.edu.

Prior to issuance of a Controlled Substances Registration, Virginia Board of Pharmacy representatives will conduct an interview and inspection to ensure that appropriate safeguards are in place to protect controlled substances.

DEA Registration

A DEA Form 225 Application for Registration is required. An Authorized Official is responsible for approval of Schedule I applications and certification of tax-exempt status.

Schedule I Applications
A paper application must be completed and forwarded to the Research Ethics Office (Green Hall Suite 2845 or iacuc@liberty.edu) for institutional review and approval. Following approval, the application should be completed online (or by mail) and sent to:

DEA Headquarters
Attn: Registration Section/ODR
PO Box 2639
Springfield, VA 22152-2639

Registrants requiring the use of Schedule I substances must also include an LU Controlled Substances Protocol which meets the requirements described in 21 CFR 1301.18 and includes the items below:

Investigator
- Name, street address, building name and room number and DEA registration number; if any.
- Institutional affiliation.
- Qualifications, including a curriculum vitae and an appropriate bibliography (list of publications).

Research Project
- Title of project.
- Statement of the purpose.
- Name of the controlled substances or substances involved and the amount of each needed.
- Description of the research to be conducted, including the number and species of research subjects, the dosage to be administered, the route and method of administration, and the duration of the project.
- Location where the research will be conducted (same as Registrant address)

- Statement of the security provisions for storing the controlled substances (in accordance with 21 CFR 1301.75 and for dispensing the controlled substances in order to prevent diversion.
- If the investigator desires to manufacture or import any controlled substance, a statement of the quantity to be manufactured or imported and the sources of the chemicals to be used or the substance to be imported.

Authority

- Institutional approval. An Authorized Official must approve the registration application.
- Approval of the Institutional Review Board (IRB) for human studies.
- Approval of the Institutional Animal Care and Use Committee (IACUC) for animal studies.
- Indication of an approved active Notice of Claimed Investigational Exemption for a New Drug (number), if applicable.
- Indication of an approved funded grant (number), if any.

Schedule II-V Applications

Schedule II-V applications can be completed online. The online forms are here: http://www.deadiversion.usdoj.gov/online_forms_apps.html

Inspection

DEA Investigators will conduct a pre-registration interview with all pending registrants. I

Information or documentation that will be required includes the following;

- Curriculum Vitae/Resume
- Copy of State License
- Copy of Certifications
- Summary of Controlled Substance Protocol (the LU Controlled Substances Protocol can be used, if desired)
- List of Controlled Substances to be used
- Quantity of controlled Substance to keep on hand
- List of Suppliers for Controlled Substances
- How the Controlled Substances will be used in the research
- Source of Funding
- Length of Research
- List of authorized personnel with contact information as required; sensitive personal identifiers should not be collected unless specifically required
- Supplier Source for the Animals (if applicable)
- Copy of the Controlled Substances Log
- Copy of the Lab's floor plan
- Specifications for Safe or Controlled Substances storage cabinet (lock information)
- Lab/Area Security Summary

Once received, a copy of each license/registration must be submitted to iacuc@liberty.edu for recordkeeping purposes.

DEA and Virginia Board of Pharmacy registrations generally remain active for a one (1) year period.

DEA Form 222 is required only for Schedule I and II transfers or acquisitions, not for disposal. Disposal must be documented via DEA Form 41 and reverse distributor processes.

Registration Certificates
As each Registration Certificate is received, a copy must be sent to iacuc@liberty.edu so that an institutional database can be maintained for compliance purposes.

Registration Amendments
Registrants may require the addition of new substances and protocols throughout the life of the registration. An amendment must be submitted in accordance with the instructions below:

- For Schedule I substances, a letter with a revised LU Controlled Substances Protocol, specifically highlighting the changed information must be forwarded to the Research Ethics Office for review and approval. Following approval, the application should be sent to:

  DEA Headquarters
  Attn: Registration Section/ODR
  PO Box 2639
  Springfield, VA 22152-2639

- For Schedule II-V substances, a revised LU Controlled Substance Research Protocol, specifically highlighting the changed information must be submitted to the Research Ethics Office at iacuc@liberty.edu for review. Upon approval by the Research Ethics Office, the form will be forwarded to the Roanoke DEA Office for updating the DEA registration and inventory records. The Roanoke DEA Office will not issue specific approvals for additional Schedule II-V substances. A copy of the Research Ethics Office approval forwarded to the Roanoke DEA Office will be sent to the Registrant.

Registration Renewals
Annual renewals for both Virginia Board of Pharmacy and DEA registrations can be completed online.

The Virginia Board of Pharmacy will send a reminder notice approximately two months prior to expiration providing a website link and passcode to enter the renewal online.

The DEA will send a reminder notice approximately three (3) months prior to expiration. DEA renewals generally can be completed online.

Separate Registrations for Separate Buildings

Individuals with a need to use controlled substances in different buildings must obtain a separate registration for each building. Separate storage, inventory, usage records, etc. must be maintained for each location.

Authorized Agents and Users
The Registrant is responsible for managing controlled substances in accordance with the requirements of the regulations including inventory, record keeping and security provisions. LU policy requires that each Registrant designate (via POA) an Authorized Agent as a back-up should there be an emergency where the Registrant is unavailable or otherwise incapacitated. Authorized Users of the Registrant may engage in approved activities under the direction of the Registrant. The Registrant is required to screen employees prior to authorization of work with controlled substances using the Personnel Screening Form and verify that the applicable Controlled Substances Training module has been completed.

Personnel Screening
The Registrant must ensure that each potential Authorized User completes the Personnel Screening Form – Authorized User (21 CFR 1301.90). The screening form includes the following questions:

1. Within the past five years, have you been convicted of a felony, or, within the past two years, any misdemeanor, or, are you presently charged with committing a criminal offense?
2. In the past 3 years, have you knowingly used narcotics, amphetamines, or barbiturates other than those prescribed to you by a physician?
3. Have you ever been denied a DEA registration, had a DEA registration revoked or surrendered a DEA registration for cause?

Make copies of the form as needed for each employee who will be working with these substances. If the answer to any of the questions is "yes", the person is not allowed to sign the Authorized Users Signature Log, and the Research Ethics Office must be contacted. Keep these questionnaires on file at the registered location. This form must also be completed by new hires before they are allowed to handle controlled substances.

Transferring Registrations and/or Controlled Substances to Liberty University
Any faculty member that intends to transfer a DEA registration or controlled substances to Liberty University must do so in accordance with federal, state, and local laws. This includes filing the necessary paperwork with the federal and state DEA offices, and coordinating with the appropriate LU departments prior to arrival on campus. All incoming faculty must abide by the contents of this document.

- An LU Controlled Substances Research Protocol must be submitted to the Research Ethics Office and approved by administration prior to transferring controlled substances to campus. Doing so allows LU to track controlled substances and the amounts to be transferred. Incoming faculty must also discuss the storage and use of controlled substances with their Dean or designated departmental representative. In certain cases, faculty may need to coordinate with departments other than their own to verify that adequate storage space is available, consistent with DEA regulations. Contact iacuc@liberty.edu for additional information on this process.

Roles and Responsibilities

Research Ethics Office -- Roles and Responsibilities:

- Provide training on LU's policies and procedures for use of controlled substances
- Provide guidance to faculty members for registering with federal and state agencies
- Provide guidance on storage of controlled substances
- Provide guidance on disposal of controlled substances
- Maintain institutional records of Registrants, Authorized Agents, and Authorized Users
- Serve as the institutional liaison for DEA inspections and compliance inquiries

Units or Departments That Process Orders for Controlled Substances for Registrants -- Roles and Responsibilities:

- Comply with federal and state regulations
- Ensure only Registrants order controlled substances using the appropriate forms
- Ensure that controlled substances ordered through the department are stored in accordance with LU policy, as well as federal and state regulations
- Verify that DEA Form 222 is used only for Schedule I and II acquisitions or transfers
- Maintain internal documentation of controlled substance orders for audit purposes

DEA Registrants -- Roles and Responsibilities:

- Comply with federal and state regulations and university policy pertaining to the possession and use of controlled substances. The Registrant is individually responsible for adherence to LU Policy, Virginia Board of Pharmacy regulations and DEA regulations.
- Obtain and maintain Virginia Board of Pharmacy and Drug Enforcement Administration registrations
- Complete the "Controlled Substances Training – Registrant" module and maintain a copy of the quiz score in his/her completion records. See Training topic outlined below.
- Identify and document individuals as Authorized Agents and Authorized Users
- Maintain documentation for Authorized Agents and Authorized Users
- Provide and maintain documentation on training of laboratory-specific operations involving controlled substances
- Maintain strict control over inventory and security and ensure proper storage of controlled substances
- Obtain DEA approval, via amendment, for substances not currently approved under their registration prior to ordering, inventorying, dispensing, or disposing of such substances
- Dispense usage amounts of Bulk Form substances to Authorized Users
- Obtain and retain usage log sheets for Bulk and Finished Form substances
- Maintain separate storage areas, logs and inventory for Schedule I controlled substances in their possession
- Maintain separate storage areas, logs and inventory for Schedule II controlled substances in their possession
- Maintain separate storage areas, logs and inventory for Schedule III-V controlled substances in their possession

- Receive, store, use, and dispose of controlled substances properly and continually maintain usage log sheets; Disposal must be conducted using DEA Form 41 through a DEA-authorized reverse distributor
- Maintain usage log sheets for two years after completing use or disposal of controlled substances
- Exercise signature authority for purchase and disposal of controlled substances
- Conduct an initial inventory
- Conduct a biennial inventory per DEA regulations
- Report in writing the theft or loss of any controlled substance to the DEA Field Division (using Form 106), Virginia Board of Pharmacy, LUPD and Research Ethics Office within one business day of discovery
- Dispose of unwanted controlled substances in accordance with DEA regulations using DEA Form 41, supplied by a DEA-authorized reverse distributor
- Dispose of controlled substances no longer supported by an active, approved protocol
- Upon receipt, send copy of registration, registration renewal or notice of lapse of registration to iacuc@liberty.edu
- Report DEA inspection and audit findings to iacuc@liberty.edu within 5 business days of notice received by Registrant
- Ensure Authorized Agents operate only within the scope of granted POA

Authorized Agents -- Roles and Responsibilities:

- Comply with federal and state regulations and university policy pertaining to the possession and use of controlled substances
- Complete the "Controlled Substances Training – Authorized Agent" module and provide documentation of completion to the Registrant. See Training topic below
- Complete all required personnel screening prior to being granted Power of Attorney (POA) authority and immediately notify the Registrant of any change in eligibility to work with controlled substances
- Maintain a valid, executed POA document authorizing the specific controlled substance activities delegated by the Registrant
- If authorized by POA, assist the Registrant with ordering controlled substances, including execution of procurement documents and DEA ordering forms
- If authorized by POA, receive controlled substance shipments on behalf of the Registrant and ensure purchased substances are promptly secured and documented in accordance with University policy
- If authorized by POA, assist the Registrant with inventory management, recordkeeping, reconciliation of usage records, and other administrative functions associated with controlled substances oversight
- If authorized by POA, maintain access to controlled substances storage areas only to the extent necessary to perform assigned duties
- Maintain confidentiality of DEA registration numbers, ordering credentials, storage locations, key assignments, lock combinations, and other security-sensitive information
- If authorized by POA, assist the Registrant in maintaining required inventories, including initial, biennial, and reconciliation inventories

- Ensure that all controlled substances remain properly secured and immediately report any actual or suspected security deficiencies to the Registrant
- Immediately report any discrepancy, inventory irregularity, loss, theft, suspected diversion, or recordkeeping concern to the Registrant
- Complete and maintain all records required for activities performed under POA delegated authority and provide such records to the Registrant for retention
- Assist the Registrant during inspections, audits, inventory reviews, and post-approval monitoring activities conducted by the DEA, Virginia Board of Pharmacy, Research Ethics Office, or other authorized entities
- If authorized by POA, serve as the Registrant's designated backup for administrative and managerial oversight of controlled substances during periods when the Registrant is unavailable, absent, or incapacitated
- Immediately surrender all keys, access credentials, records, and controlled substance-related materials upon revocation of POA authority, termination of employment, reassignment, or cessation of duties involving controlled substances.

Authorized Users -- Roles and Responsibilities:

- Complete the "Controlled Substances Training – Authorized Users" module and maintain a copy of the certificate in his/her completion records. A copy of the completion record must also be provided to the Registrant. See Training topic below.
- Complete the Personnel Screening Form – Authorized User before commencing use of controlled substances.
- Sign the Authorized Users Signature Log (Note: separate logs must be maintained for Schedule I and Schedule II-V substances)
- Complete usage log sheets – Controlled Substance Usage Log and Wastage Record
- Store controlled substances in an individual lockbox, marked with the individual's name, or a laboratory-level lockbox, in a locked cabinet at the Registrant's Location
- Authorized Users may not possess keys or combinations to bulk storage safes or cabinets
- Return unused controlled substances in Bulk Form and usage log sheet to the Registrant after each day
- Return usage log sheets of Finished Form substances when substance has been fully used or is no longer needed
- Immediately report any discrepancy or suspected theft to the Registrant
- Receive laboratory-specific training on procedures before using controlled substances
- Immediately report to the Registrant any felony violations/convictions
- Authorized Users may not transfer controlled substances to other users or laboratories.

Training

All individuals involved in the use of controlled substances must complete training prior to handling any controlled substance. Individuals must complete the applicable Controlled Substances in Research training and quiz on the Research Ethics Office website. Registrants must enroll in "Controlled Substances Training – Registrant", Authorized Agents must enroll in "Controlled Substances Training – Authorized Agent", and Authorized Users must enroll in "Controlled Substances Training – Authorized User". Registrants must retain a copy of the training completion in their records for at least two years. Laboratory-specific training must be

completed before any Authorized User handles controlled substances. Authorized Users must attach a copy of the training completion record to the completed Personnel Screening Form as proof of completion. Under LU policy, training may be refreshed annually or whenever significant regulatory or protocol changes occur.

Ordering Controlled Substances
Registrants can only order substances appearing on approved DEA Protocols (for Schedule I), and LU Controlled Substance Research Protocols (for Schedules II-V) under their current registration.

Controlled substances must be ordered and received through approved DEA and departmental processes. To ensure accurate monitoring of incoming substances, the Research Ethics Office must be notified of all controlled substance orders. Registrants may report controlled substance orders at iacuc@liberty.edu.

Schedule I or II
Any person registered to conduct research with Controlled Substances in Schedule I or II must send, in triplicate, DEA Form 222. Instructions for ordering DEA Form 222 can be found at: http://www.deadiversion.usdoj.gov/online_forms_apps.html.

Schedule I (substances that are not commercially available)
Requests to obtain Schedule I controlled substances not commercially available must be made to the National Institute on Drug Abuse (301-443-1124 or http://www.nida.nih.gov/).

Schedule III-V
Schedule III-V controlled substances must be ordered and received through approved DEA processes by a Registrant and maintenance of procurement records must also follow DEA and departmental procedures.

NIDA Drug Supply Program
The NIDA Drug Supply Program provides various controlled drugs, other chemical substances, and marijuana and nicotine research cigarettes for research purposes to research investigators working in the area of drug abuse, drug addiction, and related disciplines at academic institutions. In order to obtain these substances, research investigators and other users are required to submit their requests along with necessary documents to the NIDA Drug Supply Program for consideration.

Controlled substances must be ordered and maintained in the smallest quantity needed.

Record Keeping and Inventory Requirements
The following records must be maintained at the Registrant's Location (as identified on the registration):

- Personnel Screening Forms and training records for Registrant, Authorized Agents and Authorized Users
- Executed order forms
- Receiving record that is verified, signed and dated

- Inventory records (must be kept a minimum of two years from date of last transaction)
- Controlled substance usage records (must be kept a minimum of two years from the date of last transaction)

All controlled substance records must be kept separately from all other records, in or near the primary work area, and shall be available for inspection by LU representatives, DEA, or state inspectors at all times.

The Registrant may assign a Recordkeeper to assist with record keeping requirements. The Recordkeeper cannot dispense controlled substances.

Controlled Substance Receiving
Controlled substances must be shipped to the Registrant and address as indicated on the DEA Registration. Once received, the controlled substances must be opened and the contents verified by the Registrant. Any discrepancies must be rectified with the supplier and/or shipper. If discrepancies cannot be rectified, the Registrant must contact the Research Ethics Office at iacuc@liberty.edu and the DEA to report this within five business days. The Registrant must sign and date the purchase receipt and file it with the controlled substances records.

Controlled Substance Dispensing and Tracking
The Registrant is the only individual that can dispense a controlled substance from inventory. From the time a controlled substance is received on campus until it is fully used or disposed of, a record of the chain of custody and usage must be kept. Each point at which the controlled substance changes hands or is used must be documented. The documentation must be completed at each point by the Registrant dispensing the controlled substance and must include the substance, quantity and the signature of the Authorized User or Registrant receiving it.

Every milliliter, milligram, or tablet of a controlled substance must be accounted for in the dispensing records. Sample Controlled Substances Dispensing Record and Controlled Substances Usage and Waste Log forms are available on the Research Ethics Office website.

Controlled Substance Transfer
If needed, researchers with an active DEA registration can transfer small quantities (under LU policy, up to 5% of their current controlled substance inventory) to other DEA registrants at LU. The transferor must ensure that the transferee has a valid DEA registration for the category of substances to be transferred and approval, via an approved DEA protocol (if Schedule I) or LU Controlled Substances Research Protocol (if Schedule II-V), to receive the substance.

Transfers of Schedule I or II controlled substances must be accompanied by a DEA Form 222 completed by the Registrant receiving the substance(s).

Transfers of Schedule III-V controlled substances must be documented, be maintained in the appropriate records of both the recipient and supplier and include:
- Name, address, and DEA registration number of recipient
- Name, address, and DEA registration number of supplier
- Name, concentration, and quantity of controlled substances transferred

- Transfer date

The sample LU Controlled Substance Transfer Invoice can be used for this purpose.

It is a felony to transfer a controlled substance to a person who is not registered with the DEA.

Inventory Procedures
When issued a DEA registration, a Registrant shall take an initial inventory, which is an actual physical count of all controlled substances in their possession. The Registrant must make a record showing a zero inventory upon initial receipt of registration. LU requires that all inventories be performed in the presence of a witness.

Each person registered to handle controlled substances must maintain an inventory. The inventory must be:

- Maintained at the registered location (unless a notification has been sent to DEA notifying that records will be maintained at a specified central location).
- Available for 2 years after the substance is used or is disposed.
- Completed every 2 years (biennial) to meet DEA regulations (21 CFR 1304.11). The inventory may be taken on any date which is within two years of the previous biennial inventory date and must indicate whether it was performed at the opening or closing of the day.
- Updated on the effective date of a rule (from the DEA) when a substance is added to the Schedule (list of controlled substances).

The inventory must have the following information:

- Name, address, and DEA registration number.
- Date the inventory was taken and whether it was at the beginning or end of the day.
- Sign and date form.

For Controlled Substances in Bulk Form

- Name of substance;
- The total quantity of the substance to the nearest metric unit weight consistent with unit size.

For Controlled Substances in Finished Form

- The name of the substance;
- Each finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);
- The number of units or volume of each finished form in each container (e.g., 100-tablet bottle or 3-milliliter vial); and
- The number of containers of each such Finished Form (e.g. four 100-tablet bottles or six 3- milliliter vials).

For each substance that is expired, damaged, or defective, and for impure substances awaiting disposal, or substances held for quality control purposes, or substances maintained for extemporaneous compoundings):

- Name of substance;
- Total quantity of the substance to the nearest metric unit weight or the total number of units of finished form (i.e. fifty 10 mg tablets or 10 ml of 50 mg/ml);
- Reason for the substance being maintained by the Registrant and whether such substance is capable of use in the manufacture of any controlled substance in Finished Form;
- Best practice is to maintain substances in this category separately within the inventory, (i.e., a separate compartment, box, or bag within the storage area)

The sample Controlled Substances Inventory can be used for these purposes.

Labeling Requirements
All containers of controlled substances must be properly labeled. If the laboratory re-packages, compounds or dilutes controlled substances, the repackaged, compounded or diluted substance must be appropriately labeled and stored in the safe. The label on diluted or combined controlled substances that will be stored at least overnight in the safe must include the following information:

- Name of controlled substance
- Lot number from the supplier
- Final concentration of controlled substance
- Volume per container
- Expiration date

Storage and Security
Registrants must keep controlled substances in a substantially constructed, securely locked cabinet or safe at the Registrant's approved Location. Storage must comply with all DEA requirements:

- For Schedule I, the controlled substance must be stored in a substantially constructed, securely locked cabinet or safe, separate from other scheduled controlled substances, with the cabinet secured to a wall or otherwise not removable, as per Federal regulations.
- For Schedule II, the controlled substance must be stored in a substantially constructed, securely locked cabinet or safe, separate from other scheduled controlled substances, with the cabinet secured to a wall or otherwise not removable, as per Federal regulations.
- For Schedules III-V, the controlled substance must be in a locked cabinet or safe within a locked room.

Combination codes must not be written on or near the storage unit.

All controlled substances shall be kept locked in their storage location except for the actual time required to remove, legitimately work with, and replace them. DEA regulations require that the cabinet be secured so that it cannot be removed. A locked drawer in a lab bench that is bolted to the floor or wall is generally sufficient.

Access to locked rooms and locked storage cabinets containing controlled substances shall be restricted by the Registrant.

Each Registrant must determine how their Authorized Agents and Authorized Users will access substances. Authorized Users must store controlled substances in an individual lockbox, marked with the individual's name, in a locked cabinet when not being legitimately worked with or at the Registrant's Location for overnight storage. For Finished Form only substances, laboratory-wide lockboxes, can be established and utilized but must be stored at the Registrant's Location for overnight storage. Usage logs must be completed for each lockbox and returned to the Registrant upon completion.

Transporting Controlled Substances between University Buildings
Under LU policy, controlled substances cannot be transported between buildings (separate street addresses). Buildings connected by above-ground bridges or non-public tunnels are not considered the same building. Example: A Registrant cannot walk down the sidewalk or across the street to another building with controlled substances in his pocket.

Disposal
Expired, damaged or otherwise unusable or unneeded controlled substances can be disposed of by transferring them to a registrant who is authorized by the DEA to receive such materials. These registrants are referred to as reverse distributors. Each Registrant is responsible for appropriately disposing of controlled substances.

Schedule I and II controlled substances must be disposed of via DEA Form 222 with the DEA-authorized reverse distributor. Schedule III-V controlled substances may be transferred via invoice.

Expired or unusable substances must be labeled, separated, and stored in a cabinet or safe that meets DEA requirements for the highest level Schedule, until ready for disposal. Maintaining these substances in a separate box, or container, within the same cabinet where inventory is stored is acceptable.

The following is a non-exhaustive list of Prohibited disposal methods:

- Sink disposal
- Trash disposal
- Chemical deactivation kits (unless DEA-approved)
- Autoclaving
- Incineration by the laboratory

The Controlled Substances Inventory must be updated and copies of the records documenting the transfer and disposal of controlled substances must be maintained for a period of two years. The Controlled Substance Disposal Log can assist with this documentation.

Theft or Significant Loss
Registrants shall report theft or significant loss of controlled substances immediately (within one business day) to the Research Ethics Office, LU Police, the DEA, and the Virginia Board of Pharmacy. The DEA requires that theft or loss of controlled substances be reported on DEA Form 106, Report of Theft or Loss of Controlled Substances. A copy of Form 106 must be kept in the disposition records, and a copy must also be sent to the Research Ethics Office.

Significant loss includes, without limitation, unexplained discrepancies, repeated small losses, or any event suggesting diversion. If a container of a controlled substance is broken, it must be documented in the record and a witness must sign and date it.

Virginia Board of Pharmacy and DEA Inspections
The Virginia Board of Pharmacy normally will call to schedule a time for their inspections. The DEA can inspect an existing Registrant at any time, announced or unannounced. In preparing for their inspections, the DEA will refer to their registration and inventory records for the list of substances approved for the Registrant, so ensuring that DEA is notified via the amendment process is extremely important. Having substances in a Registrant's inventory that do not match the DEA's registration and inventory records can be cause for an adverse finding.

The Director of Environmental Health & Safety/Emergency Preparedness or designee, Human Resources Safety Program Manager, and/or Research Ethics Office designee must accompany Registrants during Virginia Board of Pharmacy or DEA inspections. On notification of inspection, the Registrant must immediately call the Environmental Health & Safety Office to request an institutional representative. For additional information reference the DEA inspection guidelines.

Institutional Monitoring
The Research Ethics Office, as a part of its Post-Approval Monitoring (PAM) program, will review Registrant records and facilities in accordance with its standard inspection schedule. Separate reports will be issued for controlled substance monitoring. To ensure compliance, additional PAM inspections may occur at the discretion of the institution. These inspections may be scheduled or unannounced.

Employee Responsibilities to Report Drug Diversion (from 21 CFR 1301.91):

- "Reports of drug diversion by fellow employees are not only a necessary part of an overall employee security program but also serve the public interest at large. It is, therefore, the position of DEA than an employee who has knowledge of drug diversion from his employer by a fellow employee has an obligation to report such information to a responsible security official of the employer. The employer shall treat such information as confidential and shall take all reasonable steps to protect the confidentiality of the information and the identity of the employee furnishing the information."

An employee who has knowledge of drug diversion associated with the actions of a fellow employee, student, or supervisor has an obligation to report such information to the Liberty University Police Department (LUPD). LUPD can be contacted on the non-emergency line at 434-592-7641 or by email, lupd@liberty.edu.

Close Out of Registration
Under no circumstances are controlled substances to be abandoned by a Registrant. Registrants are expected to properly transfer or dispose of controlled substance inventory when controlled substances are no longer required or prior to departure from their University position. Contact iacuc@liberty.edu when preparing to close out.

Any person who is registered with the DEA who violates record-keeping requirements or abandons controlled substances will be subject to the civil penalties outlined in the United States Code (USC): 21 USC Sec. 842. Please note that abandoning substances is equivalent to distributing a controlled substance to an unauthorized person.

In the event a Registrant is unable to close out their registration, the Authorized Agent or Authorized Official must properly surrender the controlled substances to the DEA using DEA-approved methods and procedures.

Controlled Substances Research Lifecycle (Institutional Flowchart)

1. PI Determines Need for Controlled Substances – The Principal Investigator (PI) determines whether Schedule I–V controlled substances are required for the proposed research protocol.

2. Institutional Review & Approval – LU Controlled Substances Research Protocol is submitted by the PI for review by the appropriate institutional offices.

3. Training & Personnel Screening – Registrants and Authorized Users complete required training and personnel screening.

4. State & Federal Registration – PI obtains Virginia Board of Pharmacy and DEA registrations.

5. Order & Receive Controlled Substances – Controlled substances are ordered and receipt verified by the Registrant.

6. Secure Storage & Inventory – Substances stored in DEA-compliant safes; initial inventory established.

7. Authorized Use in Research – Controlled substances dispensed and used under approved protocols with proper documentation.

8. Ongoing Monitoring & Biennial Inventory – Continuous monitoring and biennial inventories conducted.

9. Disposal – Expired or unused substances transferred to a DEA-authorized reverse distributor.

10. Close-Out & Registration Termination – All substances disposed of or transferred, and registrations formally closed.