Introduction

This procedure is in place to ensure that Boise State University is in compliance with both State and Federal regulations concerning the use and handling of controlled substances. Controlled substances are drugs whose general availability is restricted or outlawed because of their potential for abuse or addiction, and are regulated by the Controlled Substances Act. Please refer to the list of DEA Controlled Substances. This procedure applies to university staff and students who utilize controlled substances while teaching or conducting research. Compliance will be accomplished by proper licensing with the State and the U.S. Department of Justice Drug Enforcement Administration (DEA), record keeping, inventory, auditing and handling by university staff.

Definitions

**Authorized Users** – A university employee authorized to use controlled substances by a Unit Registrant who may also serve as the Authorized User’s direct supervisor.

**Laboratory Coordinator** – A senior authorized user assigned responsibilities by the Unit Registrant to oversee the day-to-day use of controlled substances within an individual laboratory or a suite of laboratories.

**Licensed Practitioner** – A physician, dentist, veterinarian, or other individual licensed, registered or otherwise permitted by the United States or the jurisdiction in which they practice, to dispense a controlled substance in the course of professional practice.

**List I Chemical** – a chemical that, in addition to legitimate uses, is used in manufacturing a controlled substance in violation of the Act and is important to the manufacture of a controlled substance.
**Power of Attorney** – Power of Attorney may be granted by Unit Registrants to the department head or senior administrator using the Power of Attorney form available in this document. This form may be used to order schedule I or II controlled substances and execute DEA order forms in absence of the Unit Registrant.

**Practitioner** –

(1) A physician, dentist, veterinarian, scientific investigator, or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of their professional practice or research in this state.

(2) A pharmacy, hospital or other institution licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of their professional practice or research in this state.

**Schedule I Controlled Substances** – Substances in this schedule have a high potential for abuse, have no currently accepted medical use in treatment in the United States, and there is a lack of accepted safety for use of the drug or other substance under medical supervision. Some examples of substances listed in schedule I are: diacetylmorphine (heroin), lysergic acid diethylamide (LSD), marijuana (cannabis, THC), mescaline (peyote), and 3,4-methylenedioxymethamphetamine (MDMA or ecstasy).

**Schedule II Controlled Substances** – Substances in this schedule have a high potential for abuse which may lead to severe psychological or physical dependence. Examples of single entity schedule II narcotics include morphine and opium. Other schedule II narcotic substances and their common name brand products include: hydromorphone (Dilaudid®) methadone (Dolophine®), meperidine (Demerol®), oxycodone (Oxycodone®), and fentanyl (Sublimaze® or Duragesic®). Examples of schedule II stimulants include: amphetamine (Dexedrine®, Adderall®), methamphetamine (Desoxyn®), methamphetamine (Desoxyn®) and methylphenidate (Ritalin®). Other schedule II substances include: cocaine, amobarbital, glutethimide, and pentobarbital.

**Schedule III Controlled Substances** – Substances in this schedule have a potential for abuse less than substances in schedules I or II and abuse may lead to moderate or low physical dependence or high psychological dependence. Examples of schedule II narcotics include combination products containing less than 15 mg of hydrocodone per dosage unit (Vicodin®) and products containing not more than 90 mg of codeine per dosage unit (Tylenol with codeine®). Also included are buprenorphine products (Suboxone® and Subutex®) used to treat opioid addiction. Examples of schedule III non-narcotics include benzphetamine (Didrex®), phenidimetrazine, ketamine, and anabolic steroids such as oxandrolone (Oxandrin®).

**Schedule IV Controlled Substances** – Substances in this schedule have a low potential for abuse relative to substances listed in schedule III. An example of a schedule IV narcotic is propoxyphene (Darvon® and Darvocet-N 100®). Other schedule IV substances include: alprazolam (Xanax®), clonazepam (Klonopin®),
clorazepate (Tranxene®), diazepam (Valium®) lorazepam (Ativan®), midazolam (Versed®), temazepam (Restoril®), and triazolam (Halcion®).

**Schedule V Controlled Substances** – Substances in this schedule have a low potential for abuse relative to substances listed in schedule IV and consist primarily of preparations containing limited quantities of certain narcotics. These are generally used for antitussive, antidiarrheal, and analgesic purposes. Examples include cough preparations containing not more than 200 mg of codeine per 100 ml or per 100g (Robitussin AC® and Phenergan with Codeine®).

**Unit Registrant**- A university employee delegated by his/her Unit to hold a DEA registration in the name of the Unit and to order, store, distribute, use and dispose of controlled substances within that Unit.

**Monitoring and Inspection**

Environmental Health, Safety, and Sustainability (EHSS) is responsible for monitoring the record keeping, inventory, security, and disposal of controlled substances. Inspections will be conducted on an annual basis to assist you with controlled substance handling procedures and to assure university compliance with DEA regulations. If you have questions concerning controlled substances, contact the EHSS office at ehs@boisestate.edu.

**Licensing and Registration**

Since the university cannot, by law, maintain a campus-wide registration for controlled substances or List 1 Chemicals, it is the responsibility of each individual Principal Investigator (PI) to obtain appropriate licenses and registration. These Authorized Users must adhere to applicable State and Federal regulatory requirements when working with these agents. Agencies may include the DEA and the Idaho State Board of Pharmacy.

**Registration Process:**

Prior to registering, the PI must have written approval from the Chair and the Dean of their department in order to apply for a controlled substance license. If the work will require the approval of the Institutional Biosafety Committee (IBC) or Institutional Animal Care and Use Committee (IACUC), those approvals must be completed before applying for a license. If there are no committee approvals needed, the applicant must contact EHSS regarding lab safety and waste generation disposal considerations.

1. **State Licensing:** All Idaho Authorized Users must have a valid controlled substance registration with both the Idaho State Board of Pharmacy and the DEA prior to dispensing, administering or maintaining an inventory of controlled substances in the
state of Idaho. The State recommends that researchers apply online with the DEA then submit their completed application to Board of Pharmacy.

- Idaho State Board of Pharmacy Controlled Substance Researcher Registration Application

2. Federal Registration: Applicants will need to complete the online DEA registration application. DEA registrations remain active for one year and are issued by the Attorney General.

3. Reminders: It is the responsibility of the Registrant to obtain timely renewals and prevent license lapse. Every Registrant shall be required to report any change of professional or business address in such manner as the Attorney General shall by regulation require.

4. Revocations: In the event the Attorney General suspends or revokes a registration granted under 21 U.S. Code § 824, all controlled substances or list I chemicals owned or possessed by the registrant pursuant to such registration at the time of suspension or the effective date of the revocation order, as the case may be, may in the discretion of the Attorney General, be placed under seal. No disposition may be made of any controlled substances or list I chemicals under seal until the time for taking an appeal has elapsed or until all appeals have been concluded.

The Attorney General may, in his discretion seize or place under seal any controlled substances or list I chemicals owned or possessed by a registrant whose registration has expired or who has ceased to practice or do business in the manner contemplated by his registration. Such controlled substances or list I chemicals shall be held for the benefit of the registrant or his successor in interest. The Attorney General shall notify a registrant, or his successor in interest, who has any controlled substance or list I chemicals seized or placed under seal of the procedures to be followed to secure the return of the controlled substance or List 1 chemical and the conditions under which it will be returned. The Attorney General may not dispose of any controlled substance or list I chemical seized or placed under seal under this subsection until the expiration of one hundred and eighty days from the date such substance was seized or placed under seal.

Application for Registration and Renewal Forms

- DEA Instructions for Registration
- Online Application for Registration – Research (DEA Form 225)
- Online Application for Registration – Teaching (DEA Form 224)
- Online Renewal Form – Research (DEA Form 225a)
- Online Renewal Form – Teaching (DEA Form 224a)

Documentation Needed for the Non-Practitioner Application Process:

- Applicant will need to verify their identity by providing their social security number for the DEA application.
• Applicant’s curriculum vitae.
• Copy of Boise State’s Institutional Animal Care and Use Committee (IACUC) or Institutional Biosafety Committee (IBC) protocol including signature approval page. If not applicable, a one page summary listing the procedures to be performed using the controlled substances; the types and quantities of drugs to be stored on site; specific protocols for monitoring drug usage, inventory control, destruction, security, storage, and access; and research objective.
• Names of people who will be handling or have access to storage of the controlled substance inventory and/or records.

Renewal of Registration

Both the State and Federal Agency responsible for controlled substance registration send notices prior to expiration of registrations. Do not let your registrations expire. Please copy EHSS and the Unit Registrant on all DEA correspondence.

Procurement

It is legal and acceptable under current statutes to transfer controlled substances between vendors and end users via conventional shipping methods (UPS, FedEx, USPS), however all parties must take precautions to prevent diversion of these materials during transit.

1. DEA regulations provide that the material be delivered to the addressee/licensee only. (No routing through Central Receiving).
2. The material must be inspected upon receipt and any losses reported immediately.
3. Orders for controlled substances will be tracked by the licensee until they are received so as to be able to act on any loss in transit as soon as possible.
4. Controlled substances are to be properly secured and entered into the lab and EHSS inventory immediately upon receipt.

Storage and Security Control

Controlled substances must be handled and stored in a manner consistent with state and federal law. Failure to do so can result in revocation of controlled substance license and imposition of fines.

In order to guard against theft or diversion, all controlled substances – regardless of schedule – must be kept under lock and key, and accessible only to authorized personnel. The number of
authorized staff must be kept to the minimum essential for efficient operation, and the stocks of controlled substances to the smallest quantity needed.

Controlled substances must be stored in a “substantially constructed, metal cabinet” and handled in accordance with 21 CFR 1301.71. This cabinet must be bolted to an immoveable object and kept locked at all times. The cabinet should be placed separate from other chemicals, drugs or materials. Contents should be audited monthly. The room in which the cabinet is located must have limited access during working hours and provide security after hours. All controlled substances must be kept locked except for the actual time required for authorized staff to remove, legitimately work with and replace them.

When possible, only authorized personnel should be allowed in the laboratory where controlled substances are used or stored. Authorized user names must be documented on the Controlled Substance Authorized Users List which is copied and forwarded to EHSS. Keep a copy of this form with the controlled substance inventory.

Note: Always ask visitors or individuals entering these areas for identification and why they are there. When maintenance work is done in the controlled substance storage area the research staff must maintain adequate observation.

**Purchasing Controlled Substances**

To order a controlled substance you must first have a DEA license. The Controlled Substance Ordering Form (DEA Form 222) is a paper-based form used to order Schedule I and Schedule II controlled substances that is requisitioned directly from the DEA. The DEA Form 222 also allows the exchange of controlled substances from the registrant to another party registered with the DEA (typically used when a controlled substance is sent to a reverse distributor for credit or disposal).

Registrants may also order controlled substances through the DEA’s Controlled Substance Ordering System (CSOS), which allows for electronic ordering of Schedule I-V controlled substances without using DEA Form 222. Only the Unit Registrant can sign DEA Form 222.

**DEA Ordering Forms**

Schedule I or II registrants can request Controlled Substance Ordering Forms online:

- [DEA Form 222](#)

You will receive the maximum number of order form books allowed for your business activity. Unexecuted or outdated versions of DEA Form 222 must be returned to the DEA for destruction.
Schedule III, IV, and V drug orders do not require a DEA Form 222. These drugs can be ordered directly from the manufacturer. However, you may be asked to provide a copy of your DEA Registration before your order will be prepared and shipped.

Each form must be completed with no errors, otherwise the supplier will reject the order. The forms must be stored in a locked location. All copies of DEA Form 222, including voided, used and unused forms, must be tracked using a Record of DEA Form 222 to maintain accountability. This form meets the DEA requirements for accountability of all DEA Form 222s.

Lost or stolen DEA Form 222 serial numbers must be reported to the local DEA Field Office immediately upon discovery. In the event of a lost DEA Form 222, the registrant must execute a second DEA Form 222 and include an attachment with the serial number and date of the missing form. The registrant must also indicate that the items on the first form were not received due to the missing form and submit this attachment with the second form. A copy of the first form, attachment and second form must be retained by the registrant. If an unused form is found or recovered, registrants must notify the DEA Field Office immediately.

Receiving

All orders are to be received at the Unit Registrant’s physical work address. When receiving a controlled substance in the mail, the Unit Registrant or Authorized User must:

- Verify the contents
- Rectify any discrepancies
- Sign and date the purchase receipt
- File it with the controlled substances records
- Provide a copy of the receipt to the DEA Registrant
- Add the container to an Administered/Dispensed Log

Labeling

Ensure that each controlled substance that has been removed from its original container and, or has been compounded or diluted, is labeled according to Federal 21 CFR 1302 and State IDAPA 24.36.01 regulations. Labels of all controlled substances used in research must include the following:

- Name of substance
- Schedule of drug
- Lot number
Ensure that the compounding or diluting of a controlled substance is documented in the Administered/Dispensed Log.

The act of compounding each concentration of the solution and the number of new containers must be documented.

Each new container must be accounted for and labeled in the same manner as original containers.

**Use of Controlled Substances**

Record each use of a controlled substance in the Controlled Substance Administered/Dispensed Log, the Single Drug Disposition Record, and/or the Combined Drug Disposition Record.

NOTE: The person performing a task (i.e., receiving, using, disposing) is responsible for documenting the necessary information in the logs noted above.

This information below is required on the forms above and should also be noted in research records/lab notebooks.

- Date of use
- Name of drug
- Strength or concentration of drug
- Purpose of use (i.e. protocol number or other info)
- Amount used
- Amount disposed of, if any
- Amount combined or diluted, if any
- Amount transferred, if any
- Initial of user

**Authorized Users**

Authorized users must be University faculty, staff, or students. Provisions can be made for visiting faculty on a case by case basis. The number of Authorized Users must be limited to the minimum number of people necessary to conduct the research. All Authorized Users
conducting research and/or teaching activities involving controlled substances must be approved by the university prior to beginning the work.

All authorized users must also sign the Authorized User Signature Log. Once approved, the Signature Log must be submitted to the Unit Registrant overseeing the activities. The Unit Registrant must maintain a file of all approvals and Signature Logs. All authorized users must be trained on this program prior to using controlled substances.

Only Registrants and Authorized Users may work with controlled substances. Controlled Substance work is limited to the scope of the approved protocol.

**Transfer of Controlled Substances**

Boise State University does not allow the transfer of Controlled Substances between Boise State principal investigators as this is not allowed in the DEA registration. Please note that it is a felony to provide/possess a controlled substance that is not registered with the DEA.

In addition, researchers may not transfer controlled substances to or from other institutions and they cannot be carried across state lines.

**Classroom or Academic Administration of Controlled Substances**

When controlled substances are needed for classroom experiments or exercises, the instructor must submit a detailed written request (planned use, quantities, date of activities, security plan and disposal details) to the Unit Registrant at least 30 days in advance. When needed, the controlled substance will be removed from storage and transported to the use location by the Unit Registrant or designee. The Unit Registrant or designee must witness the administration and log the use, along with the person administering the controlled substance. The Unit Registrant or designee is responsible for returning the remaining controlled substance and the log to the secure storage location. The controlled substance must never leave the control of the Unit Registrant or designee.

**Expired Material or Unused Product**

- All expired or unused controlled substances must be accumulated and stored under lock and key until ready for disposal.
• Excess controlled substances in syringes after a research procedure are required to be collected in a labeled bottle. Document the contents of the bottle on a Controlled Substance Disposal Form.

• The use of expired pharmaceuticals, biological, and supplies is not consistent with acceptable veterinary practice or adequate veterinary care. Euthanasia, anesthesia and analgesia agents should not be used beyond their expiration date, even if a procedure is terminal.

• Other expired materials should not be used unless the manufacturer verifies efficacy beyond the expiration date, or the investigator is able to document, to the satisfaction of the IACUC, that such use would not negatively impact animal welfare or compromise the validity of the study.

Controlled substances injected into research animals, consumed in a reaction, or converted into a non-recoverable hazardous waste mixture may be disposed of through routine waste disposal procedures by EHSS.

Spills

Breakage, spills, or other witnessed controlled substance losses do not need to be reported as lost. This type of loss must be documented by the Registrant and a witness on the Inventory Record. Controlled substances that can be recovered after a spill, but cannot be used because of contamination (tablets), must be placed in a labeled waste bottle and stored in the secured location until disposal (Completion of DEA Form 41 required). If the spilled controlled substance is not recoverable (liquids); the Registrant must document the circumstances in their Inventory Record and the witness(es) must sign.

Theft of or Missing Controlled Substances Reporting

The DEA Registrant must have complete accountability of all controlled substances stored or used in their area. Detailed record keeping practices are essential to ensure that any shortages or missing controlled substances will not go unnoticed. Theft or misuse of a controlled substance is a criminal act that must be reported to the following agencies:

• Environmental Health, Safety and Sustainability
• Risk Management
• Department of Public Safety
• Dean of the College of Arts and Sciences
• Dean of the College of Engineering
• VP for Research
In addition to the immediate phone reporting, a Report of Theft or Loss of Controlled Substances (DEA Form 106) must be completed and submitted to the DEA.

Reporting is also necessary if small quantities of controlled substances become unaccounted for on a re-occurring basis. Bookmark DEA Form 106 for easy access. Contact EHSS with any questions or concerns.

Disposal and Loss Records

To minimize waste, DEA Registrants should only purchase quantities they intend to use. Damaged, expired, unwanted, unusable, or non-returnable controlled substances must be accounted for, retained, and disposed of in accordance with applicable State and Federal regulations.

A Registrants Inventory of Drugs Surrendered (DEA Form 41) must be completed prior to disposing of any DEA controlled substance (1) copy should be retained by the registrant for at least 2 years.

Controlled substances in their original container which need to be disposed of should remain in the original container with the volume recorded on the Controlled Substance Disposal Form.

The disposal record must be dated to reflect when the products were sent for destruction and left your inventory.

Abandoned substances that were obtained PRIOR to the substance being classified as controlled substances (i.e. clean outs of old labs) are still the Registrants responsibility. The Unit Registrant’s department should make every effort to contact the Registrant. EHSS should be consulted if this situation presents itself.

EHSS will coordinate the disposal between the Unit Registrant and a licensed disposal contractor. Because of this scheduling requirement, disposal may take up to 90 days from request.

Disposal of Controlled Substances
**Reverse Distribution:**
This option transfers ownership of the controlled substance to a DEA-approved Pharmaceutical Returns Processor for re-use, re-sale or destruction at a hazardous waste incinerator. This process may involve the completion of DEA Form 222 or DEA Form 41. Contact information for three reverse distributors is listed below. Contact EHSS to coordinate your disposal.

**Recordkeeping**

- Every registrant shall maintain records and inventories and shall file reports required by [21 CFR 1304.03](https://www.gpo.gov/fdsys/). A registered individual practitioner is required to keep records of controlled substances in schedules II, III, IV, and V which are administered in the lawful course of professional practice if they regularly engage in dispensing or administering.
- All records required shall be maintained for at least two years from the date of such inventory or records, for inspection and copying by authorized employees of the DEA. Retaining records for five years is advisable due to the statute of limitations. These records must be in conformance with the record keeping and inventory requirements of federal law.
- Schedules I and II must be maintained separately from all other records of the registrant, and Schedule III, IV, and V must be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant. The phrase "readily retrievable" means they can be separated out from other records in a reasonable time.
- Note: Records must be made available within five (5) working days after a request by the Idaho Board of Pharmacy for such records or information on controlled substances transactions.

Records must be stored in or near the primary work area and be available for inspection during regular work hours. The use of codes, symbols, or foreign languages in identifying a controlled substance or person in the record is prohibited. In the event that any controlled substances are lost, destroyed, or stolen the kind and quantity of the material and the date of discovery of such loss must be recorded in detail and properly reported.

**The recordkeeping system should include the following information.**
*All forms below meet DEA requirements.*

**Purchasing Records**: The purchasing record (invoice, shipping document, or packing slip) must be annotated with the handwritten date of receipt. The date written on this document must match the date entered in the "Date Received" column on your Record of Controlled Substance Purchases Form.
**Receipt of controlled substance:** A separate and current record of the receipt of controlled substances, indicating date received, name and address of supplier, the type, strength or concentration, and amount of the controlled substances received.

**Administered/Dispensed:** A separate and current record for the storage and use of each controlled substance, indicating the date, laboratory location/class, test subject description, and manner and dose of each administration. By noting starting volume or mass of substance in the container, each use is a subtraction from the starting quantity, and the running (decreasing) amount should equal the total amount remaining on hand.

**Physical Inventory:** A complete and accurate inventory of the stock of controlled substances within each registrant’s possession must be performed initially. The type, strength, and quantity of all controlled substances must be recorded at this time. The person conducting the inventory must also date and sign the record. After the initial inventory is taken, a new inventory of all stocks of controlled substances on hand should be conducted at least every two years. For additional information on DEA inventory requirements, review **21 CFR 1304.11**.

**Bi-Annual Inventory:** As part of the biannual inspection, Unit Registrants must complete an inventory to compare the actual count of controlled substances in the safe to the amount in the written disposition records. More frequent inventories are recommended for laboratories using Schedule I or Schedule II drugs, higher volumes, multiple controlled substances or with many Authorized Users. Registrants must send a copy of the inventory annually to EHSS.

**Discrepancy**

If inventory and Disposition records cannot be reconciled report the discrepancy within 24 hours to the DEA using **DEA form 106** and report to the ISBP per **IDAPA 24.36.01 Subchapter F Section 501**.

Idaho State Board of Pharmacy: 208-334-3233

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**Controlled Substance Links**

- Code of Federal Regulations Schedule of Controlled Substances
- Idaho Administrative Code, Idaho Board of Pharmacy
- Idaho Administrative Code Rules Governing Controlled Substances
- Idaho State Board of Pharmacy
- U.S. Department of Justice Drug Enforcement Administration Office of Diversion Control
  - DEA Security Regulation (21 CFR 1301.71 thru 21 CFR 1301.76)