FLORIDA ATLANTIC UNIVERSITY

Division of
Administrative Affairs

ENVIRONMENTAL HEALTH AND SAFETY
Policy #P&P-10

Controlled Substances Used in Research

Version #1

Effective: 10/16/2024	Revised: New

1. PURPOSE:

The purpose of this policy is to establish the minimum requirements for the use of regulated prescription and federally controlled substances in research and create a program that ensures compliance with all federal, state, and local regulations for the lawful purchase, possession, use, storage, protection, and destruction of controlled and non-controlled prescription drugs and medical gases associated with research conducted under FAU.

2. POLICY STATEMENT:

This procedure applies to all faculty, visiting scholars, staff, students, and affiliates who procure, store or use controlled substances or prescription drugs for lawful research, teaching, and testing purposes at Florida Atlantic University (FAU).

Variances or deviations from this policy must be approved in writing by EH&S and only where such activities are compliant with all Federal, State, and Local regulations.

PIs may find it necessary to use prescription or legend drugs, including DEA analytical standards or federally controlled substances, during lawful research, teaching, or testing. Various federal and state statutes and regulations address such use. FAU is responsible for ensuring that all departments, units, and employees comply with all applicable laws and requirements regarding these substances. Prescription or legend drugs and controlled substances are considered restricted hazardous materials.

Controlled substances are those materials that may have a narcotic, stimulant, depressant, or hallucinogenic effect on the central nervous system, as well as other regulated chemicals. These substances tend to be subject to abuse and induce physiological or psychological dependence. They have been identified as substances needing extensive licensing, registration, storage, security, use, and disposal requirements. State and federal agencies (e.g., the DEA) have comprehensive regulatory and enforcement structures that are designed to prevent the diversion of legitimately produced controlled substances and regulated chemicals to illicit or illegal activities. PIs are a powerful resource for protecting public health and safety by their adherence to the law.

Both state and Federal law classify controlled substances into five categories according to their medical use and potential for abuse. Schedules I and II substances, categorized as having the highest potential for abuse, are the most regulated. Schedule I substances are classified as having no medical value and include designated opiates, LSD, and marijuana. Schedule II drugs include barbiturates, morphine, and designated opiates. Schedule III drugs include many medically relevant chemicals (cough suppressants, anesthetic agents, narcotic pain killers), and Schedule IV covers the potential stimulants and depressants with a lower potential for abuse. Schedule V is categorized as

having the least potential for abuse. Due to their high risk for abuse, orders for Schedule I or II substances must be in writing and accompanied by DEA Form 222 (DEA official order form).

This procedure was developed in accordance Chapters 499 and 893 of the Florida Statutes, Rule 64F-12 of the Florida Administrative Code; and the Code of Federal Regulation, Title 21, Parts 1300-END. The following information is provided to university researchers as guidance for obtaining necessary exemptions, licenses, and permits, as well as instruction on the purchase, storage, record keeping, and destruction or disposal of such substances.

Failure to comply with this procedure may be grounds for suspension or termination of research by the university, referral for academic misconduct proceedings, and/or reporting to external licensing authorities. Further, failure to comply with these requirements may result in criminal charges or fines from federal, state, or local authorities. FAU does not pay any fines or damages resulting from individual noncompliance with controlled substances requirements; such fines, damages, or legal fees are the sole responsibility of the PI.

The Florida Department of Business & Professional Regulation (DBPR) delegates the authority to administer and enforce regulations related to the preparation, manufacture, repackaging, or distribution of drugs, devices, and cosmetics through Florida Statutes, Title XXXII Chapters 455 Business and Profession Regulation: General Provision, Florida Statutes, Title XXXIII Chapters 499 Drug and Cosmetic Act, and Rule 61 –Florida Administrative Code, Regulations for Drugs, Devices and Cosmetics.

The Federal Drug Enforcement Agency governs the control and enforcement of importation, manufacture, distribution, possession, and use of controlled substances through the Title 21 United States Code (USC) Controlled Substances Act.

By authority of University Policy 4.1.2, Environmental Health and Safety, the Director of Environmental Health and Safety is responsible for the administration and oversight of all health and safety regulations for FAU. Under this authority, EH&S is charged with developing applicable policies and procedures and performing audits to monitor for compliance.

PIs and authorized agents with access to controlled substances must abide by all policies and procedures that regulate the use of controlled and non-controlled prescription substances for research purposes, including this policy. Every effort has been made to align FAU requirements with those of the DEA, however, wherever there is a dissimilarity between FAU policy and those of the DEA or the State of Florida, the most stringent requirement must be followed.

If controlled or non-controlled prescription substances are proposed to be administered as part of a research protocol or if research is to be conducted on the drugs themselves, the applicant must ensure that all Florida State and DEA requirements, including registration, inspection, and certification, as applicable, are met. EH&S will assist researchers with the exemption and registration processes. Additionally, regional DEA offices can supply forms and information concerning the type of registration required for a particular substance for research use.

FAU requires that all individuals working with non-controlled prescription drugs and medical gasses to obtain an Exemption Letter from the State of Florida to lawfully purchase or possess those substances.

FAU requires that all individuals working with DEA-controlled substances have a current registration with the DEA and comply with all state and federal regulations regarding the acquisition, storage, use, record keeping, security, and disposal of those controlled substances.

3. CONCEPTS AND DEFINITIONS:

3.1. **Authorized Agent**: Lab employees, graduate students, or other controlled substance handlers who have been given authority to access the controlled substances by a PI who has received a Letter of Exemption from the state of Florida and has registered with the U.S. Drug Enforcement Agency (DEA).

3.2. **Controlled Substance**: A drug, substance, or chemical that manufacture, possession, or use is regulated by the government. These include behavior-altering, addictive, and illicitly used drugs, or prescription medications that are designated as controlled drugs. Controlled substances are divided into five categories, or "Schedules," based on the use for medicinal purposes.

3.3. **Controlled Substance Manual**: A collection of materials maintained in each lab to remain compliance with Florida and DEA regulations on the purchase and possession of prescription drugs included controlled and non-controlled substances. The Controlled Substance Manual should include all materials referenced herein and maintained for the specified timeframes.

3.4. **Prescription Drug**: An FDA-approved drug that must, by federal law or regulation, be dispensed only pursuant to a prescription (e.g., finished dose form and active ingredients subject to the stipulations of the Federal Food, Drug, and Cosmetic Act). For the purposes of this document, prescription drugs include controlled substances, pharmaceutical and analytical grade non-controlled substances, and medical gases. The drugs are also commonly referred to as "Legend Drugs."

3.5. **Practitioners:** Practitioners, including medical doctors and veterinarians, are authorized to prescribe, administer, and dispense controlled substances for legitimate medical purposes within their professional practice

3.6. **Analytical Standard**: An analytical standard is a compound of suitable purity and known concentration to be used as a calibration standard for an assay.

3.7. **Registrant**: For the purposes of this policy, a PI is a person who is licensed and registered with the U.S. Drug Enforcement Agency (DEA), and/or the Florida DBPR to possess and handle controlled and uncontrolled prescription substances for research, teaching, or testing or in support of the same. Registrants under this policy are limited to principal investigators, practitioners, or members of EH&S.

3.8. **Schedule I Controlled Substances**: Drugs, substances, or chemicals with no currently accepted medical use and a high potential for abuse

3.9. **Schedule II Controlled Substances**: Drugs, substances, or chemicals with a high

potential for abuse, with use potentially leading to severe psychological or physical dependence. These drugs are also considered dangerous.

3.10. **Schedule III Controlled Substances**: Drugs, substances, or chemicals with a moderate to low potential for physical and psychological dependence.

3.11. **Schedule IV Controlled Substances**: Drugs, substances, or chemicals with a low potential for abuse and low risk of dependence.

3.12. **Schedule V Controlled Substances**: Drugs, substances, or chemicals with lower potential for abuse relative to substances listed in Schedule IV and that consist of preparations containing limited quantities of certain narcotics.

3.13. **Controlled Substance Waste**: For the purposes of this document, controlled substance waste refers to controlled substances that are no longer needed for research, has been dispensed for use but could not be used, have expired, no longer suitable for the intended purpose, or otherwise classified as waste by the PI or authorized agent. Such materials require specific procedures for disposal, as defined herein, and will be recorded on the Controlled Substance Use Log or Controlled Substance Diluted Solution Log and on the DEA Form 41.

3.14. **Controlled Substance Wastage**: For the purposes of this document, controlled substance wastage refers to the trace amounts of controlled substances trapped in a container or delivery system (vial or syringe or other similar containment) which is unrecoverable and typically de minimis. Such materials require specific procedures for disposal, as defined herein, and are not recorded as a waste in use logs or DEA Form 41.

4. RESPONSIBILITIES:

4.1. Principal Investigator (PI)

Principal investigators with a DEA Registration and/or letter of exemption from the State of Florida are responsible for the following:

- Complying with all Federal, State, and Local regulations regarding the acquisition, possession, use, storage, security and proper disposal of uncontrolled and controlled substances.
- Record keeping, use, storage, security, assigning and supervising authorized agents, and ensuring compliance with all state and federal laws.
- Providing required training to authorized agents.
- Maintaining the requirements herein for the controlled substances program within the PI's laboratory.
- Reporting any suspected loss or theft to EH&S and the U.S. Drug Enforcement Agency.

- Complying with DEA and DBPR requests for inspection.

4.2. Authorized Agents

Laboratory workers designated by a PI as an authorized agent are responsible for the following:

- Complying with all Federal, State, and Local regulations regarding the acquisition, possession, use, storage, security and proper disposal of uncontrolled and controlled substances.
- Completing all required forms and training prior to work with controlled substances.
- Reporting any suspected loss or theft to the PI and EH&S immediately.
- Complying with DEA and DBPR requests for inspection.

4.3. Environmental Health and Safety (EH&S)

The Director of EH&S is responsible for establishing a program that ensures:

- Oversight of the lawful purchase, use, storage, protection, and disposal of controlled and non-controlled prescription drugs and medical gasses at FAU.
- Providing guidance to PIs for registering with state and federal agencies to become registrants, including guidance on processes and form requirements.
- Assisting researchers with registration and program compliance.
- Auditing, monitoring, and reporting compliance with this policy.

5. PROCEDURE

APPLYING FOR STATE OF FLORIDA PRESCRIPTION EXEMPTION

Introduction

Obtaining and possessing prescription drugs, analytical standards or medical gasses without a valid prescription from an authorized licensed practitioner is illegal. However, the Florida Department of Business and Professional Regulation (DBPR) is authorized to issue Letters of Exemption to facilitate lawful possession of prescription drugs, analytical standards and medical gases. Qualified purposes for such exemptions include lawful research, teaching, and testing. University employees who are performing research protocols or teaching professional programs are qualified to receive Letters of Exemption. The State of Florida Letter of Exemption is valid for two years.

Application Requirements

Applications must be submitted online, but a printable, paper application may be mailed to DBPR. The information requirements that must be collected by the applicant prior to beginning the application process are as follows:

- Explanation/summary of the conditions of research, teaching, or testing.
- Exact physical and mailing address of the location where the prescription drugs, analytical standards, controlled substances or gases will be stored.
- The specific drugs and or gases required for research, teaching, or testing activities.
- The name of the suppliers for each controlled substance, prescription drug, analytical standards and or gases.
- The state permit or license number of the suppliers for each prescription drug.
- The application requires information from Florida Statutes Chapter 499, Florida
- Drug and Cosmetic Act. Failure to fill out the application in its entirety, or failure to have it signed by an authorized representative, may result in delay or denial of processing exemptions.

Applying

Online submission: It is highly recommended to submit an online application for a quicker response. Instructions for creating an online account with the Florida Department of Business and Professional Regulation can be found here, and the application for an exemption can be found here.

The following is a brief description of how to complete each section of the Application for Exemption Registration:

Section I – Application Type

- Check the appropriate application type. If this is an exemption renewal or amendment, the current exemption number is required.

Section II – Exemption Qualification Criteria

- Check the applicable qualification criteria. Check the “State, federal, or local governmental officer or employee” box and then check the “research” box.

Section III – Applicant Information

- The name of the Organization/Business is always Florida Atlantic University.
- The mailing address is the address of the applicant’s office location.
- The physical address corresponds with the exact location where the drugs or gases will be received and stored, including building and room numbers.

Section IV – Qualified Person Information

- This section requires the full name and educational information of the
- qualified person. Fill in any related training, coursework, and experience
- working with prescription drugs.

Section V – Purchasing Information

- Enter the name under which all purchases will be made for prescription

drugs and gases, and provide a DEA Registration number, if applicable.

- Enter the purpose of the use of the prescription drugs for research, teaching, or testing purposes.
- Enter each supplier and its Florida License Number for each prescription drug or gas that will be required. Also list all possible information for the prescription drugs' names, quantities, and frequency of purchase.

Section VI – Application Contact

- Provide the primary contact person's information.

Exemption letters can be amended during the effective cycle to include new prescription drugs and medical gasses, if those substances will be maintained and used in the same location as the original exemption letter.

6. APPLYING FOR DEA REGISTRATION (NEW APPLICANTS ONLY)

PIs must determine if the drugs they intend to use during lawful research, teaching, or testing are categorized as controlled substances. A list of current controlled substances, in alphabetical order, can be found here. If the drugs are deemed to be controlled substances, the PI must apply for a DEA Registration, which may take up to twelve weeks for Schedule III-V to process or up to 12 months for Schedule I-II, provided that the application is accurate and complete. New registrants should consult the DEA Researcher Manual for a full understanding of all program requirements.

Application Forms

In most cases, PIs will be required to submit DEA Form 225. It may take one to twelve months depending on the drug Schedule(s) to receive the registration certificate from the DEA, so researchers must plan accordingly. There is no fee for researchers working at state institutions.

DEA Form 224 is used for hospitals, clinics, qualified practitioners, and clinical/medical teaching institutions where controlled substances could be prescribed or distributed to patients. This business activity is not for individuals but for medical education that takes place under the authority of a state-accredited college or university. The applicant should consult EH&S if additional assistance is needed to determine which form to use.

The online application forms can be found on the DEA Diversion website. DEA encourages the use of the online forms system to apply for registration

The researcher must attach the research protocol, including an up-to-date curriculum vitae (CV), to conduct research with schedule 1 controlled substances.

DEA registrations can be amended during the effective cycle to include name, schedule, drug code, and address changes.

7. RE-APPLYING FOR A STATE OF FLORIDA PRESCRIPTION EXEMPTION AND DEA LICENSE

If either the DBPR Exemption or the DEA Registration expires while possessing prescription drugs, analytical standards, medical gases, and or controlled substances, the PI will be categorized as in non-compliance with state and federal regulations and will be required to start the process from the beginning. PIs cannot use, buy, or dispose of any DEA drugs without a valid registration. Lacking a valid registration while the lab is still in possession of DEA controlled substances may become a felony violation by DEA regulations; penalties could be severe and include prison time and/or criminal fines.

The U.S. DEA registration is valid for one year and must be renewed annually by completing DEA Form 225a. The DEA will send one reminder, usually 60 days in advance via mail.

The State of Florida Letter of Exemption is valid for two years. The Department of Business and Professional Regulation (DBPR) requires a new application form to be submitted 30-60 days before the exemption's expiration. The DBPR sends a reminder via mail about 60 days before the expiration date. PIs should plan accordingly so they do not fall out of compliance. Exemption applications must be submitted through DBPR's online services. A copy of the renewed exemption letter must be sent to EH&S and any approved vendors.

The DEA permits a one-month grace period after the renewal window expires, after which a new registration application (Form 225) must be submitted.

If the DEA registration expires and is renewed later, any controlled substances purchased under the expired registration will not be covered by the new registration. Products from an expired registration are held by the PI illegally but must be secured by the PI until special permission is obtained from the DEA for their disposition.

As long as the DEA registration and DBPR exemption renewals are submitted before the expiration date on the registration, the PI may continue operations as authorized by their registration/exemption letter until they receive a final decision on the renewals.

8. ORDERING

Initial completion DEA Form 222s must contain zero (0) errors. If an error is made, the form must be voided and a new form completed. Date and initial the voided form and retain.

PIs must follow this policy for the lawful purchase/acquisition and possession of prescription or legend drugs and controlled substances. The PI must purchase/acquire drug products only through approved vendors that appear on their DBPR exemption letter and ensure that the products are received, inventoried, and stored correctly. The PI must track any purchases/acquisitions and deliveries of controlled substances. Lost shipments must be reported to the DEA, EH&S, and the FAU Police Department (561-297-3500) as soon as possible.

Use Spend Category: Controlled Substances for requisitions and purchase orders for controlled substances. P-cards cannot be used.

Upon receipt of the substances, the accompanying documents (packing slips, DEA Form 222, shipping documents, etc.) must be signed and retained in the controlled substances records. The PI must maintain records to include vendor name, invoices, shipping documents, and packing slips, on all exempted or registered products for a period of 2 years from the date of the record. All records must be available for periodic inspection by EH&S, DEA and DBPR.

8.1. DEA FORM 222

Ordering Schedule I and II Controlled Substances

The PI may only order Schedule I and II controlled substances as authorized by their current DEA Registration. DEA Form 222 must be submitted with any Schedule I and II orders. If any errors occur while filling out the form, the form must be voided and retained with the PI's Controlled Substance Manual. DEA Form 222 may be ordered using the online DEA Order Form Request. DEA Forms 222 must be stored securely in the safe to prevent loss or theft. Blank DEA Form 222s cannot be pre-signed by the PI.

8.2. Lost and Stolen DEA Forms 222

If a PI ascertains that an unfilled DEA Form 222 has been lost, the PI must execute another and attach a statement containing the order form number and date of the lost form and stating that the goods covered by the DEA Form 222 were not received through loss of that DEA Form 222. A copy of the form and a copy of the statement must be retained with a copy of the DEA Form 222 first executed. A copy of the statement must be attached to the DEA Form 222 sent to the supplier. If the original DEA Form 222 is subsequently received by the supplier to whom it was directed, the supplier must mark upon the face "Not accepted" and return the original DEA Form 222 to the PI, who must attach it to the statement.

If any DEA Form 222 are lost or stolen, and the PI is unable to provide the order form numbers of the DEA Form 222, the PI must report, in lieu of numbers of the forms, the date or approximate date of issuance to the DEA.

8.3. Recordkeeping of DEA Form 222

The PI must retain a copy of each executed DEA Form 222 and all copies of unaccepted or defective forms with each statement attached.

Voided DEA Form 222s must be retained with the laboratory controlled substance records for 2 years from the initial completion/voiding date.

The supplier must retain the original of each DEA Form 222 for filled orders

DEA Form 222 must be maintained separately from all other records of the PI.

DEA Form 222 is required to be kept available for inspection for two years.

If a DEA Form 222 is voided, it must be retained for two years.

9. USE OF PRESCRIPTION OR LEGEND DRUGS, ANALYTICAL STANDARDS, AND CONTROLLED SUBSTANCES FOR LAWFUL RESEARCH, TEACHING, AND TESTING

The PI is legally responsible for the prescription or legend drugs, analytical standards, and controlled substances for which they have exemptions or registrations per regulation, including inventory, recordkeeping, and security provisions.

Controlled and uncontrolled substances are for the specific use of the PI and authorized agents of that registration. Transfer, dispensing, or distribution of controlled and uncontrolled substances to unregistered individuals is not permitted. Practitioners are permitted to transfer, dispense, or distribute uncontrolled substances.

The PI must pre-screen and authorize individuals to engage in approved activities under their direction. Those individuals must complete the FAU Employee Questionnaire prior to becoming an authorized agent. The PI will file a copy of the completed questionnaire(s) in the Controlled Substances Manual. These records must be readily retrievable upon request during inspections.

Authorized agents must know controlled substances laws and regulations, including storage, security, recordkeeping, inventory, and disposal requirements.

Approval from the DEA and EHS must be obtained prior to transport of controlled substances. Controlled substances may only be transported when both the origin and destination are registered under the same PI.

Transfer of any controlled and uncontrolled prescription drugs from researchers to other researchers is prohibited at FAU.

PIs are prohibited from making their own analytical standards for use as a testing standard. The DEA does not require a DEA registration for the purchase of analytical standards, but a Florida Letter of Exemption must be obtained.

Laboratories possessing such analytical standards after obtaining approval from DBPR will be inspected by EH&S at any given time.

While controlled substances may be dispensed and administered in a separate room of the storage location building, all controlled substances must be returned to the storage location and secured by the end of the day, i.e. controlled substances cannot be stored away from the registered, secure storage location overnight.

10. INVENTORIES

Federal regulations require an inventory of all controlled substances. PIs must maintain accurate and complete inventories, stored and secured separately from other records, and readily available for inspection. The PI will maintain the FAU Initial Inventory Log. Inventories can be taken at either the open or close of business and should be indicated as such on the form. The annual self-inspection is conducted every year from after completing an Initial Inventory Form. If no drugs are in possession, an annual inventory must be created that states no drugs are in inventory.

Schedule I and II controlled substances must be recorded on a separate inventory form from all other drug Schedules.

The *Initial Inventory* is used only once upon receiving a new DEA Registration. At this time, the PI should have no inventory, and the form must be filled out in its entirety, entering zero (0) inventory.

The *General Inventory* is a perpetual inventory that must reflect each container of controlled substances on hand with the PI. It is updated with each new change to the inventory, including receiving new drugs/containers, loss or theft of existing inventory, and destruction.

The *Annual Inventory* must be completed once per year, together with the FAU Controlled Substances Self-Inspection Checklist Form. This satisfies the requirement for the DEA Biennial Inventory.

The *Close Out Inventory* is used only one time upon disposing of all Form 41 controlled substances associated with the DEA registration. At this time, the PI should have no inventory, and the form must be filled out in its entirety, entering zero (0) inventory.

Diluted Materials and Cocktail Mixtures: A dilution created and used entirely during one application does not require the creation of a Use Log. If any dilution remains for intended use later, the PI must fill in a FAU Diluted Solution Use Log.

The PI must maintain an inventory of DEA analytical standards. Inventories must be readily available upon request by DBPR and EH&S.

11. SECURITY AND STORAGE

The PI must store prescription drugs, including DEA analytical standards and controlled substances, with adequate controls to guard against theft or diversion. PIs may not share the same controlled substances storage unit, store other chemicals or supplies in the controlled substances storage unit, or store controlled substances in corridors. The PI must secure the area from unauthorized entry or access when authorized personnel are absent. Storage must provide at least two levels of security. FAU requires the use of an approved cabinet with two locks for entry.

Schedule I-V controlled substances must be stored in “a securely locked, substantially constructed cabinet”. Schedules III-V drugs must be physically separated from Schedule I and II controlled substances. Non-controlled prescription substances should not be stored with

controlled substances. All inventories must be stored in separate, clearly marked areas to avoid confusion or contamination. A separate isolation area must also be maintained for all prescription drugs and controlled substances that are out of date, deteriorated, mislabeled, or otherwise unfit for use. The products must be maintained within the manufacturer's recommended temperature tolerances.

Some controlled substances (thiafentanil, carfentanil, or etorphine hydrochloride and diprenorphine) must be secured in a GSA Class V security container. If the security container weighs less than 750 lbs., then it must be bolted or cemented to the building structure.

Steel cabinets are preferred for storage and should be resistant to entry by tools such as screwdrivers, crowbars, tire tools, or pry bars. Cabinets for controlled substances should have two separate locks that are separately keyed. Keys are to be stored separately, ideally in lock boxes. Locks can be digital/electronic. Hinges must be pinned to prevent removal, and deadbolt-type locks should be permanently installed.

Contact EH&S for information about acceptable storage cabinets. EH&S has final approval of storage cabinets used for controlled substances. Please see the following suppliers for examples of acceptable cabinets: Medicus Health (https://www.medicus-health.com/safety/medication-storage/double-door-double-lock-narcotic-boxes.html); and Global Industrial (https://www.globalindustrial.com/c/storage/cabinets/medical_cabinets#PG-74140-22344).

The PI must limit access to as few personnel as possible and maintain control of the keys. The PI must change combinations and/or locks and retrieve keys whenever authorized agents leave their positions in the lab. The PI must document authorized agent changes in the Controlled Substance Manual and notify EH&S.

12. SPILLS INVOLVING CONTROLLED SUBSTANCES (SCHEDULES I-V) AND NON-CONTROLLED PRESCRIPTION DRUGS

If there is a spill of a controlled substance, first notify everyone in the lab and put up a sign to alert people of the spill area. If the spill is larger than you believe you can handle, call EH&S for assistance (561-297-3129). Two people **must** be involved in the clean-up process for DEA witnessing purposes.

For a liquid spill:

a. Put on appropriate PPE (disposable lab gown, gloves, eye/face protection)
b. Retrieve an absorbent material from the chemical spill kit (e.g. absorbent pad or a universal granular spill absorbent).
c. Gently lay the absorbent pad on top of the spill (or apply the granular spill absorbent starting from the outside of the spill working towards the center). Use more pads or granular absorbent as needed to absorb all the spilled material.
d. Once the spill has been absorbed, collect the pad or absorbent and place into a hazardous waste container.
e. Wash the spill area with a detergent followed by a water rinse (Repeat twice).

f. Discard PPE into a biohazard container.

For a solid spill:

a. Put on appropriate PPE (disposable lab gown, gloves, eye/face protection).
b. Wet an absorbent pad with water, then lay the pad on top of the spilled material.
c. Gather up the spilled material in the pad and dispose of in a hazardous waste container.
d. Repeat steps 2 and 3 until there is no additional spilled material left.
e. Wash the spill area with a detergent followed by a water rinse (Repeat twice).
f. Discard PPE into a biohazard container.

After spills have been cleaned up, contact EH&S for a pickup as soon as possible. A DEA form 41 will need to be filled out and witnessed.

Spills of non-controlled prescription drugs should be managed similarly to those procedures above but are not recorded on a Form 41.

13. DISPOSAL

Hazardous Waste Pharmaceuticals (Controlled Substances)

Controlled substances for disposal at FAU must be destroyed by methods approved by EH&S. Methods that may be utilized include, but may not be limited to:

- EH&S-approved onsite drug deactivation system

To minimize waste, the PI should only purchase quantities of prescription drugs and controlled substances that they intend to use before the expiration date.

Controlled substances that are considered Form 41 waste:

- Unused substances dispensed in syringes or other delivery systems
- Excess dilutions that cannot be used in the present experiment and are not slated to be used in the future.
- Substances that have expired.
- Substances no longer needed by the PI

Controlled substances that are not considered Form 41 waste:

- Materials from spill cleanup include but not be limited to saturated disposable towels from cleanup, gloves, bags, etc. These materials are considered biohazardous wastes and are disposed of in red bags.
- De minimis quantities of controlled substances trapped in syringes, vials, and other containment that cannot be extracted. These materials are considered biohazardous wastes and are disposed of in sharps containers.

Waste dilutions may not be combined into a single waste container. Each dilution container must be disposed of individually.

The method of destruction shall be consistent with the purpose of rendering all controlled substances to a non-retrievable state to prevent the diversion of any such substance to illicit purposes and to protect public health and safety.

The PI is responsible for the proper disposal of prescription drugs and controlled substances and for associated recordkeeping in accordance with applicable state and federal regulations. The PI must maintain the transfer and disposal records for at least two (2) years after disposing of a controlled substance.

The PI must properly dispose of all controlled substances prior to leaving the university. Any PI who orphans or leaves controlled substances within their lab is in violation of federal law. The PI's department will be held responsible for disposal expenses associated with orphaned drugs.

The PI is ultimately responsible for using an EH&S-approved method and completing the required steps for destruction.

Empty containers or containers/syringes with nominal wastage must be disposed of in a secure sharps container.

Form 41 destruction must be witnessed by two authorized agents on the DEA registration, one of which may include the registrant.

Hazardous Waste Pharmaceuticals (Non-Controlled Substances)

Uncontrolled pharmaceutical waste must be disposed of as hazardous waste through EH&S.

The PI must dispose of any unusable, non-scheduled prescription or legend drugs as hazardous waste through EH&S. Many chemical and/or pharmaceutical compounds used in research or in the treatment of disease are regulated by the EPA as listed wastes and must be treated as hazardous waste when disposed; those that contain even minute amounts of EPA-listed chemicals are considered hazardous waste. Accumulation of pharmaceutical-related hazardous waste includes:

- Waste material generated by the use or delivery of the pharmaceutical compound (gloves, aprons, towels, spill clean-up, etc.)
- Packaging and/or empty containers associated with P-listed chemicals and U-listed chemicals (commonly used commercial chemicals)
- Pharmaceuticals that contain even minute amounts of EPA Characteristic chemicals

The following are examples of common Hazardous Waste Pharmaceuticals:

P-listed and U-listed Hazardous Waste Pharmaceuticals: P-listed and U-listed pharmaceuticals are both considered acutely hazardous by the EPA. Any unused portions of these materials,

including unused dilutions or formulations, or wastes generated by spill clean-up or contamination by the original product, are considered hazardous waste.

Packaging and/or empty containers associated with these items must either be collected as hazardous waste or triple-rinsed before being considered empty. P-listed rinsates must be collected as hazardous waste.

Noncontrolled pharmaceuticals containing P-listed chemicals include epinephrine, phentermine, nicotine and salts, nitroglycerin, and physostygmine.

Characteristic Hazardous Waste Pharmaceuticals: Pharmaceutical chemicals or formulations may also contain components that are regulated as characteristic waste. The presence of these components is often not clearly identified in labeling. EPA-regulated chemicals and pharmaceutical compounds may be present only as a small component of the overall product makeup. The EPA regulates Toxicity Characteristic chemicals at the parts per million (ppm) level.

Knowledge and understanding of the entirety of product makeup is critical for safety and proper waste determination.

Pharmaceuticals classified as characteristic hazardous waste by the EPA include insulin, barium sulfate, thimerosol, merthiolate, styptic pens, selenium sulfide, and silvadene.

Non-Regulated Prescription Pharmaceuticals (Non-Controlled Substances):
Many other pharmaceutical compounds are not regulated as hazardous waste. Still, they may pose a threat to human health or the environment and have the potential to be misused if not disposed of properly. All unusable prescription or non-prescription pharmaceuticals and pharmaceutical compounds used in research that are not classified as controlled substances should be disposed of through EH&S as hazardous waste to prevent potential abuse.

If the products to be disposed of are other types of non-controlled pharmaceuticals, EH&S can perform a hazardous waste pick-up. A waste pick-up request must be submitted through SciShield.

NOTE: This short list of hazardous waste pharmaceuticals is intended to highlight common examples of EPA-regulated chemicals and pharmaceutical compounds used in research and treatment of disease and is not exhaustive. Contact EH&S for more information on hazardous waste pharmaceuticals.

EH&S is not responsible for the disposal of personal and pet prescriptions.

14. INSPECTIONS

Registrant Inspections

PIs perform an annual Controlled Substance Inspection Self-inspection, including completing the Annual Inventory Form and the FAU Controlled Substance Self-Inspection Checklist.

FAU Inspections

EH&S will conduct annual inspections to assist with controlled substances handling procedures and ensure university compliance with DEA regulations. All records and controlled substances must be immediately available for review.

At the time of inspection by EH&S, the following are subject to evaluation:

- Proper licensing obtained by researchers.
- Adequate storage and security arrangements.
- Accuracy, completeness, and timeliness of all records and inventories.
- Notes to file recorded by the PI to correct errors and prevent recurrence.
- Correction of deficiencies found during previous inspections.
- Procedures for use and disposal of controlled substances.

If major discrepancies are found, EH&S will notify the PI immediately and schedule a reinspection. The PI should make every effort to correct deficiencies immediately.

Where findings are discovered during the inspection, corrective and preventive action plans (CAPAs) are warranted, EH&S will develop CAPAs and present them to the PI for implementation, including:

- Detailed information on the specific findings of noncompliance and/or deficiencies
- Steps that must be taken to address/correct the findings
- A timeline in which the steps must be completed
- CAPAs may include increased monitoring and retraining

The PI must correct all deficiencies within 30 days of the initial inspection. Any suspected potential for criminal activity will be reported to the FAU Police Department.

Drug Enforcement Administration (DEA) Inspections

The DEA conducts periodic, unannounced inspections of registered controlled substance storage locations and laboratories to determine whether the PI complies with the Controlled Substances Act. PIs or authorized agents must be in attendance and provide the DEA Inspectors with all credentials, records, storage arrangements, and logs upon request.

The DEA may assess criminal penalties for non-compliance violations that may result in fines, suspension of registration, and prison sentences.

Florida Department of Business and Professional Regulations

The Florida Department of Business and Professional Regulation can perform inspections for PIs who have been granted an exemption for the use of controlled substances, analytical standards, medical gases, and prescription or legend drugs. The PIs must still follow all Florida Statutes and regulations for the storage, use, record-keeping, and disposal of prescription drugs.

PIs should inform EH&S of any outside agency inspections and request EH&S presence for the inspection.

15. RECORDKEEPING

All forms must be clearly printed in indelible ink.

The PI must maintain controlled substances and prescription drugs inventories in conformance with the State of Florida and federal regulations required by 21 CFR 1304.03. Records must be retained for two (2) years following final disposal or use of the prescription or legend drug, as per Florida Administrative Code (64F-12.012 / 10D-45.053, subsection 10). Records must be retained beyond two (2) years if an investigation has been initiated and not yet completed within the two-year limit.

PIs must retain the following controlled substance records:

Policy and Procedures: Copies of this policy and any other laboratory-specific procedures associated with controlled substances.

Applications and Registrations: Copies of all applications, renewal information, registrations, and exemptions.

Authorized Agent Logs: Copies of all Authorized Agent logs listed all persons

Employee Questionnaires: Copies of all FAU Employee Questionnaires completed by authorized agents before listing them as authorized agents.

Verification of Training: Copies of CITI certificates or other verification that training for the PI and authorized agents is current.

Purchase and Order Records: All invoices for purchasing prescription drugs and controlled substances. (A copy of the DEA Form 222 will be attached to the purchase order records for Schedule I and II controlled substances.) All records of receipt of the materials, including invoices and packing slips (signed and dated by the PI on the day received).

All Inventory Forms: Track and inventory all substances on hand.

Use and Diluted Mixture Logs: Real-time inventories for each substance, using a separate Use log for each vial, from acquisition to disposition. Multiple vials may not be recorded on an individual Use Log. The Use Log must show a final volume and weight of zero (0) when a vial is empty. If the vial is empty and the Use Log does not reconcile to zero, within one business day of discovery (21 C.F.R. § 1301.76 (b)), the PI must notify the DEA Field Division Office in their area, in writing, of what the researcher may consider a significant loss or theft.

Self-Inspection Records: Copies of self-inspections (including inventory verification) have been conducted once every 12 months. Records are maintained for two years.

Disposal Records: A copy of DEA Form 41 as a record of disposal of the controlled substance. Regulations require the disposal of all damaged, expired, unwanted, or unusable controlled substances. A copy of the completed DEA Form 41 must be filed in the Controlled Substances Manual.

Loss Reports: Copies of losses reported on Form 106.

The PI will also retain all voided and completed copies of Form 222 in the Controlled Substance Manual. Unused Form 222s will be maintained in a safe location.

If the PI leaves the institution or otherwise closes out a DEA registration with FAU, the completed Controlled Substance Manual must be returned to EH&S, which will be retained for two years.

16. LABORATORY CONTROLLED SUBSTANCE MANUALS

The PI will maintain all required FAU Laboratory Controlled Substances Manual records. Use logs must be kept separately in the double-locked cabinet with the controlled substances, and unfilled DEA Forms 222 must be stored and secured independently from the Controlled Substances Manual.

All voided forms must be maintained with all other used forms for two years from the last entry date on the form.

Records should be stored separately from all other records in a secure, designated file space and readily available for inspection.

Maintain all records for two years from the last entry date on the form.

17. NOTIFICATIONS TO DEA

It is recommended that all notifications to the DEA come from a single point of contact, i.e., EH&S. However, as the registrant, PIs can contact the DEA directly to fulfill their regulatory requirements. It is highly recommended that PIs notify EH&S when separate communications with the DEA are made.

PIs are responsible for notifying the DEA under each of the following conditions:

- Suspected loss or theft of controlled substances (requiring Form 106), 1 business day.
    - Repeated errors in the use log that result in more than trace losses
    - Single inaccuracy in the use log that results in a significant loss*
    - Significant loss not attributed to everyday research activities
    - Signs of container tampering
    - Unexpected animal response to controlled substance administration
    - A use log does not reconcile to zero (0) when a container is empty (excluding wastage)
    - Missing substances

- Controlled substances need to be transported outside of the registered location or between registered locations. Must notify before the transport.
- Closing out a registration

Also, contact EH&S regarding any of the above conditions.

Significant Loss

The following factors must be considered in determining whether a loss is significant.

- The actual quantity of controlled substances lost concerning the type of business.
- The specific controlled substances lost (schedule IIs as opposed to schedule IIIs, IVs, and Vs).
- Whether the loss can be associated with access by specific individuals or attributed to unique activities that may take place involving the controlled substances.
- A pattern of losses over a specific time, whether the losses appear random, and the results of efforts taken to resolve the losses, and, if known.
- Whether the controlled substances are likely candidates for diversion and
- Local trends and other indicators of diversion potential of the missing controlled substances. 21 C.F.R. §§ 1301.74(c) and .76(b).

18. TRAINING

All PIs and authorized agents are required to complete the triennial CITI Controlled Substances Online Training. EH&S will conduct in-lab training for researchers using only non-controlled pharmaceutical and analytical-grade substances.

19. ERRORS AND CORRECTIVE ACTIONS

The PI and authorized agents must address errors as soon as possible. Except DEA Form 222, in which no errors are permitted, other handwritten controlled substance records must be corrected in the following manner:

- Draw a single line through the incorrect entry
- Record the correct data
- Initial and date the correction
- Indicate the reason for the error (calculation error, date error, entry error, late entry)

Errors must be corrected immediately by those making the entry. Late corrections or late entries can only be made by the PI, regardless of how they are discovered and must include a separate note to file outlining the following:

- Date and title of the record containing the error or mistake
- A detailed description of the error or mistake
- The cause of the error or mistake. If it is determined that the mistake did not occur due to significant loss or theft, a statement by the PI affirms this.

- Corrective actions undertaken by the PI and authorized agents that prevent recurrence

Notes to file must be retained for the duration of retention of the record they reference.

Corrective actions for the PI or authorized users may include a probationary period with additional monitoring and retraining.

Repeated errors or mistakes may trigger notification to the DEA as outlined in the prior section and may require restricting or prohibiting the use of controlled substances in research.

20. CONTACTS

Florida Department of Business and Professional Regulation (DBPR)

Drugs, Devices, and Cosmetics Program
2601 Blairstone Road
Tallahassee, FL 32399-1047
(850) 717-1819
Tehelia McGlockton
tehelia.mcglockton@myfloridalicense.com

Drug Enforcement Administration (DEA)

Miami Field Division
2100 N Commerce Pkwy
Weston, FL. 33326
Diversion Number: (954) 306-4650
Diversion Fax: (954) 306-5351
Diversion Program Manager Fax: (954) 306-5352
Diversion Program Manager - Susan Langston
Jurisdiction: Southeastern Florida
DEA Diversion Control Division
http://www.deadiversion.usdoj.gov/index.html

EH&S

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18. RELATED INFORMATION:

- University Policy 4.1.2, Environmental Health and Safety
- FAU Controlled Substance Authorized Agent Log
- FAU Controlled Substance Diluted Solution Log
- FAU Controlled Substances Program Lab Preparation Checklist
- FAU Controlled Substances Program Lab Annual Self-Inspection Checklist
- FAU DEA Controlled Substance Usage Log
- FAU Employee Questionnaire
- FAU Controlled Substance Inventory Form (Used for Initial, General, Annual, and Closeout inventories)
- DEA Researcher's Guide
- DEA Form 41
- DEA Form 106
- DEA Form 222 Ordering Paper Forms

Approved and issued by order of:

Wendy Ash Graves DATE: 10/16/24

Wendy Ash Graves
ENVIRONMENTAL HEALTH AND SAFETY

POLICY MAINTENANCE SECTION

Last Revision Date	New document
Last Revision By	W. Ash Graves
Next Review Due	10/16/2027
Review Frequency	3 years
Version	1.0
Time-sensitive Items	

THIS POLICY RESCINDS ALL OTHER WRITTEN DIRECTIVES REGARDING THIS TOPIC.

19. RECORD OF CHANGES/STATUS CONTROL:

Version	Date	Summary of Changes	Reviewed By
1.0	10/16/2024	New Document to comply with Federal and State laws for the use of prescription drugs and controlled substances in research.	• W. Ash Graves • F. Novembre • R. Brust