Regulated Drugs, Pharmaceuticals, and Ether

University researchers may, in the course of research, teaching or testing, find it necessary to use diethyl ether, prescription or legend drugs or federally controlled substances. Various federal and state statutes and regulations address this need. FSU has the responsibility to ensure that all departments, units and employees comply with all applicable laws and requirements with regard to these substances. The "Regulated Drugs, Pharmaceuticals and Ether" policy was developed to assist researchers in complying with Chapters 499 and 893 of the Florida Statutes, Chapter 64F-12 of the Florida Administrative Code and the Code of Federal Regulation, Title 21, Parts 1300-1308. The following information is provided to University researchers as guidance for obtaining necessary exemptions, licenses and permits as well as instruction on purchasing, storage, record keeping and destruction or disposal of such substances.

Diethyl Ether

Persons who either purchase or possess ether in the quantity of 2.5 gallons (9.5 liters) or more to use for research, teaching, or testing must obtain a letter of exemption from licensing from the Florida Department of Business and Professional Regulation (DBPR). EH&S will assist researchers in obtaining the letter of exemption by preparing an application form for the researcher and submitting it to the DBPR. In order to prepare the form, a researcher requesting the exemption must provide the following information:

- The conditions of the lawful research, teaching, or testing (brief description of the experiment or process for which diethyl ether is required).
- The exact physical address/location where the ether will be used/stored
- The quantity that will ordinarily be purchased at one time.
- The frequency of the purchases
- The name and state license/permit number of the supplier(s)

The form requires a signature from the researcher to affirm that the ether will be secured and that access will be restricted to authorized individuals only, and to state that the ether is not for resale. EH&S will submit the request to the DPBR on the PI's behalf. The PI will be provided the DPBR letter granting exemption from licensing upon receipt and EH&S will assist researchers in obtaining subsequent biennial renewals.

Records

All persons who are exempt from licensure must keep records of ether purchases, use, or disposition. A copy of the letter of exemption must be kept with the required record documentation.

Documentation must include the name, address, and license/permit number of the seller/transferor and purchaser/recipient as well as the date of transfer and the signature of the purchaser. All records shall be retained for five (5) years. Electronic records of purchases and transactions are allowed. Records are subject to audit by the University, Department of Business and Professional Regulation, or the Florida Department of Law Enforcement (FDLE).

Ether Security

Every person in the State who possesses ether shall secure it in a manner that functionally and practically deters unauthorized access to the ether.

Prescription (Pharmaceutical) or Legend Drugs

Principal Investigators (PIs) who are not licensed in the State of Florida to practice medicine or pharmacology must purchase pharmaceuticals (Rx drugs) used in research using a license or license exemption issued by the Florida Department of Business and Professional Regulation (DBPR).

Alternatively, to permit researchers to obtain Rx drugs without obtaining their own licenses or license exemptions, researchers may order drugs using the EH&S Restricted Drug Distribution license.

Prior to placing orders on the EH&S license, PI's must register with EH&S by filling out and submitting the form "Rx drug registration" (FSUID Login Required).

Researchers who prefer to establish their own accounts with veterinary supply companies to order pharmaceuticals directly from these companies may do so, but all DEA regulated drugs must be ordered on the EH&S accounts using the EH&S licenses, then transferred to the researcher/lab.

To establish an account with a veterinary supply company, researchers must provide a faxed copy of their own DBPR license exemptions. To apply for a license exemption directly (instead of using the EH&S Rx license for ordering drugs) go to http://www.myfloridalicense.com/dbpr/ddc/exemptions.html

Ordering Pharmaceutical drugs and devices

Pharmaceuticals may be purchased by researchers who have established an account with veterinary or medical suppliers. Generally, the vendor will require that researchers supply a State of Florida DBPR license or license exemption to establish an account. Alternatively, researchers may order pharmaceutical drugs and supplies on established EH&S accounts after submitting a one-time Rx-drug registration form (FSUID Login Required) to EH&S as described above. Drugs and other prescription items ordered on the EH&S license will be delivered to EH&S at 1225 Milton Carothers Hall. EH&S will contact the researcher to arrange for delivery/transfer of drugs to the laboratory. Non-drug veterinary supplies ordered on the EH&S account may be picked up from EH&S at Milton Carothers Hall, suite 1200. Contact the Laboratory Safety Office at 644-0818 or 644-8916 for more information about veterinary supply companies and prices.

Records

Whether purchased using researcher license exemptions or the EH&S license, specific records must be kept to provide a complete audit trail from drug receipt to disposition in accordance with state law. Records will include a shipping invoice, transfer form (if transferred from EH&S), an accurate use log, and a copy of biennial inventories. Records must be retained for a period of three (3) years following disposition of the drug. To assist the researcher in keeping detailed receipt and use records, EH&S has prepared a Controlled Substance Use Record (Form EHS 9-5).

Audits of prescription or legend drug records and inventories will be performed at least biennially by EH&S. Discrepancies found during these audits must be corrected in a timely manner. Suspected potential for criminal activity will be reported to the FSU Police Department for investigation. Records must be retained beyond three (3) years if an investigation has been initiated and not yet completed by the three-year limit.

Security and Storage

Areas where prescription or legend drugs are stored must be secured against unauthorized entry or unauthorized access when authorized personnel are not present. All prescription or legend drugs must be maintained within the recommended temperature tolerances by the manufacturer and must be kept separate from other laboratory chemicals. An isolation area must be maintained for all prescription or legend drugs that are out of date, deteriorated, mislabeled, or otherwise unfit for use. This area must be

clearly marked and separate from other storage areas so that products within it are not confused with usable products.

Disposal

Researchers must sequester expired drugs from in-use drugs by placing expired drugs in a labeled container or cabinet. Expired drugs may be disposed of by transferring to EH&S. For information on disposal of unwanted or outdated prescription or legend drugs contact EH&S at 644-0818. EH&S may not dispose of personal use prescription medicines. Information regarding disposal of personal use medications may be found at http://www.dep.state.fl.us/waste/quick_topics/publications/shw/meds/DEPMedicationDisposalFlyer.pdf Contact the Laboratory Safety Office at 644-8916 or 644-0818 if you have any questions regarding registration or purchase of prescription or legend drugs.

Substances Controlled by the U.S. Drug Enforcement Administration (DEA)

The Florida State University 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 substances.

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, physiological or psychological dependence and, as such, have been identified as items needing extensive licensing, registration, storage, security, use and disposal requirements. State and Federal agencies (e.g. the DEA) have comprehensive regulatory and enforcement schemes 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. Schedule I and II substances are categorized as having the highest potential for abuse and are the most regulated. Schedule I substances are classified by the U.S. government as having no medical value and include designated opiates, heroine, MDMA (ecstasy), LSD and marijuana. Schedule II drugs include the barbiturates, morphine, designated opiates, and highly addictive drugs like cocaine, amphetamine, pentobarbital, oxycodone. Schedule III drugs include many medically relevant chemicals (ketamine, diazepam, testosterone, buprenorphine) and Schedule IV covers the balance of lower abuse potential stimulants and depressants. 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 accompanied by DEA Form 222 (DEA official order form).

A list of all controlled substances is available at the DEA Diversion Program website. http://www.deadiversion.usdoj.gov/schedules/index.html

Responsibilities

Each PI working with DEA controlled substances will be responsible for registering for a DEA controlled substance license. EH&S will assist the researcher in registering for a DEA controlled substance license using the information provided on the EH&S form "Controlled Substances Request for Registration Information." Access to this form may be obtained by contacting the Laboratory Safety Office (644-8916 or 644-0818). Using the information provided, EH&S will complete a DEA225 application to request a DEA license.

After the application is submitted to the DEA online, EH&S will contact the local field office and provide further information to enable the DEA investigators from this office to assess the application for the license. A DEA investigator will schedule an in-person interview with the researcher and observe the lab security.

Use of Controlled Substances in Research, Teaching, or Testing - Completing the DEA License Application

Each PI working with DEA controlled substances must provide EH&S with the necessary information to register the PI for a DEA controlled substance license (see previous paragraph). It may take 3-12 months to receive the registration certificate (DEA license) from the DEA, so researchers need to plan accordingly. There is no fee for researchers working at state institutions.

Information which must be provided through the "Controlled Substances Request for Registration" form includes:

- Curricula Vitae
- Project - Title, statement of purpose of research (e.g. Controlled substances are used in a study of the neurochemical basis for anxiety in rats), controlled substance(s) name and estimated amount needed each year, location of drug storage, description of security (EH&S can help with this), and a description of the use of the substance(s) in the research (e.g. ketamine is used for anesthesia in rodents for cardiac catheter implantation). Researchers may provide an ACUC protocol (pending or approved) to provide this information.
- Funding agency and grant number if applicable.

EH&S will assist researchers in obtaining annual renewal of DEA registrations. The DEA will send the licenses directly to the PI.

Researchers intending to use Schedule I drugs (heroin, marijuana, THC, ecstasy, etc.) for research should contact the Laboratory Safety Office at 644-8916 or 644-0818 for guidance on additional security measures and documentation that is required by the DEA.

Authorized Use

The license holder is legally responsible for managing the controlled substances in accordance with federal and state regulations, including record keeping and security provisions. Lab workers may engage in approved activities under the direction of the DEA permit/license holder. The license holder is required to screen those employees prior to authorization. As part of the screening process, EH&S provides a questionnaire, available here (Form EHS 9-3), that is filled out by the lab worker and signed by the PI. The original is kept in the license holder's file and a copy is submitted to EH&S. This form is provided to the DEA.

Completed questionnaires must either be kept with the records of controlled substances acquisition and use or able to be readily retrieved upon request during inspections. An individual that answers "yes" to either of the questions may not be permitted to access any controlled substances.

Procurement of Controlled Substances

Procurement of DEA controlled substances must be coordinated with EH&S. Controlled substances are ordered on the EH&S DEA licenses and are shipped to EH&S at 1225 Carothers Hall. EH&S will secure the controlled substances and contact the researcher to schedule a transfer of the materials to the researcher or his/her authorized lab workers. A transfer form and a DEA 222 form (for schedule I or II

drugs) will be signed at the time of transfer, and other required paperwork will be provided. Contact EH&S for additional information concerning this process.

Procurement process for Schedule I and II Controlled Substances:

Orders are placed through OMNI using the PI or department account and the EH&S DEA license number. An order worksheet, available here (Form EHS 9-8), may be used to facilitate the order by providing important information about the order to the Department fiscal staff. This order worksheet is not required. The following information should be entered into OMNI for a controlled substance order:

- An account code # for controlled substances must be entered on the OMNI requisition. This account code will alert Purchasing to request EH&S approval for the order. (see form at link above)
- The requester must enter the EH&S DEA and the EH&S DOH license numbers so that these will appear on the purchase order, and
- The EH&S "ship to" code as indicated in the Controlled Substance order worksheet.

Orders for Schedule I and II controlled substances may not be faxed; the PO and a DEA 222 form must be mailed to the vendor by EH&S. The controlled substance will be shipped to the EH&S Laboratory Safety Office in Milton Carothers Hall room 1225. Upon receipt, EH&S will open the packaging to verify the contents and ensure that no damage to the contents has occurred. EH&S will notify the PI or authorized representatives that the controlled substance has been delivered. EH&S will deliver the controlled substance to the PI or an authorized representative. At that time, the PI or authorized representative will verify the contents of the order, sign an EH&S transfer form, and enter the receipt onto the PI's "Controlled Substance Use Log." EH&S must be notified of receipt of any controlled substances directly to the laboratory.

Procurement Process for Schedule III-V Controlled Substances.

The DEA Form 222 is not required. For these materials, PI's may order through the OMNI system. The Requester must enter the controlled substance account code, which alerts Purchasing that the order will need EH&S approval. Fiscal representatives or PI's must also indicate the EH&S shipping code and note the EH&S DEA and EH&S DOH license numbers on the requisition. Shipping, receipt, and transfer are handled as above.

NOTE: Controlled substances and pharmaceuticals are not transferable between researchers or laboratories.

Storage and Security

Environmental storage conditions should meet manufacturer's recommendations.

License holders shall provide effective controls to guard against the theft or diversion of controlled substances. Substances are required to be stored in securely locked, substantially constructed cabinets (i.e. not easily broken into or moved) or safes. The securing device must be approved by the DEA. (In recent years, the DEA has approved all burglary safes if bolted to the floor or countertop, e.g. a Sentry A350 for Schedule II-V drugs). In addition, the safe must be kept in a room that is locked or otherwise secured after hours. The intent of the law is that controlled substances must be adequately safeguarded. Therefore, depending upon other security measures, a wooden cabinet or impermanent mounted metal cabinet may not be considered adequate.

Permit holders for Schedule I drugs will be required to contain the regulated materials in a GSA Class V safe which will be alarmed to a 24-hour monitoring service or police department. Access to storage area

must be controlled and properly designated. Employee Questionnaires completed by authorized personnel (personnel with drug access) and signed by the PI/licensee must be maintained in the laboratory and a copy be provided to EH&S.

Record Keeping

Real time inventories (Controlled Substance Use Logs) are required for each substance and must be kept for 3 years after disposition (via use or disposal) of the substance. Inventories and other records including certificate of registration (DEA license), purchase orders (DEA Form 222), loss records, biennial inventories, and employee screening questionnaires are required to be kept in a designated location by the permit holder for at least 2 years. Records for schedule I and II substances are required to be maintained separately from all other records (i.e. a separate notebook section, file or folder for different classes of controlled substances). All records must be readily retrievable and are subject to audit.

Records must include:

- the name of the drug,
- the date and amount received,
- the number of units or volume in each commercial container,
- the date and amount used,
- the use or purpose and
- the name or initials of the individual making the written entry.

A Controlled Substance Use form (Form EHS 9-5) is available for record keeping or receipt and use of controlled substances. Minor loss occurring in routine use and handling should be recorded when noticed to maintain an accurate inventory. Any loss due to breakage, contamination or related circumstances should be reported to EH&S for determination of appropriate actions and the loss should be noted on the use log. A Controlled Substance Spill form (Form EHS 9-6) has been provided to record the loss of a controlled substance through spilling. The entry must include:

- the date,
- the estimated amount lost,
- the reason for loss (e.g. spillage) and
- the name or initials of the individual responsible.

All permit holders are required to report any loss from theft or suspected theft to the FSU Police immediately. EH&S will assist the PI in filling out DEA form 106 for report of the theft or loss to the local DEA office.

Inventory

EH&S will assist each registrant in conducting an inventory initially (upon receiving a license) and reconciliation of all controlled substances biennially. Inventory records must be kept for three (3) years from the date of inventory.

Disposal

Please contact EH&S at 644-0818 for information concerning disposal of DEA Controlled Substances. Researchers must fill out appropriate EH&S transfer paperwork at the time of transfer of expired or unwanted substances to EH&S for disposal. A copy of this form must be kept with other records for a

period of three (3) years following disposal. Researchers are responsible for disposal of controlled substances within 30 days of the expiration date by transferring these substances to EH&S. Materials will be picked up by EH&S with completed EH&S transfer/disposal form and disposed of in accordance with DEA protocols.

Controlled substances that are mixed with radioactive waste, chemical hazardous waste, or medical waste are not eligible to be disposed of using the regular controlled substance methods. Contact EH&S for disposal instructions.

References:

- Florida Statute 499 (Drug, Cosmetic and Household Products)
- Florida Statute 893 (Drug Abuse Prevention and Control)
- FAC 64F-12 (Regulations for Drugs, Devices and Cosmetics)
- 21 CFR 1300-1308
- US DEA Office of Diversion Control