Environmental Health and Safety	Effective Date: 05/12/2022	Procedure Number: EHS_SOP350
	Revision: 3	Page 1 of 21
TITLE: Possession of Prescription Drugs and Controlled Substances Procedure	**Approved by** Director of Environmental Health and Safety **Date**: 5/12/2022	

1. APPLICABILITY

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 the University of Central Florida (UCF.) Environmental Health and Safety (EHS) is the designated authority for compliance with this procedure, as per UCF Policy 3-122, Campus Safety and Health Policy, and UCF Policy 3-107.2, Procurement, Use, and Possession of Hazardous Materials and Regulated Devices and Equipment.

Authorized users with access to controlled substances must review and sign the EHS_SOP350_FORM002 Controlled Substances and Prescription Drugs Procedure Consent Form, and acknowledge to abide by all policies and procedures that regulate the use of controlled substances for research purposes. The consent must be reviewed and signed every three years from the date of the first submitted consent form. The Consent Form must be submitted to the EHS Health Sciences Campus (HSC) Safety Coordinator.

If controlled 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 DEA requirements, including registration, inspection, and certification, as applicable, are met. Regional DEA offices can supply forms and information concerning the type of registration required for a particular substance for research use. The main registration office in Washington, DC may be reached at 800-882-9539. Information also is available from the National Institute on Drug Abuse at 800-662-4357.

2. PROCEDURE STATEMENT

University researchers may in the course of lawful research, teaching, or testing, find it necessary to use prescription or legend drugs, including DEA analytical standards or federally-controlled substances. Various federal and state statutes and regulations address such use. UCF has the responsibility to ensure that all departments, units, and employees comply with all applicable laws and requirements with regard to these substances. Prescription or legend drugs and

controlled substances are considered restricted hazardous materials and are subject to UCF Policy 3-107.2.

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 have a tendency to be subject to abuse, and physiological or psychological dependence, and, as such, 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. Registered researchers, by their adherence to the law, constitute a powerful resource for protection of public health and safety.

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 the 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 with Policy 3-107.2; 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 (see references). The following information is provided to university researchers as guidance for obtaining necessary exemptions, licenses, and permits, as well as instruction on the purchasing, 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.

The objective of this procedure is to ensure compliance with state and federal regulations governing the use of prescription drugs, medical gases, controlled substances, or chemicals, and in accordance with Title 21 United States Code (USC) Controlled Substances Act.

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 UCF Policy 3-122, the Department of Environmental Health and Safety (EHS) is the designated office at UCF in charge of administration of, and compliance with, all health and safety regulations. Under this authority, EHS is charged with developing applicable policies and procedures and performing inspections to monitor for compliance.

3. DEFINITIONS

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

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.

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).

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

Registrant: A person who is licensed and registered with the U.S. Drug Enforcement Agency (DEA) to possess and handle controlled substances. This person is responsible to ensure compliance with state and federal laws for recordkeeping, storage, and security.

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

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.

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

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

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.

4. RESPONSIBILITY

The University of Central Florida requires that all individuals working with DEA-controlled substances have current registration with the DEA and comply with all state and Federal regulations regarding the acquisition, storage, use, record keeping, and disposal of those controlled substances.

Principal Investigator (PI)

Each PI working with DEA-controlled substances will be responsible for submitting an Application for Exemption Registration Form (#DBPR-DDC-227) to the Florida Department of Business and Professional Regulation. If the PI will be working with controlled substances, he or she must also register with the DEA to obtain a DEA Registration (license). The HSC Safety Coordinator can assist the PI with the Application for Exemption Registration Form and DEA registration process.

Animal Research

If controlled substances and/or prescription drugs are planned to be used in a research project using animals, the PI must obtain a Florida Exemption Letter and a DEA Registration prior to starting research. Note an IACUC approval letter is also required for obtaining a DEA registration.

The PI, also known as the registrant, has the utmost responsibility for record keeping, storage, security, assigning and supervising authorized agents, and ensuring compliance with all state and federal laws. Failure to do so may result in criminal charges or fines. The registrant shall select and screen a limited number of people to be authorized agents and inform and train them on the procedures and protocols associated with handling, storage, and documentation of controlled substances. Most importantly, the registrant is responsible for reporting any suspected loss or theft to the U.S. Drug Enforcement Agency.

Authorized Agents

Authorized agents (users) fall under the direction of the registrant, and are required to follow all state and federal regulations governing controlled substances, or be faced with criminal charges or fines. Each authorized agent must complete the EHS_SOP350_FORM007 questionnaire and submit it to the registrant.

The authorized agents must receive appropriate training from the registrant regarding lab procedures, protocols, documentation, safety, security, and handling of controlled substances. Authorized agents shall ensure that controlled substances are stored in a way that will not lead to theft or misuse. Each authorized agent shall ensure that proper records are updated. Authorized agents must ensure proper disposal of controlled substances, and must report any suspected theft or loss immediately to the registrant.

Environmental Health and Safety

EHS personnel will provide guidance to PIs for registering with state and federal agencies to become registrants, including guidance on processes and form requirements. They will provide advice and guidance for storage and assist with disposal of controlled substances.

5. ASSOCIATED DOCUMENTS

EHS_SOP350_FORM001 Biennial Inventory Log
EHS_SOP350_FORM002 Controlled Substances & Prescription Drugs Procedure Consent Form
EHS_SOP350_FORM003 Controlled Substance Receipt Form
EHS_SOP350_FORM004 Controlled Substance Spill Record Form
EHS_SOP350_FORM005 EHS Controlled Substance Inspection Self-Audit Checklist
EHS_SOP350_FORM006 Initial Inventory Log
EHS_SOP350_FORM007 Employee Questionnaire
EHS_SOP350_FORM008 Use Log
EHS_SOP350_INST002 Controlled Substance Purchasing SOP
UCF Policy 3-107.2 Procurement, Use, and Possession of Hazardous Materials and Regulated Devices and Equipment
DBPR Application for Exemption Registration (outside document)
EHS_SOP340 Laboratory Close-out Procedures
DEA Registered Reverse Distributors List

6. PROCEDURE

APPLYING FOR STATE OF FLORIDA PRESCRIPTION EXEMPTION
Introduction

Obtaining and possessing prescription drugs, analytical standards or medical gases 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, and may be renewed thereafter.

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:

1. Explanation/summary of the conditions of research, teaching, or testing.
2. Exact physical and mailing address of the location where the prescription drugs, analytical standards, controlled substances or gases will be stored.
3. The specific drugs and or gases required for research, teaching, or testing activities.
4. The name of the suppliers for each controlled substance, prescription drug, analytical standards and or gases.
5. 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

Paper form:

1. The applicant will fill out Form #DBPR-DDC-227. The EHS HSC Coordinator will assist, as needed.
2. The applicant will send a copy of the form to the EHS HSC Safety Coordinator for review and approval, prior to submitting it to the DBPR via mail.

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**
    - **Name of Organization/Business** is always University of Central Florida.
    - **Mailing address** is the address of the applicant's office location. Look up the building address here. Please DO NOT enter 4000 Central Florida Boulevard, as it is incorrect.
    - The **physical address** corresponds with the exact location where the drugs or gases will be received and stored; include 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, course work, 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.

- **Section VII – Affidavit**
    - Read the affidavit; then sign, date, and print name.

7. APPLYING FOR DEA REGISTRATION (New Applicants Only)

PIs must determine if the drugs they intend to use in the course of 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 four 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.

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 need to plan accordingly. There is no fee for researchers working at state institutions. The Director, Environmental Health and Safety waives the exemption from the application fee.

DEA Form 224 is used for hospitals, clinics, qualified practitioners, and clinical/medical teaching institutions where controlled substances would potentially be prescribed or distributed to patients. This business activity is not for individuals, but where medical education takes place under the authority of a state-accredited college or university. The applicant should check with the EHS HSC Coordinator to determine which form should be used, or for additional assistance.

The online application forms can be found at the DEA Diversion website. Instructions to complete the application may be found here. DEA encourages to use the online forms system to apply for a registration

Researcher must attach 3 copies of research protocol, including curriculum vitae, to conduct research with schedule 1 controlled substances.

8. 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.

If the DEA registration expires and is renewed at a later date, 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.

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 prior to the exemption's expiration. The DBPR sends a reminder via mail about 60 days from expiration date. PIs should mark their calendars 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 the HSC Coordinator, Purchasing Department, and to any approved vendors.

9. PURCHASING

PIs (registrants) must follow UCF Policy 3-107.2 Procurement, Use, and Possession of Hazardous Materials and Regulated Devices and Equipment, for the lawful use of prescription or legend drugs and controlled substances. The PI must purchase drug products through the PI's approved vendors and ensure that the purchased products are received, inventoried, and stored properly. Any purchases and deliveries of controlled substances must be tracked by the registrant. Lost shipments must be reported to the DEA, the EHS HSC Coordinator, and the UCF Police Department (407-823-5555) as soon as possible.

The PI must maintain records to include vendor name, invoices, shipping documents, and packing slips, on all exempted or registered products. The PI must update his or her EHS_SOP350_FORM003 Controlled Substance Receipt Form upon receipt of any controlled substances in the UCF Controlled Substances Manual. All records must be available for periodic inspection by EHS, DEA and DBPR.

The PI must ensure that all controlled substances requests have been approved by EHS before they are submitted to Purchasing, using a departmental purchase order form. Your departmental Purchaser should use category code 51210000 (Miscellaneous Drug Categories), for requisitions and purchase orders for controlled substances. Purchasing will not process purchase orders without the

departmental purchase order approval by EHS. The EHS_SOP350_INST002 Purchasing Controlled Substances Instruction must be followed.

10. DEA FORM 222

Purchases of Schedule I and II Controlled Substances

The registrant may only order Schedule I and II controlled substances as authorized by his or her 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 registrant's controlled substance records. DEA Form 222 may be ordered using the online DEA Order Form Request. DEA Forms 222 must be stored securely in a safe box to prevent loss or theft.

Lost and Stolen DEA Forms 222

If a registrant ascertains that an unfilled DEA Form 222 has been lost, the registrant 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 registrant, who must attach it to the statement.

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

Recordkeeping of DEA Form 222

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

The supplier must retain the original of each DEA Form 222 that it has filled.

DEA Form 222 must be maintained separately from all other records of the registrant. DEA Form 222 are required to be kept available for inspection for a period of two years.

More information on purchasing of controlled substances, the use of DEA Form 222, and obtaining approval of controlled substances purchases can be found in the Purchasing Controlled Substances Instruction Form EHS_SOP350_INST002.

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

The registrant is legally responsible for the prescription or legend drugs, analytical standards, and controlled substances for which he or she has exemptions or registrations, in accordance with all regulations, including inventory, recordkeeping, and security provisions. Controlled substances are under no circumstances transferable nor shared between researchers and/or laboratories. Researchers with IACUC protocols must obtain their own Florida Letter of Exemption and DEA registration. In addition, each PI with an approved research grant must obtain their own licenses as well.

The registrant must pre-screen and authorize individuals to engage in approved activities under his or her direction. Those individuals must complete EHS_SOP350_FORM007 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 be aware of controlled substances laws and regulations, including storage, security, recordkeeping, inventory, and disposal requirements.

Controlled substances may only be transported when both the origin and destination are registered under the same registrant. PIs are prohibited from making a solution and transferring it to an unregistered individual, or transporting it to a location in which the PIs are not registered. Such movement is illegal and may subject the registrant to fines and imprisonment. Approval from the DEA must be obtained prior transportation of such drug(s) and EHS must be notified.

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 EHS any given time.

12. INVENTORY

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 EHS_SOP350_FORM001 Biennial Inventory Form. Inventories can be taken at either the open or close of business and should be indicated as such on the form. The biennial inventory is taken every two years from after completing an Initial Inventory Form. The form must include all controlled substances in the

registrant's possession. If no drugs are in possession, it must be stated in the inventory form.

Schedule I and II controlled substances must be recorded on a separate inventory form from all other drug Schedules.
The Initial Inventory Form is used only one time upon receiving a new DEA Registration. If the registrant has no inventory, the form must be filled out in its entirety, entering zero (0) inventory. The EHS_SOP350_FORM003 Controlled Substance Receipt must be filled out upon receiving shipments of controlled substance(s).

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 at a later date, the PI must fill in a Use Log, as it is considered a "new product" and dilution.

Waste: A dilution, created and not used in its entirety in one application, is considered waste if there are no plans to use the material at a later date. Waste dilutions may not be combined into a single waste container. Each dilution container must be disposed of through a Reverse Distributor.

Empty drug containers must be defaced and may be discarded after defacing the manufacturer's label. Refer to the UCF Environmental Management Program on the EHS website for disposal instructions on empty containers.

An inventory of DEA analytical standards must be maintained by the authorized user. Inventories must be readily available upon request by DBPR and EHS.

13. SECURITY AND STORAGE

The registrant must store prescription drugs, including DEA analytical standards and controlled substances with effective controls to guard against theft or diversion. Registrants 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 registrant must secure the area from unauthorized entry or unauthorized access when authorized personnel are not present. Storage must provide at least two levels of security, such as a locked cabinet within a locked room, or a lockbox within a locked cabinet. Schedules III-V drugs and prescription drugs or other chemicals may not be stored with Schedule I and II 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.

Schedules I and II controlled substances must be secured in a GSA Class V safe. If the safe weighs less than 750 lbs., then it must be bolted or cemented to the building structure.

Schedules III-V controlled substances must be stored in safes or in securely locked, substantially- constructed cabinets, provided that they are not accessible from above or below, and are preferably permanently bolted or cemented to the building structure. Metal cabinets are preferred and should be resistant to entry by tools such as screwdrivers, crowbars, tire tools, or pry bars. Hinges should not be mounted on the outside, and deadbolt-type locks should be permanently installed.

The registrant must limit access to as few personnel as possible and maintain control of the keys. The registrant must change combinations and retrieve keys when authorized agents leave their positions in the lab. The registrant must document personnel changes in the Controlled Substance Manual and notify the HSC Safety Coordinator of any changes by using the Authorization Update form.

More information can be found in the DEA Controlled Substances Security Manual.

14. DISPOSAL

Hazardous Waste Pharmaceuticals (Controlled Substances)

To minimize waste, the registrant should only purchase quantities of prescription drugs and controlled substances that he or she intends to use.

The registrant 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 registrant must maintain the transfer and disposal records for at least two (2) years after disposal of a controlled substances. For instructions on proper disposal of empty vial containers, click here.

The registrant must properly dispose of all controlled substances prior to leaving the university. Any PI who orphans or leaves controlled substances within his or her lab is in violation of federal law. The PI's department will be held responsible for disposal expenses associated with orphaned drugs. EHS does not hold a DEA registration, and therefore cannot hold or dispose of controlled substances.

UCF employs the Reverse Distribution method for the disposal of controlled substances, and disposal costs are the responsibility of the registrant. Click here for the disposal process. The registrant must contact one of the reverse distribution vendors listed on the Reverse Distributor List. EHS does not endorse any vendor. The registrant must complete vendor-supplied forms and submit

them for approval from the Reverse Distributor selected. Upon approval, the vendor will send pre-addressed shipping labels to the registrant to return the substances to the vendor for disposal.

Hazardous Waste Pharmaceuticals (Non-Controlled Substances)

The registrant must dispose of any unusable, non-scheduled prescription or legend drugs as hazardous waste through EHS or through a Reverse Distributor.

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.

Pharmaceuticals that are non-controlled substances 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 which 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 very 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 make-up 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 but 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 EHS as hazardous waste in order to prevent potential abuse.

If the products to be disposed of are other types of non-controlled pharmaceuticals, EHS can perform a hazardous waste pick-up. A waste pick-up request must be submitted through the Environmental Health and Safety Assistant (EHSA) Hazardous Materials Management system.

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 by no means exhaustive. For a more comprehensive method of identifying all potential hazardous wastes, refer to the EHS Hazardous Waste website.

15. INSPECTIONS

Registrant Inspections

Registrants are encouraged to perform a Controlled Substance Inspection Self-Audit, using the EHS_SOP350_FORM005 Inspection Audit Checklist.

UCF Inspections

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

At the time of inspection by EHS, the following are subject to evaluation:

- Proper licensing obtained by researchers.
- Proper storage and security arrangements.
- Accuracy, completeness, and timeliness of all records and inventories.

- Correction of deficiencies found during previous inspections.

- Procedures for use and disposal of controlled substances.

If major discrepancies are found, EHS will re-inspect the area immediately, in accordance with UCF Policy 3-122. The registrant must correct all other discrepancies found within 30 days of the initial inspection. Any suspected potential for criminal activity will be reported to the UCF Police Department.

Drug Enforcement Administration (DEA) Inspections

The DEA makes periodic unannounced inspections to audit registered controlled substances storage locations and laboratories to determine if the registrant is compliant with the Controlled Substances Act. PIs or authorized agents are required to be in attendance and provide the DEA Inspectors with all credentials, records, storage arrangements, and logs upon request.

DEA Inspectors may send advance notice of an inspection to EHS, and in turn EHS will inform all registrants. All PIs or authorized agents must be present, as the DEA does not inform the university which registrant(s) will be inspected. If the PI refuses to take part in the inspection, the inspectors will get a court order (within hours) to proceed. An inspection conducted under a court order will be stricter and may be adversarial.

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 exemption for the use of controlled substances, analytical standards, medical gases, prescription or legend drugs. The PIs must still follow all Florida Statutes and regulations for storage, use, record keeping, and disposal of prescription drugs.

16. RECORDKEEPING

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 a minimum period of 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.

The PI should maintain all records listed in the UCF Controlled Substances Manual, which addresses procedures, DEA Registration, employee questionnaire, receipts, purchase order forms and DEA Form 222, packing slips, use and inventory records, disposals, loss reports, and training information or records. Records should be stored in a secure, designated file space, and be readily available for inspection.

Registrants must retain the following controlled substance records:

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

Employee Questionnaire: Copies of all EHS_SOP350_FORM007 questionnaires submitted by authorized agents.

Purchase and Order Records: All invoices for the purchase of 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.)

Receipt Form: A tracking and inventory of all shipments as they are received.

Use Logs: Real-time inventories for each substance, using a separate EHS_SOP350_FORM008 Use Log for each individual 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 registrant must notify the DEA Field Division Office in his or her area, in writing, of what the researcher may consider a significant loss or theft.

Inventories: Two separate inventories: an EHS_SOP350_FORM006 Initial Inventory, which must be completed upon receiving a DEA Registration; and an EHS_SOP350_FORM001 Biennial Inventory, which must be completed every two years thereafter. If the registrant does not have any inventory at the time of the registration, then the Initial Inventory Form must show a zero (0) inventory. A continuous general inventory is also required, to maintain accurate records.

Disposal Records: A copy of DEA Form 41, as a record of disposal of the controlled substance. Damaged, expired, unwanted, unusable, or non-returnable controlled substances must be disposed of in accordance with regulations. The DEA Form 41 must be completed and obtained from the Reverse Distributor of choice upon disposal of any controlled substances. A copy of the completed DEA Form 41 must be filed in the Controlled Substances Manual.

Federal regulations require that registrants report any theft or significant loss of any controlled substances to the nearest DEA Field Division Office (Miami) within

one (1) business day of the discovery (21 C.F.R. § 1301.76 (b)). A DEA Form 106 must also be completed and submitted to the DEA Field Division Office. The online DEA Form 106 is the preferred method due to timeliness and convenience. Registrants should notify the UCF Police Department (407-823-5555) and EHS after reporting theft or loss to the DEA.

In the event that the PI leaves the institution, the recordkeeping logbook must be returned to the EHS HSC Coordinator. The EHS_SOP340 Laboratory Close-out Procedures are to be used in the event that UCF laboratories will be vacated due to a PI leaving the institution, the relocation or termination of research activities in a particular laboratory, or planning for a renovation project.

The EHS_SOP350_FORM004 Controlled Substance Spill Record Form must be completed for controlled substance spills. It is highly encouraged to include pictures and/or other documentation, for recordkeeping and to help account for the amount spilled.

17. TRAINING

It is a UCF EHS requirement for all registrants and authorized agents to complete the Controlled Substances Online Training biennially. For researchers using DEA analytical standards, training will be required. Additional training is available upon request.

Contacts

Florida Department of Business and Professional Regulation
Drugs, Devices, and Cosmetics Program
2601 Blairstone Road
Tallahassee, FL 32399-1047
(850) 717-1800
Stephanie.Prine@myfloridalicense.com

Drug Enforcement Administration (DEA)
Orlando District Office, Division: Miami
Heathrow Business Center
300 International Parkway, Suite #424
Heathrow, FL 32746
Diversion Number: (407) 333-7046
Diversion Fax: (407) 333-7056
GS Linda A. Stocum, (407) 333-7006

DEA Diversion Control Division
http://www.deadiversion.usdoj.gov/index.html

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18. ARCHIVES

19. DISTRIBUTION

This document is shared through:

□ EHS only	□ Facility and Safety	☑ UCF community
□ Secured Document	□ Contractor	☑ EHS Web site
□ Other: _____		

20. REVIEW

	Name	Signature	Date
Coordinator	Thaismary Morales	Thaismary Morales Digitally signed by Thaismary Morales Date: 2022.05.13 16:59:42 -04'00'	5/14/2020
Coordinator	Thaismary Morales	Thaismary Morales Digitally signed by Thaismary Morales Date: 2022.05.13 16:59:55 -04'00'	7/15/2021

21. DOCUMENT HISTORY

Date	Revision number	Author	Modifications
07/01/2019	0	Thaismary Morales	Annual review
5/14/2020	1	Thaismary Morales	Annual review
7/21/2021	2	Thaismary Morales	Annual review
5/12/2022	3	Thaismary Morales	Annual review