



**Division of
Research Safety
Controlled
Substance
Surveillance
Program**



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PURPOSE

This program outlines the responsibilities and requirements for the possession and use of controlled substances for research activities and the Animal Care Program at the University of Illinois Urbana Champaign (UIUC). The University must comply with both state and federal regulations. The use, storage, and disposal of controlled substances are regulated by the U.S. Drug Enforcement Administration (DEA) in the Code of Federal Regulations (CFR) Title 21, Part 1300-1308, by the Illinois Controlled Substance Act [720 ILCS 570] and the Illinois Department of Professional Regulation (IDPR) requirements.

SCOPE

Anyone who manufactures, distributes, dispenses, imports, exports, conducts research, or performs chemical analysis with a controlled substance must be in compliance with DEA and IDPR regulations. Possession of controlled substances at UIUC is limited to the DEA registrant, authorized agents, and authorized users. All authorized agents and users operate under the supervision of a registrant in accordance with the license and follow all federal, state, and University requirements. Failure to comply with the requirements of this program may result in disciplinary action, research termination, or reports to the DEA field office and IDPR.

Permitted Use: DEA registrants, authorized agents, and authorized users are only permitted to use controlled substances for approved research activities.

DEFINITIONS

Schedules: Five categories, also known as schedules, are defined by the DEA and the State of Illinois. Controlled substances are assigned to one of the five categories. The federal and state lists of drugs in each schedule are identical except for a few drugs. If there is a discrepancy between the state and federal controlled substance list, the more restrictive schedule will apply (e.g., Schedule II is more restrictive than Schedule III).

- Schedule I: Drugs or other substances that have no currently accepted medical use and a high potential for abuse. Examples of Schedule I substances are heroin, lysergic acid diethylamide (LSD), peyote, methaqualone, and 3,4-methylenedioxymethamphetamine ("Ecstasy").
- Schedule II/IIN: Drugs or other substances that have a high potential for abuse, currently have an accepted use in medical treatment in the United States or have a currently accepted medical use with severe restrictions. Abuse may lead to severe psychological or physical dependence. Examples of Schedule II substances are hydromorphone (Dilaudid®), methadone (Dolophine®), meperidine (Demerol®), oxycodone (OxyContin®, Percocet®), and fentanyl (Sublimaze®, Duragesic®) amobarbital, glutethimide, and pentobarbital. Schedule IIN stimulants include amphetamine (Dexedrine®, Adderall®), methamphetamine (Desoxy®), and methylphenidate (Ritalin®).
- Schedule III/IIIN: Drugs or other substances that have a lower potential for abuse than Schedule I or II drugs and have an accepted use in medical treatment in the United States. Abuse is associated with moderate or low potential for physical or psychological dependence. Examples of Schedule III (narcotics) substances are products containing not more than 90 milligrams of codeine per dosage unit (Tylenol with Codeine®), and buprenorphine (Suboxone®). Schedule IIIN (non-narcotics) includes benzphetamine (Didrex®), phendimetrazine, ketamine, and anabolic steroids such as Depo®-Testosterone.
- Schedule IV: Drugs or other substances that have a low potential for abuse relative to those listed in Schedule III and currently have an accepted medical use in the United States. Abuse may lead to limited physical or psychological dependence. Examples of Schedule IV substance are alprazolam (Xanax®), carisoprodol (Soma®), clonazepam (Klonopin®), clorazepate (Tranxene®), diazepam (Valium®), lorazepam (Ativan®), midazolam (Versed®), temazepam (Restoril®), and triazolam (Halcion®).
- Schedule V: Drugs or other substances that have an accepted medical use in the United States and contain limited quantities of certain narcotics. Abuse may lead to limited physical or psychological dependence relative

to those in Schedule IV. Examples of Schedule V substances are cough preparations containing not more than 200 milligrams of codeine per 100 milliliters or per 100 grams (Robitussin AC[®], Phenergan with Codeine[®]), and ezogabine.

DEA registrant: The responsible individual (Principal Investigator) who holds the state license and DEA registration. The individual is ultimately responsible for all activities that fall under the terms of their license and registration.

Authorized Agent: An individual affiliated with the University that has access to the secured location in addition to the ability to handle the controlled substance(s). An authorized agent is an individual who has the complete trust of the DEA registrant and is authorized by the registrant to oversee dispensing and control of the substances in the absence of the DEA registrant. To minimize drug diversion, this role should be limited to as few individuals as possible in a research group. An agent may order controlled substances on behalf of the registrant if they have power of attorney and follow procedures below.

Authorized User: An individual who can have the ability to handle controlled substances under a registrant's license but does not have physical access to the secured location containing the bulk quantities of controlled substances. The DEA registrant or authorized agent dispenses limited quantities of controlled substances to the authorized users for immediate use.

ROLES AND RESPONSIBILITIES

University Administration

University administration has the responsibility for providing support for the establishment of policies and programs that are in accordance with applicable requirements.

DEA Registrant

- Maintain current DEA registration and Illinois license.
- Register with the Division of Research Safety
- Follow federal, state, and University requirements for the possession, handling, purchasing, and disposal of controlled substances.
- Identify authorized individuals and participate in screening procedures with DRS and other units as required (e.g., Illinois Human Resources, Graduate College, local HR unit).
- Maintain an up-to-date list of all authorized users and agents operating under their registration and license.
- Train all authorized individuals on proper handling, storage and recordkeeping.
- Participate in annual monitoring visits conducted by the Division of Research Safety. Respond to any identified deficiencies immediately.
- Dispose of or destroy controlled substances in an appropriate manner with the aid of DRS or the DEA field office when necessary.
- Maintain accurate inventory of controlled substances. Conduct an annual inventory that is submitted to DRS. Update use record for each container.
- Participate in any investigation into theft or loss of a controlled substance led by DRS, Public Safety, or the DEA field office.
- Notify DRS, the DEA field office, and Illinois Department of Professional Regulation upon discovery or report of theft or loss of a controlled substance.
- Submit DEA Form 106 if it is determined that theft or significant loss of a controlled substance has occurred.
- Maintain records and documentation required by this program for the required amount of time.
- Maintain up-to-date training for the use of controlled substances.

Authorized Agent

- Maintain up-to-date training for the use of controlled substances.
- Follow federal, state, and University requirements for the possession, handling, purchasing, and disposal of controlled substances.

- Maintain inventory and usage logs for controlled substances.
- Work under the direction of the DEA registrant.
- Maintain security of storage location. Obtain materials for authorized users, if necessary.
- Immediately report any missing controlled substances or suspicion of diversion to DRS and the registrant.

Authorized User

- The authorized user does not have access to the storage location of the controlled substances.
- Maintain up-to-date training for the use of controlled substances.
- Follow federal, state, and University requirements for the possession, handling, purchasing, and disposal of controlled substances.
- Maintain inventory for controlled substances.
- Work under the direction of the DEA registrant.
- Immediately report any missing controlled substances or suspicion of diversion to DRS and the registrant.

Division of Research Safety

- Maintains the written program.
- Communicates to registrants and authorized users if requirements or policies change.
- Provides guidance on storage and disposal of controlled substances.
- Provides guidance for registration with federal and state agencies.
- Coordinates annual inventory process.
- Provides awareness information and online training on the controlled substance program and requirements.
- Participates in investigations into possible theft or missing controlled substances.
- Maintains list of all active DEA registrants in research.
- Performs periodic monitoring checks of DEA registrant's records and procedures.

Human Resources

Review authorized individual applications, process background checks and maintain records according to the authorized individual application process. Communicate with DRS and the registrant when individuals are cleared to be authorized users or agents.

Public Safety

Respond to reported thefts or missing controlled substances. Work with the registrant, DRS, and other law enforcement or regulators as necessary in the investigation.

REGISTRATION

License and Registration: Investigators must obtain a state license through Illinois Department of Financial Professional Regulation and DEA registration before any controlled substance enters their possession. The license and registration must remain current. The listed address must match where the controlled substance is stored, including room number. All registrants must be registered and enrolled in the DEA Controlled Substance Surveillance Program with the Division of Research Safety before they are authorized to purchase or begin using controlled substances at the University.

- Illinois license is obtained first by filling out the application [IDFPR 097](#)
- Next, register with the Federal Drug Enforcement Administration (DEA) using the appropriate form for your activity.

New faculty holding a federal DEA number and license in another state must apply for an Illinois controlled substance license in order to use their current DEA number in the state of Illinois and at the University of Illinois.

1. For activities related to **research** and **chemical analysis**, submit form [225](#). Use Form [225A](#) to renew an existing registration.

2. For **instructional activities** and for **dispensing controlled substances** as a practitioner (physicians, dentists, veterinarians, nurse practitioners, hospitals, and pharmacies), submit form [224](#). These activities are authorized only for schedules II through V. Use form [224A](#) to renew the registration.

Types of Licenses/Registrations: When filling out applications for Illinois license and DEA registration, you will need to select the appropriate choice for the type of research you are performing. There are two options that will cover most research applications.

1. **Research:** For use in vivo and in vitro. Need to list drugs on application.
 - a. Researcher Schedule I: allows use of ONLY schedule I controlled drugs. May administer to animals and/or used in vitro.
 - b. Researcher Schedules II-V: allows use of only schedule II-V controlled drugs. May administer to animals and/or use in vitro.
2. **Chemical Analysis (Analytical Laboratory):** license and registration allow use of schedule I-V controlled drugs. In vitro use only. Cannot administer to animals. Do not need to specify exact drugs in application.

Fee exemption: DEA registrations and state licenses at UIUC used for university business are fee exempt. Registrant should attach/enclose a letter, printed on official University letterhead, stating their affiliation with the University and their research purpose, and signed by their department head.

License/registration renewal: The DEA registrant is responsible for maintaining a current DEA registration and Illinois license. They must be renewed as necessary. Renewal for the DEA is annual, and every two years for the state of Illinois.

Change of Address: If a fee-exempt license is being maintained, and only a change of address is needed, the licensee should contact the Licensure Maintenance Unit (LMU) directly at FPR.LMU@illinois.gov.

Termination of license/registration: When an appointment is ending at the University, registrant must contact the State of Illinois (IDFPR) and DEA (Springfield Resident Office) to cancel their university State of Illinois controlled substance license and DEA registration. The registrant is responsible for notifying IDFPR and DEA of their license status change. The registrant has 10 days to make the necessary changes including end of business or professional practice, name change, or address change on the license. The termination process includes the following steps:

1. Notification should take the form of a letter from the registrant stating that:
 - a. They want to cancel/terminate the State of Illinois Controlled Substance license and DEA registration. The licensee/registrant should provide all identifiers (name, date, and address) and the license number.
 - b. The final date of employment or research at the university.
 - c. The letter should also indicate the disposition of all controlled substances in their possession (i.e., returned, fully used, or destroyed via a form 41). If no controlled substances were in the registrant's possession, then this should be stated.
2. The notification letter should be emailed to the State of Illinois, IDFPR Drug Compliance Unit at FPR.DrugComplianceUnit@illinois.gov, faxed to the DEA Springfield Resident Office at 571-362-1878 and copied to the Controlled Substance Surveillance Program Manager (DRS).

Emeritus professors may keep their university-associated licenses if continuing work requiring the license at the University, and they must report the accurate address for where controlled substances are legally stored/used.

Register with Division of Research Safety

Complete a registration with DRS for the location specified on your license. This is the location where the controlled substances are secured in an appropriate locked cabinet or refrigerator. This can be a laboratory, office, or other location deemed secure by the registrant. If a registrant has multiple registrations, each location must be registered with DRS. Email drs@illinois.edu to begin your DRS registration.

AUTHORIZATION REQUIREMENTS

Screening of individuals with access to controlled substances is critical in preventing the diversion of these materials at UIUC. The DEA recommends that registrants should not employ individuals who will have access to controlled substances if:

1. The individual has been convicted of a felony offense related to controlled substances.
2. The individual has been denied a DEA registration.
3. The individual has had a DEA registration revoked.
4. The individual has surrendered a DEA registration for cause.

The University has developed a screening process for individuals who wish to use controlled substances under the direction of a DEA registrant. All employees (faculty, staff, graduate students, postdocs, etc.) who wish to use controlled substances under a DEA registrant must complete the screening process in collaboration with the registrant, DRS, and either IHR or the Graduate College before they are allowed access. Any undergraduate student wishing to use controlled substances must complete the screening process in collaboration with the registrant, DRS, and Student Financial Aid.

Authorized Personnel are separated into two tiers:

Authorized Agents have access to the secured location in addition to the ability to handle the controlled substance. An authorized agent is an individual who has the complete trust of the DEA registrant and is authorized by the registrant to oversee dispensing and control of the substances in the absence of the DEA registrant. Only the authorized agent has access to the license number. To minimize drug diversion, keep the number of authorized agents to a minimum. An agent with power of attorney can order controlled substances if following the ordering guidelines stated below.

Authorized Users are individuals who have the ability to handle controlled substances under a registrant's license, but do not have physical access to the secured location containing the bulk quantities of controlled substances. The DEA registrant or authorized agent dispenses limited quantities of controlled substances to the authorized users for immediate use. All handling of controlled substances is conducted under direct supervision of the registrant or agent.

Record keeping of authorized individuals

All registrants must maintain an accurate list of authorized individuals (agents and users) operating within the limits of their registration/license. This list must be kept current at all times. DRS will review the records annually. This list must be updated as individuals come and go both locally and in the DRS registration database.

Reporting change in status

Any change in status that may affect eligibility to handle or have access to controlled substances must be reported immediately to the registrant and DRS. A new Screening Questionnaire to determine eligibility must be completed.

Screening process

Authorized agents are required to have a criminal background check on file and complete the screening questionnaire form (Appendix B). Authorized users are required to only complete the screening questionnaire form. Illinois HR and the registrant (PI) will maintain records of the results of the screening and communicate to DRS the outcome.

TRAINING REQUIREMENTS

All registrants, authorized agents, and authorized users are required to take the online "Controlled Substance Use in Research" training. This training is renewed every three years. Additional specific training must be provided by the registrant to all authorized agents and users detailing the terms of the license and additional group-specific procedures/policies. An established authorized agent may be delegated by the registrant to perform this training.

Significant changes to the training due to program or law changes may require individuals to refresh the training prior to the three-year expiration.

Any individual not demonstrating proficiency in the requirements of this program or regulations may be required to repeat training.

ORDERING AND RECEIVING

Schedule I controlled substances must be ordered through the DEA's [Controlled Substance Ordering System](#). Schedule II-V controlled substances may be ordered via an established list of approved vendors.

The following vendors have established accounts with the University and should be used for all purchases of controlled substances.

- Covetrus
- MWI Veterinary Supplies
- Patterson Veterinary Supplies
- Sigma Aldrich

Exceptions to this policy may be granted in rare cases, where the following guidelines apply in establishing accounts with vendors who supply controlled substances.

- Contact UIUC Purchasing to establish a purchasing contract or to identify an existing contract to use with a commercial supplier.
- P-cards cannot be used to order controlled substances.
- Only vendors with distribution licenses may be used to purchase controlled substances.

ORDERING

The individual who orders the drugs must be the DEA registrant or an authorized agent who has been granted power of attorney. These are the only individuals with access to the license number.

Prior to an order for controlled substances being placed to a vendor, the individuals with power of attorney must send an email to the DEA registrant notifying them which controlled substance(s) will be ordered, the vendor, and the quantity requested. The order can be placed after the DEA registrant replies with their approval.

RECEIVING

The authorized agent or DEA registrant must sign and date invoices/packing slips upon receipt.

If receiving a schedule I or II controlled substance, the [DEA Form 222](#) order form must be completed in addition to steps below.

1. An authorized agent or registrant and a witness must be present in order to receive controlled substances.
2. Pull out and count the drugs on the invoice and/or packing slip.
3. Record date, invoice number, bottle or box number, lot number, expiry date, transferred from opened to unopened, balance, and initials.
4. Invoices and/or packing slips must match the order and they need to be attached to the order by double stapling.
5. The authorized agent and the witness must review, print, sign, and date the invoice and/or packing slip.
6. Create a controlled substance record for each bottle.
 1. Assign a number to each bottle of controlled substance.
 2. Weigh the bottle and record the initial weight in the controlled substance record.
7. Keep original invoices and packing slips on site. Make a copy of each invoice and packing slip to place in the readily retrievable file.

USE, STORAGE, and SECURITY

Use

Controlled substances may be used for research purposes. Use must be registered with the Division of Research Safety.

Storage and Security

Controlled substances must be kept in a securely locked, sturdy cabinet or safe that is secured to a wall or otherwise not removable. A locked refrigerator or freezer is acceptable for materials required to be stored at low temperatures. The location of this locked storage must match the location listed on the license.

Keys to the secured location must be kept in the possession of the registrant or authorized agents. Anyone with access to the keys or combination for controlled substance storage is considered an “authorized agent” and must be screened as indicated above.

Reporting loss/theft

If there is a theft or loss of controlled substances, report immediately to the DRS Controlled Substance Surveillance Manager. The DEA Field Division Office must be notified in writing within one business day of discovery and the registrant must also submit a [DEA Form 106](#) to the Field Division Office. Please refer to the current rules regarding reporting [here](#). Additionally, a copy of the DEA Form 106 must be sent to the Illinois Department of Financial and Professional Regulation Drug Compliance Unit within one day of notifying the DEA. Please refer to the current rules regarding submission to the Illinois Department of Financial and Professional Regulation Drug Compliance Unit [here](#).

Any theft or significant loss of unknown origin must be reported **immediately (upon discovery)** to the DRS Controlled Substance Surveillance Program Manager. DRS will include the necessary parties in the investigation. These may include authorized individuals, registrant, public safety, or the DEA field office.

In addition, report the following:

- a. All unresolved discrepancies in inventory relating to controlled substances;
- b. Possible significant loss or theft/diversion of controlled substances;
- c. Improper removal of controlled substances from UIUC premises;
- d. Any signs that a controlled substance may have been interfered or tampered with;
- e. Signs that a co-worker may be impaired due to self-administration of controlled substances;
- f. Discovery of misplaced or unsecured controlled substances; and
- g. Any other situations where policies and procedures relating to controlled substances may not have been followed.

Abandoned materials

Under no circumstances are controlled substances to be abandoned by a DEA registrant. If a registrant leaves the University without properly disposing of unused controlled substances, contact DRS for disposal instructions. If the researcher was not registered with the DEA and/or the controlled substance(s) was acquired prior to registration requirements (pre-1970 for many substances), the department must contact the DRS for disposal instructions.

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

INVENTORY

Every registrant shall conduct an annual inventory that includes an inventory with an actual count of the inventory on hand for all Schedule I and II controlled substances and an approximate inventory for all Schedule III, IV and V controlled substances. The inventory shall be maintained for a period of not less than 2 years.

Inventory/Usage logs: All controlled substances must be tracked by container and properly inventoried. This includes concentrated or diluted material.

- a. Annual/Biennial Inventory template or similar must be used to fulfill the requirements for both annual inventory (State of Illinois) and biennial inventory (DEA). See Appendix C

- b. A usage log is to be created for each container. This tracks the containers and the amount dispensed from the container. This is updated as the material is used. If a stock material is diluted in a secondary container, create a usage log for the secondary container. See Appendix D

Both the usage logs and master inventory must be kept in the locked box with the containers.

Inventory Transfer

Please note that it is a felony to provide a controlled substance to a person who is not registered with the DEA. Transfers of controlled substances can occur only between two DEA registrants. Transfers of schedule I or II controlled substances must be accompanied by a DEA Form 222 completed by the registrant receiving the substance(s).

A DEA registrant may transfer controlled substances to another DEA registrant under the following conditions:

- a. The controlled substances are being transferred to another DEA registrant with a license in good standing with an address that accurately reflects the intended storage location.
- b. The total amount of drug transferred to another registrant must not exceed 5% of the total amount ordered by the registrant supplying the drug during that calendar year.
- c. All required documentation is completed and maintained in accordance with UIUC policies and legal requirements.

Before transferring a controlled substance, inform DRS about the change in ownership. DRS may request documentation that the volume being transferred, in addition to all other transfers during that calendar year, is less than 5% of the total amount of controlled substances ordered that year.

The procedure for transferring controlled substances from one DEA registrant to another is:

- a. CI-II controlled substances: The person receiving the drug initiates a DEA Form 222 as the purchaser. The supplier will complete their portion. All sections of Form 222 must be completed accurately with no cross outs. Each party must maintain the required copies of Form 222 for at least 2 years. A copy must also be emailed to the DEA, based on the directions included on the form.
- b. CIII-V controlled substances: An invoice must be generated that clearly indicates the name, DEA license number, and licensed address of both the supplier and the purchaser. If the drug is not being paid for, then a price of \$0 should be indicated on the invoice. The invoice also needs to indicate the drug, strength, dosage form, and volume being transferred and the date of the transfer. Both the supplier and the purchaser need to sign the invoice. This invoice must be maintained for at least 2 years.
- c. When transferring controlled substances, the supplier must ensure that the volume is removed from their inventory with a line entry indicating the details of the transfer. The purchaser must ensure the volume is added to their inventory with a line entry indicating the details of the transfer.

DISPOSAL/WASTING

All unused controlled substances must be disposed of in a way that renders them non-retrievable. Options include use of a reverse distributor or a chemical digestion system. Only registrants and authorized agents can perform destruction of excess controlled substances.

Definitions

- Wasting: Destruction of a substance that was removed for a specific patient/animal/purpose but not administered. For example, a dose of a controlled substance for sedation was prepared, but only half of it was administered. The remainder would be wasted. In this case, the substance would have already been subtracted from the running inventory.
- Disposal: Destruction of a substance that is still contained in a stock bottle (either partial bottle/vial or still sealed). In this case, the amount disposed of must be documented as disposed and subtracted from the running inventory.

Disposal Methods

A reverse distributor is a company that is licensed to act in this manner and is contracted with the University to pick up and appropriately dispose of controlled substance waste.

A chemical digestion system is a product that contains a substance to inactivate controlled substances. Examples include RX Destroyer and Cactus Smart Sink. The system used must be appropriate for the formulations being disposed of. If solid dosage forms (e.g., tablets, patches, capsules, powders, etc.) will be disposed of, the digestion system must be intended for non-liquid dosage forms.

Note: Placing a syringe containing a measurable amount of a controlled substance or dumping the controlled substance into a sharps or DRS drug waste container is NOT an acceptable method of disposal.

Documentation

Documentation of all controlled substance disposal must be maintained for at least 2 years.

For spillage, breakage, or other damage to controlled substances where recovery is possible, substances must be promptly destroyed using an on-site method of destruction, sent to a reverse distributor, or registrant should contact the local DEA Diversion Field Office to request assistance. A record of the destruction should be logged and signed by two individuals.

For spillage or breakage where the controlled substance is not recoverable, the registrant should document the circumstances of the event in their records. This should be recorded on a DEA Form 41 and should be logged and signed by two individuals.

- Waste Log: If a controlled substance is being wasted, a waste log should be utilized which documents the date, identification of the patient/animal for which the substance was intended, substance name and concentration, amount being wasted, and signature/initials of the person wasting it and a witness.
- DEA Form 41: If a controlled substance is being disposed of a DEA Form 41 must be completed.

RECORDKEEPING

Researchers must maintain complete and accurate records on a current basis for each controlled substance manufactured, imported, purchased, received, stored, delivered, distributed, dispensed, or otherwise disposed of. All controlled substance records must be maintained for two years from the end of use or disposal. These must be maintained by the registrant at the registered address in a readily retrievable manner.

Required Records

The following records must be maintained:

- Executed official order forms (DEA Form 222) or the electronic equivalent
- Unexecuted official order forms (DEA Form 222)
- Power of Attorney authorization to sign order forms, if applicable
- Receipts and/or invoices for schedules III, IV, and V controlled substances
- Records of controlled substances distributed (i.e., sales to other registrants, returns to vendors, distributions to reverse distributors)
- Records of dispensing
- All inventory records of controlled substances
- Reports of Theft or Significant Loss (DEA Form 106), if applicable
- Inventory of drugs wasted (Waste log)
- Inventory of drugs disposed (DEA Form 41)
- Documentation of training provided to authorized agents and users.
- Employee screening questionnaires

Required records must contain the information listed below for each controlled substance:

- Name of substance
- Each finished form (e.g., 10-milligram tablet) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle)
- Number of units of finished forms and/or commercial containers acquired from other persons, including date of and number of units and/or commercial containers in each acquisition to inventory and the name, address, and registration number of the supplier.

- The number of commercial containers distributed to other persons, including the date of and number of containers in each reduction from inventory, and the name, address, and registration number of the person to whom the containers were distributed.
- The number of units of finished forms and/or commercial containers distributed or disposed of in any other manner by the researcher, including the date and manner of distribution or disposal, the name, address, and registration number of the person to whom distributed, and the quantity in finished form distributed or disposed.
- In addition, dispensers using a dispensing log must record the number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser.

Records for CI-II substances must be maintained separately from records for CIII – V substances.

MONITORING VISITS

All registrants enrolled in the DRS Controlled Substance Surveillance Program must participate in an annual monitoring visit conducted by the Surveillance Program Manager. This visit will be conducted at the location listed on the license and all records will be reviewed for accuracy. The visit will be summarized in a formal report from DRS. Any areas for improvement will be documented and responses by the registrant must be completed within two weeks of receiving the report. Additional monitoring visits can be requested by the registrant or required at the discretion of the program manager, department head, Dean, or Vice Chancellor for Research and Innovation.

APPENDIX A

Regulatory Differences for ACP Clinical Veterinarians

- Practitioners must renew their DEA registration every 3 years.
- Register with form 224, renew with form 224a.
- The DEA Administrator may extend an expired registration if no decision has been made on a submitted renewal.
- DEA allows reinstatement of an expired registration if the renewal form is submitted within a calendar month of the expiration date of a current registration.

APPENDIX B

QUESTIONNAIRE FOR EMPLOYEES OR STUDENTS WHO WILL HAVE ACCESS TO SUBSTANCES REGULATED BY THE DRUG ENFORCEMENT ADMINISTRATION OF THE UNITED STATES OF AMERICA

UNIVERSITY OF ILLINOIS AT URBANA-CHAMPAIGN

The Drug Enforcement Administration requires that any person who will have access to controlled substances as a result of his or her status as authorized personnel of a DEA registrant at the University of Illinois at Urbana-Champaign answer the following questions during the screening process to determine if they are eligible to access controlled substances. Any false information or omission of information may jeopardize your position with respect to the University. Information revealed by this questionnaire will not necessarily preclude employment or educational status but will be considered as part of an overall evaluation of your qualifications. The responses on this questionnaire will be held in the strictest confidence. Any changes to your status during the course of your employment must be reported to the DEA registrant and Illinois Human Resources. Completed forms must remain in a secure location by the registrant and a copy submitted to Illinois Human Resources.

1. In the past five years, have you been convicted of a felony, or within the past two years of any misdemeanor or are you presently charged with committing a criminal offense? (Do not include traffic violations, juvenile offenses or military convictions, except by general court-martial.)

Yes No

If the answer is yes, furnish details of convictions, offense, location, date, and sentence.

2. In the past three years, have you ever knowingly used any narcotics, amphetamines or barbiturates, other than those prescribed to you by a physician?

Yes No

If the answer is yes, furnish details.

3. Have you ever surrendered a controlled substance registration or had a controlled substance registration revoked, suspended or denied?

Yes No

If the answer is yes, furnish details.

I authorize the University of Illinois to make inquiries of courts and law enforcement agencies for possible pending charges or convictions. I further authorize such courts, law enforcement agencies, and their respective employees, officers, or agents, to release to University of Illinois and its employees, officers, or agents any and all records or information in their control or possession regarding me and any possible pending charges or convictions. If I have knowledge of drug diversion at the University of Illinois, I agree that it is my obligation to report such information to the DEA registrant, the Division of Research Safety, or University of Illinois Public Safety.

Signature

Date:

Printed Name

Licensee/Registrant Signature: _____ Date: _____

Licensee/Registrant Printed Name: _____

Note: A copy of this completed form must be retained in the Registrant's Controlled Substance Record for at least two years following the cessation of controlled substance activities.

APPENDIX C



Annual Controlled Substance Inventory Form

The State of Illinois requires a physical inventory be conducted annually for each registered location. The DEA requires a physical inventory be conducted every two years. Completing this will satisfy both requirements. The inventory Form must be kept at least for an additional two years at the registered site after completion.

Reference: 21 CFR 1304.04; 21 CFR 1304.11 Inventory Requirements

| Date: | | | | Opening <input style="width: 40px;" type="text"/> | Closing <input style="width: 40px;" type="text"/> | of Business | |
|---------------------------------|--------------|--------------------------|--|---|---|-------------|--------------|
| Registrant Name: | | | | | | | |
| Registrant Address: | | | | | | | |
| DEA Registration Number: | | | | | | | |
| Controlled Substance Name | DEA Schedule | Strength and Dosage Form | # of units or volume of each finished form per container | # of containers in use | # of containers awaiting disposal | Total | |
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| Inventory Performed By: | | | | Signature: | | | Date: |
| Witness: | | | | Signature: | | | Date: |



APPENDIX D

DEA Controlled Substance Usage Log

For the use of controlled substances in research

DEA Registrant (Print Name): _____ DEA Registration Number: _____

Name of Substance and Schedule #: _____ Unique Container Number: _____

Amount Received: _____ Date Received: _____ Expiration Date: _____ Concentration: _____

Form: Solid Liquid Tablet

| Date of Use | Species | ID Number | Procedure | Amount Withdrawn (mL, mg, etc.) | Balance (mL, mg, etc.) | Person Administering Print Name and Initial | Witness Print Name and Initial |
|-------------|---------|-----------|-----------|---------------------------------|------------------------|--|-----------------------------------|
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For questions, contact Controlled Substance Surveillance Program Manager at DRS-drugcompliance@illinois.edu.