Controlled Substance Guideline
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1.0 Objective
This laboratory guideline for "Managing Controlled Substances in Research Laboratories (CSG)" has been prepared to assist the University of Iowa researchers in properly managing the purchase, storage, use, and disposal of controlled substances used in their research.

2.0 Regulations
- The Controlled Substances Act, Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, regulates the manufacture and distribution of narcotics, stimulants, depressants, hallucinogens, anabolic steroids, and chemicals used in the production of controlled substances.
- State of Iowa Administrative Code, Chapter 657; and Iowa Controlled Substances ACT (CSA), Chapter IC124.

3.0 Applicability
Controlled substances must be used only in research locations and situations described in the registrant's DEA and IBPE registrations. The researcher must address specific aspects of controlled substance utilization as stated in the research project justification.

Typical examples of research situations where controlled substances are used include: (a) animal anesthesia, analgesia, restraint, or experimentation; (b) analysis including quantitation and/or characterization; and (c) synthetic chemistry involving development of new drugs.

This guidance document on controlled substances management includes: (a) registration; (b) purchasing; (c) storage and security; (d) dispensation and disposal; (e) dispensation and disposal records; (f) inventory and self-audit; and (g) retention of documentation.

4.0 Responsibilities
Each Principal Investigator (PI, defined as a “Researcher” on the DEA registration application) who is authorized to use controlled substances is responsible for understanding and complying with all applicable rules and regulations of the Federal Drug Enforcement Administration (DEA) and the State of Iowa - Iowa Board of Pharmacy Examiners (IBPE) regarding registration, purchase, use, and proper disposal of controlled substances used in his/her research work. The PI is responsible and liable for any loss, theft, or misuse of any controlled substance acquired through his/her registration.
A Researcher must purchase controlled substances using his/her Federal DEA registration number through DEA/IBPE approved distributors.

The use of controlled substances is approved for individual researchers and only for the research location(s) described in his/her DEA application. Therefore, researchers must not distribute, transfer, or share the controlled substances to non-licensed researchers or other PIs. To do otherwise is considered a diversion of controlled substances and is against the IBPE/DEA rules and regulations. Each PI who needs to use controlled substances in his/her research is required to register with the IBPE and DEA for a specific research location.

Researchers must maintain proper registration and documentation for the control of controlled substances by tracking the purchase, daily use, and disposal by maintaining specific records (see forms Authorized Users Signature Log & Disposal in a DEA Registrant’s Location).

Authorized laboratory personnel (also known as authorized daily users) must perform research activities under the supervision of the registered PI or his/her authorized agent. The authorized personnel must complete the daily use forms accurately and return the unused chemicals and partially used vials to the PI or his/her authorized agent at the end of the day for proper secured storage.

Used, expired, unwanted, or partially consumed controlled substances container(s) must be disposed of through EHS.

Controlled substance waste (used, expired, partially consumed, and generated from synthetic or analytical processes) is regulated by DEA. Researchers must treat the controlled substance waste separately and not treat them as a hazardous waste, biological waste or regulated medical waste. The researcher who wants to dispose of controlled substances that are mixed with hazardous chemical waste must consult with EHS to ensure compliance with RCRA regulations.

Researchers may contact EHS for answers to specific questions related to the registration, purchase, storage and security, and disposal of controlled substances.

**5.0 Definitions/Abbreviations**

**An Authorized Agent** is an individual who has the complete trust of a DEA registrant (licensed researcher). An authorized agent with the authorization of licensed researcher may oversee the ordering and dispensing, in addition to managing the controlled substances in the absence of the licensed researcher. To minimize the risk of drug diversion, only 1-2 individuals in a laboratory should be provided the status of an authorized agent. Licensed researchers are ultimately responsible for the management of controlled substances acquired under their DEA registration or license. Only licensed researchers and respective authorized agents may have keys or combination access to the safe or locked cabinet where controlled substances are stored. Only authorized agents are permitted to know the licensed researcher's respective registration number and order controlled substances on behalf of her/him. Authorized agents do not require a DEA background check or screening. The DEA does not specify how licensed researchers should...
conducted due diligence credential checks for their staff. Therefore, each licensed researcher is responsible for checking their staff’s credentials, authorizing specific roles, and providing required training for proper handling of controlled substances.

**Authorized Laboratory Personnel** are research staff, including graduate students and postdoctoral scholars, working under the direct supervision of a researcher. In addition to the researcher and authorized agents, the authorized laboratory personnel (also known as daily users) may participate in using controlled substances during experiments or treatments of research animals. Authorized laboratory personnel can perform these functions but only without keys or combination access to the safe or cabinet where bulk quantities of controlled substances are stored. Licensed researchers or their authorized agent are responsible for dispensing limited quantities of controlled substances to authorized laboratory personnel for daily use and maintaining unused substances in the safe or locked cabinet for proper storage. Authorized laboratory personnel do not require a DEA background check or screening. Each licensed researcher is responsible for authorizing specific roles, and providing required training for proper handling of controlled substances.

**Certificate of Registration:** DEA Certificate of Registration (DEA Form 223) must be maintained and displayed at the registered location in a readily retrievable manner and must be available for DEA/IBPE inspection. An example of DEA Form 223 is shown below.

**CONTROLLED SUBSTANCES REGISTRATION CERTIFICATE**

**UNITED STATES DEPARTMENT OF JUSTICE**

**DRUG ENFORCEMENT ADMINISTRATION**

**WASHINGTON, D.C. 20537**

The Controlled Substance Act of 1970 made it unlawful to possess, distribute, or dispense a controlled substance without the proper authorization and registration. The certificate must be maintained and displayed at the registered location in a readily retrievable manner and must be available for DEA/IBPE inspection.

**DEA REGISTRATION NUMBER:** AB1234567  
**THIS REGISTRATION EXPIRES:** MMM/DD/YYYY  
**FEE PAID:** $XX.XX

**SCHEDULES:** 1, 2, 3, 3N, 4, 5  
**BUSINESS ACTIVITY:** RESEARCHER  
**DATE ISSUED:** MMM/DD/YYYY

**YOUR INSTITUTION**  
1 MAIN STREET  
TOWN, STATE XXXXX

**THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION OR BUSINESS ACTIVITY**

**Controlled substances:** controlled substances are defined as chemicals that are addictive, can be abused, and are illegal to possess. Therefore, the manufacture, possession, use and proper disposal of controlled substances (drugs or other drug products) are regulated by DEA. A complete listing of controlled substances may be viewed on the DEA website. The same information can also be found in the DEA orange book.
**Controlled substance folder**: the file or folder where transactions of controlled substances (e.g., receipt, use, and disposal) are recorded. Examples of typical internal forms are included in Appendix B.

**CSA**: the Controlled Substances Act (CSA), Title II and Title III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, is the legal foundation of the U.S. Government’s fight against the abuse of drugs and other substances. This law is a consolidation of numerous laws regulating the manufacture and distribution of narcotics, stimulants, depressants, hallucinogens, anabolic steroids, and chemicals used in the illicit production of controlled substances. Also, CSA is the abbreviation for Controlled Substances Act Iowa Code chapter IC124.

**Disposal**: the approved method of discarding a controlled substance that is outdated, redundant, contaminated, is waste, or is no longer needed.

**Disposition records**: an accurate, continuous and current record used to track the purchase, use and disposal of controlled substances.

**Drug Enforcement Administration (DEA)**: the unit within the United States Department of Justice that establishes and enforces the regulations for the handling and use of controlled substances.

**IBPE**: Iowa Board of Pharmacy Examiners (IBPE) authorized by the State of Iowa Administrative Code 657 to administer the controlled substances Program. The IBPE requires initial application and biennial renewal application for registration of any person engaging in animal-based research, teaching or educational projects involving the use, study or testing of controlled substances.

**Licenses**: There are 11 classes of licenses (registrations). The most significant classes for registration as researcher are highlighted below.

<table>
<thead>
<tr>
<th>License Class</th>
<th>License Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class 1:</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>Class 1a:</td>
<td>Manufacturer (Out-of-State)</td>
</tr>
<tr>
<td>Class 2:</td>
<td>Distributor</td>
</tr>
<tr>
<td>Class 2a:</td>
<td>Distributor (Out-of-State)</td>
</tr>
<tr>
<td>Class 3:</td>
<td>Institutional Dispenser</td>
</tr>
<tr>
<td>Class 3a:</td>
<td>Institutional Dispenser Limited</td>
</tr>
<tr>
<td>Class 4:</td>
<td>Researcher (Schedules II-V) (Individual and Institutional)</td>
</tr>
<tr>
<td>Class 5:</td>
<td>Instructional Activities (Schedules II-V)</td>
</tr>
<tr>
<td>Class 7:</td>
<td>Research and Instructional Activities (Schedule I) (Individual and Institutional)</td>
</tr>
<tr>
<td>Class 8:</td>
<td>Analytical Laboratory</td>
</tr>
<tr>
<td>Class 9:</td>
<td>Importer</td>
</tr>
<tr>
<td>Class 9a:</td>
<td>Importer Broker</td>
</tr>
<tr>
<td>Class 10:</td>
<td>Exporter</td>
</tr>
<tr>
<td>Class 10a:</td>
<td>Exporter Broker</td>
</tr>
<tr>
<td>Class 11:</td>
<td>Pharmacy - Automated Dispensing System</td>
</tr>
</tbody>
</table>
Practitioner: any individual that is registered with DEA and IBPE to practice or perform research, distribute, dispense, conduct research with respect to administering, use in teaching, or for chemical analysis of controlled substances. If a clinical practitioner wishes to do research, he/she will need to obtain a researcher license using the DEA Form 225.

Reverse Distributors: reverse distributors (third party companies) are registered with DEA as registrants. They are authorized to receive out-of-date, damaged, or otherwise unusable or unwanted controlled substances, including unwanted bulk controlled substance samples from registered researchers. The reverse distributors dispose of controlled substances using appropriate procedures with the approval from DEA.

Registration: the formal grant of specific authority to a researcher (certificate or license) by DEA and IBPE. Researchers must “register” with DEA and IBPE for purchase and possession of controlled substances. Any researcher who handles or intends to handle controlled substances must obtain a registration issued by DEA. A unique number is assigned to each legitimate handler of controlled drugs: importer, exporter, manufacturer, distributor, hospital, pharmacy, practitioner, and researcher. This number must be made available to the supplier by the customer prior to the purchase of a controlled substance.

Registrant (see also licensed researcher): the individual that holds DEA and Iowa registrations and is responsible for ordering, storing, using, and disposing of controlled substances. This individual is fully responsible to ensure compliance with controlled substance regulations at the location where the controlled substances are held. Registrants are the only ones authorized to use controlled substances. Registrants may appoint a subordinate to manage the controlled substances and the records; however, the registrant is solely responsible for its proper recordkeeping, storage, and use. Deficiencies or discrepancies in recordkeeping are the responsibility of the registrant. Clinicians holding a clinical license must obtain a researcher license to perform non-clinical research using controlled substances.

Research: this covers any research activity (non-clinical research) that includes new product synthesis, methods development, testing, teaching, and use in animal care/procedures, etc.

(Licensed) Researcher: throughout this document, ‘licensed researcher’ refers only to the Principal Investigators (PIs) who possess a “Researcher” class license through the DEA and the IBPE.
6.0 Registration

- New applications Forms 224 and 225
- Renewal Applications Forms 224a and 225a
- IBPE Applications and Forms

Each researcher (PI) who intends to use DEA controlled substances in her/his research must obtain and maintain a concurrent registration with DEA and IBPE. Registration certificates must be obtained prior to the purchase of controlled substances. A DEA registration certificate allows the licensed researcher to use controlled substances as specified in the DEA issued certificate. The registration and licenses must be displayed in a prominent location where the controlled substances are stored and these documents must be readily available for inspection by DEA or IBPE.

**State of Iowa Registration:** The Iowa initial registration and renewal forms can be downloaded as a pdf file at the IBPE website. The reregistration is required no later than the expiration of the current registration.

- Note for new applicants using Iowa’s registration form: respond to question 6 (Federal DEA#) as “pending”, unless you already have a DEA registration number from another state; answer question 7 (Iowa Professional License#) to state ”N/A”, unless you have license, e.g. Pharmacist.
- Although the IBPE form does not state that you need to include a copy of your protocol that describes how you intend to use the controlled substance, you will avoid further delays by sending the protocol with your application and check.

The State of Iowa controlled substance registration is required prior to application for a DEA permit. You should anticipate that it may take several weeks for the State of Iowa application to be processed. Once the Iowa license is acquired, the DEA registration process can be initiated.

**DEA Registration:** the registration application for DEA must be completed online. The online application also allows the applicant to obtain an electronic receipt of the application as soon as it is complete. Researchers and analytical laboratories must complete DEA Form 225. Departments or units with instructional activities or practitioners must complete DEA Form 224.

Information concerning the DEA registration process can be obtained from the DEA field office, by contacting the Registration Call Center at 1-800-882-9539, or online at: [http://www.deadiversion.usdoj.gov/drugreg/process.htm](http://www.deadiversion.usdoj.gov/drugreg/process.htm). The DEA Call Center is staffed from 8:30 a.m. to 6:00 p.m., EST. During non-business hours, information is available through an automated Call Center Menu.

- When completing the online application, please note the following:
  - On the second screen, **UI Researchers are fee exempt.**
On the third screen you are asked to provide information regarding the 'certifying official'. That individual at the University of Iowa is **Susan Klatt, University Secretary**. Her phone no. is 319-335-3552. Email: susan-klatt@uiowa.edu

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### Requirements for handling controlled substances, per CSA, are summarized below.

- **DEA Order Form-222** (All requests for official order forms (DEA Form 222) can be made by registrants who are registered in Schedule I and/or II)

- **Theft or Loss of Controlled Substances - DEA Form 106** (Only those persons registered with DEA to handle controlled substances may utilize this form)

- **Theft or Loss of Controlled Substances - IBPE Form 106**

<table>
<thead>
<tr>
<th></th>
<th>Schedule I &amp; II</th>
<th>Schedule III &amp; IV</th>
<th>Schedule V</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Registration</strong></td>
<td>Required</td>
<td>Required</td>
<td>Required</td>
</tr>
<tr>
<td><strong>Ordering</strong></td>
<td>Licensed Researcher</td>
<td>Licensed Researcher</td>
<td>Licensed Researcher</td>
</tr>
<tr>
<td><strong>Purchasing and Receiving Records (Example forms in Appendix B)</strong></td>
<td>Order Forms (DEA Form-222)</td>
<td>Invoice</td>
<td>Sign and Date</td>
</tr>
<tr>
<td><strong>Daily Use</strong></td>
<td>Spiral or Bound Logbooks is Recommended</td>
<td>Spiral or Bound Logbooks is Recommended</td>
<td>Spiral or Bound Logbooks is Recommended</td>
</tr>
<tr>
<td><strong>Distribution Between Registrants</strong></td>
<td>Order Forms (DEA Form-222)</td>
<td>Invoices</td>
<td>Invoices</td>
</tr>
<tr>
<td><strong>Inventory</strong></td>
<td>Initially; and updated every 2 years</td>
<td>Initially; and updated every 2 years</td>
<td>Initially; and updated every 2 years</td>
</tr>
<tr>
<td><strong>Security</strong></td>
<td>Locked Drawer/Cabinet or Safe</td>
<td>Locked Drawer/Cabinet or Safe</td>
<td>Locked Drawer/Cabinet or Safe</td>
</tr>
<tr>
<td><strong>Theft or Significant Loss</strong></td>
<td>Report and Complete the DEA Form 106 and Iowa Form 106.</td>
<td>Report and complete DEA Form 106 and Iowa Form 106</td>
<td>Report and Complete DEA Form 106 and Iowa Form 106</td>
</tr>
<tr>
<td><strong>Disposal</strong></td>
<td>By EHS</td>
<td>By EHS</td>
<td>By EHS</td>
</tr>
<tr>
<td><strong>Disposal Records</strong></td>
<td>At least 2 years after disposal</td>
<td>At least 2 years after disposal</td>
<td>At least 2 years after disposal</td>
</tr>
</tbody>
</table>
7.0 Storage and Security

This document is to provide guidance to University of Iowa research personnel regarding the proper storage of small quantities of DEA controlled substances. DEA’s Office of Diversion Control website is: [http://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_72.htm](http://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_72.htm)

Although these guidelines were developed to be consistent with DEA guidelines, unique situations may cause DEA inspectors to require alternative storage solutions.

- **General storage rule**
  - All controlled substances must be stored behind at least two differently keyed locks at all times.
  - For keyed lockboxes
    - Do not store the keys near the lockbox; and
    - Do not store the keys together.
  - For combination lock lockboxes
    - Only the registrant and as few responsible individuals as possible should know the combination.
    - Whenever anyone who knows the combination is terminated from employment, the combination(s) must be changed.

- **Schedule I and II substances (e.g., Pentobarbital is a Schedule II drug)**
  - Must be stored in a safe or steel cabinet of substantial construction.
    - If the safe or cabinet is less than 750 lbs., it must be mounted or secured to something of substantial construction (e.g., bolted to a wall or the floor, or the base imbedded in concrete).
    - The safe/cabinet should have an inner and outer door with the locks for each door keyed differently.
    - Standard “narcotics cabinets” can be purchased through a variety of resources, e.g.:
      - Health Care logistics: [www.hcl-intl.com](http://www.hcl-intl.com)

- **Schedule III, IV, and V controlled substances (e.g., Ketamine and Buprenorphine, are Schedule III controlled substances)**
  - Should be stored using one of the following methods:
    - Preferred method: a wall mountable controlled substance lockbox with two doors and two locks (each lock is keyed differently).
    - A single-lock lockbox that is stored in a drawer or cabinet that is secured at all times with a hasp and padlock. The drawer and cabinet
should be substantially constructed such as in a drawer that is part of either a bench or cabinet that is mounted to the wall or floor.

- If a lab is not accessible to the public, then an option is to use a single-lock lockbox, stored in a drawer or cabinet in a room that is kept locked at all times.
- Schedule III, IV and V substances can also be stored with Schedule I and II substances.

- Cold storage for controlled substances
  - For storage at 4°C or colder, a single-lock lockbox in a refrigerator or freezer that can also be locked is permitted. The room must also be lockable, and locked after hours.

8.0 Background Check/Employee Screening

A background check is conducted by the DEA when an individual applies for a DEA registration. As such, a redundant screening by the University is not required. The DEA strongly advises all registrants and employers to assess and determine the likelihood of an employee committing a drug security breach. Further information on the screening process is available at: http://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_90.htm

For any questions related to security screenings for University employees, please contact the following University of Iowa administrative officers:

Wendy Loney, Senior HR Director, Research & Economic Development
Ian Arp, Deputy Counsel in the Office of the General Counsel; phone 335.0400.

Please contact the DEA field office in Des Moines if you have specific questions related to DEA registration process:

DES MOINES RESIDENT OFFICE
Federal Building, Room 937
210 Walnut Street
Des Moines, IA 50309
Phone Number: (515) 284-4709

9.0 Purchasing Controlled Substances

Purchases of controlled substances must follow the DEA rules and regulations: Orders for Schedule I and II controlled substances must be accompanied by DEA Form 222. These forms are available only through DEA.

See http://www.deadiversion.usdoj.gov/faq/dea222.htm. Upon completion of Form 222, the licensed researcher should submit copies 1 and 2 to the supplier and retain copy 3.
Note: Utmost care must be taken when filling out the Official Order Form 222. A Form 222 that shows any alteration, erasures or changes in description will be rejected (CFR 1305.15). The Licensed researcher must void any forms with corrections and keep them on file together with all DEA Form 222 records. All DEA Forms 222 must be accounted for; therefore, voided DEA forms must not be discarded.

Form 222 must not be used to purchase III-V Scheduled substances. An example of a properly completed DEA Form 222 can be viewed on the University of Michigan EHS website.

A Power of Attorney (POA) is needed when someone other than the registrant will sign an official order form.

- Registrants may authorize one of more individuals to obtain and execute a DEA Form 222 through the use of a POA. An example of a POA form is shown in Appendix B6. The POA must be signed by the individual who signed the most recent application (or renewal) for registration as well as the individual being authorized to obtain and execute a DEA Form 222.
- The POA may be revoked at any time by the person who granted and signed the POA.
- The POA should be filed with the executed DEA Form 222 as a readily retrievable record and is not submitted to the DEA.

A list of distributors can be downloaded from the DEA website. The list below is provided for planning purposes only.

<table>
<thead>
<tr>
<th>Burns Veterinary Supply</th>
<th>Fort Dodge Laboratories</th>
<th>JA Webster</th>
<th>Vortech Parmaceutical</th>
</tr>
</thead>
<tbody>
<tr>
<td>3400 West Lake Ave.</td>
<td>800 5th St., Northwest</td>
<td>86 Leominster Rd.</td>
<td>6851 Chase Road</td>
</tr>
<tr>
<td>Glenview, IL, 60025</td>
<td>Fort Dodge</td>
<td>Sterling</td>
<td>Dearborn</td>
</tr>
<tr>
<td>1-800-922-8767</td>
<td>IA 50501-0518</td>
<td>MA 01564-2198</td>
<td>MI 48126</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Butler Schein, Inc.</th>
<th>Butler Schein, Inc.</th>
<th>Sigma-Aldrich, Inc</th>
<th>Diamondback Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>135 Duryea Rd.</td>
<td>3820 Twin Creeks Dr.</td>
<td>3050 Spruce St.</td>
<td>7901 East McDowell Rd</td>
</tr>
<tr>
<td>Melville, NY 11747</td>
<td>Columbus, OH 43204</td>
<td>St. Louis, Mo 63103</td>
<td>Scottsdale, AZ 85257</td>
</tr>
<tr>
<td>1-800-483-8329</td>
<td>1-800-552-8387</td>
<td>1-800-325-3010</td>
<td>1-866-578-4420</td>
</tr>
</tbody>
</table>
10.0 Schedules of Controlled Substances

Drugs with addictive potential are divided into five categories (known as ‘Schedule’ and ‘class’) and are based on DEA's perception of their potential for abuse, history and current pattern of abuse, risk to public health, etc. A complete listing of controlled substances may be viewed on the DEA website: [http://www.deadiversion.usdoj.gov/21cfr/cfr/2108cfrt.htm](http://www.deadiversion.usdoj.gov/21cfr/cfr/2108cfrt.htm)

11.0 Disposal of Controlled Substances

The disposal of controlled substances is the final action necessary to ensure proper management of controlled substances.

As of April 2013, EHS has been approved by the DEA to dispose of controlled substances through the application of an approved procedure. Licensed researchers who want to dispose of controlled substances that are mixed with hazardous chemical waste must consult with EHS to ensure compliance with RCRA regulations.

Each licensed researcher is ultimately responsible to ensure controlled substances are properly disposed of and all necessary disposal forms are completed and submitted to the appropriate agency. To dispose of outdated, damaged, or otherwise unusable or unwanted controlled substances, contact EHS- Bill Murray at 5-4624.

The typical EHS procedure for disposal of expired/residual controlled substances (injectable solution) is summarized below:

- The laboratory notifies EHS that it has a controlled substance that needs disposal;
- An EHS representative will visit the lab prior to disposal;
- On the agreed upon date of disposal, EHS will bring a Controlled Substance Disposal Kit and provide directions on how to conduct the disposal;
- Disposal will be conducted by the Registrant or their duly appointed authorized employee and witnessed by an EHS employee;
- Disposal consists of blending an aqueous solution of the controlled substance within a container of kitty litter; and
- EHS will take possession of and dispose of the container of controlled substance/kitty litter blend.
12.0 Handling Abandoned/Orphaned Controlled Substances

“Orphan” DEA controlled substances: Occasionally, a controlled substance is found but the ‘owner’ is not known or has left the UI. The substances may have been purchased before they were classified as controlled substances, may have abandoned during the process of closing down a laboratory, or other extenuating circumstances. In these types of situations, the controlled substance is called an “Orphan” controlled substance. An official from the responsible department must take temporary possession of “orphan” controlled substances and work to ensure it is properly stored, prior to its destruction.

The department must contact EHS - Bill Murray, 335-4624 for proper destruction of the abandoned/orphaned controlled substances by providing the following information: (a) Registrant’s Name (if known); (b) DEA Registration number (if available); (c) location where the Orphan was found (lab number, building, and originating department); (d) name of the controlled substance; (e) controlled substance content in each individual container; (f) number of containers; and (g) size of each container.

13.0 Transportation

Controlled substances must be shipped to the licensed researcher’s address, as indicated in the DEA registration. Once received, the controlled substance should be opened to verify the contents and any discrepancies should be rectified with the supplier. If discrepancies cannot be rectified, DEA should be contacted.

From the time a controlled substance is accepted until it is consumed or disposed of, a disposition record (also known as the chain of custody) must be kept at each point where the substance changes hands or is used. The record is completed at each point by the person delivering the substance and includes the name of the substance, the quantity, and the signature of the person receiving it. The person making the withdrawal must document all records of withdrawals of controlled substances from storage (see form Controlled Substances Dispensed/Used Record).

Transferring controlled substances between laboratories in a licensed researcher’s location requires documentation for receiving controlled substances for daily use by the authorized daily user. The transport between laboratories of the registrant must be in a locked storage container (or safe) and transported by the registrant or authorized agent with appropriate dispensation/custody forms. However, researchers must not leave the controlled substances unattended. Unless a controlled substance is in the process of being used for research, it must be securely stored in a safe or vault. The authorized researcher is responsible for ensuring any transport is conducted in a secure manner to prevent any diversion. See SOP for Transporting Controlled Substances Through Public Spaces.
A non-clinical practitioner who also possesses a “Researcher” category license for a separate location must transfer and transport the controlled substances only after receiving the approval of DEA/IBPE, using appropriate DEA Form 222 or invoices (the same way it was purchased).

14.0 Recordkeeping
The controlled substances tracking requirements are available at [http://www.deadiversion.usdoj.gov/21cfr/cfr/1304/1304.22.htm](http://www.deadiversion.usdoj.gov/21cfr/cfr/1304/1304.22.htm).

Controlled Substances Log: a controlled substances log will be maintained at each location where controlled substances are stored. Dedicated notebooks are strongly recommended for maintaining records for all controlled substances. A separate page shall be maintained for each controlled substance. Inventories and records for Schedule I and II drugs must be kept separate from all other records maintained by the licensed researcher. Records for Schedule III-V drugs must be kept separate from all other records. Alternatively, a folder for controlled substances records can be created so they are easily and “readily retrievable” from other records.

Basic record keeping includes:
- Records of receipt
- Records of use (including loss or theft)
- Records of disposal of controlled substances
- Annual inventory (an example of an annual inventory form can be found in Appendix B7)

The following information will be kept in the receiving log:
- The date the substance was received at the storage location
- The substance name assigned by the manufacturer
- The manufacturer of the substance or vendor
- The quantity and strength of the substance added to the storage area
- Name of individual adding product to the inventory

Dispensing controlled substances: whenever drugs are dispensed either for teaching purposes, research or surrendered for disposal the following information must be logged.
- Date used or disposal of waste
- Quantity dispensed for aliquots, dilution
- Strength dispensed (concentration and volume)
- Name of person (authorized user)
- Quantity remaining in inventory

Labeling Containers: for controlled substances that are removed from their original packaging and compounded, diluted or combined, must be labeled with a new control number, the final concentration, the amount per container and the expiration date.
Inventory Audits: the licensed researcher must maintain a complete and accurate accounting of all controlled substances, from the time they are ordered until they are used up or disposed of.

- These inventories and records should be kept at the location where the licensed activity is conducted, and must be readily available for inspections.
- Chemical inventories of controlled substances are up-to-date and discrepancies reconciled at least annually.
- All records of inventories and logs of controlled substances shall be kept a minimum of two years and be available for inspections and for copying by a member of DEA or IBPE, if requested.
- The licensed researcher should maintain copies of the records documenting the transfer and disposal of controlled substances for a period of at least two years.

15.0 Useful Links for Federal and Iowa Board of Pharmacy Examiners Forms

15.1 DEA Forms
- Registrants Inventory of Drugs Surrendered (for Disposal or Transfer) (DEA Form 41)
- Report of Theft or Loss of Controlled Substances (DEA Form 106)
- U.S. Official Order Form for Controlled Substances (DEA Form 222)
- Application for Online Registration form (DEA Form 225) and Instructions
- Renewal Application for Online DEA Registration (DEA Form 225a) and instructions

15.2 IBPE Forms:
- Address Change Request IBPE.
- Iowa Quarterly Report of Compliance Form from IBPE.
- Iowa –Report of Theft or Loss Form from IBPE.
- Iowa – CSA New Application Form from IBPE.
- Iowa – CSA Renewal Application Form from IBPE.

16.0 References
5. Teaching with Controlled Substances, Iowa State University, Ames, Iowa.
10. Controlled Substances. Purdue University
15. Wayne State University Controlled Substances Program.

Appendix

- Authorized Users Signature Log
- Annual Inventory Record
- Controlled Substances Dispensed – Used
- Record of Controlled Substance Initial Inventory
- Power of Attorney (POA) Letter
- Record of Controlled Substance Purchases
- Pre-planning Activities
- Elements of Controlled Substances Management in Research Labs
- Controlled Substance(s) Disposal in a DEA Registrant’s Location
- Tare Weight Recordkeeping Form