

Laboratory Guideline For Managing Controlled Substances in Research Laboratories (CSG)

Table of Contents

1.	Objective	2
2.	Regulations	2
3.	Applicability	2
4.	Responsibilities	2
5.	Definition/Abbreviation	3
6.	Registration	6
7.	Storage and Security	7
8.	Background Check/ Screening of Employees	7
9.	Purchasing Controlled Substances	8
10.	Schedules of Controlled Substances	8
11.	Disposal of Controlled Substances	9
12.	Handling Orphan Controlled Substances	10
13.	Transportation	10
14.	Recordkeeping	11
15.	Useful Links for Federal and Iowa Board of Pharmacy Examiners Forms	12
16.	References	13
	Appendix A1: Pre-planning Activities	14
	Appendix A2: Elements of Controlled Substances Management in Research Labs	15
	Appendix B1: Controlled Substance Authorized Users Signature Log (Example)	16
	Appendix B2: Record of Controlled Substance Purchases (Example)	17
	Appendix B3: Record of Controlled Substance Initial Inventory (Example)	18
	Appendix B4: Record of Controlled Substances Dispersion/Use (Example)	19
	Appendix B5: Controlled Substance Physical Inventory (Example)	20

Laboratory Guideline

For Managing Controlled Substances in Research Laboratories (CSG)

1.0 Objective

- 1.1 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 in their research.

2.0 Regulations

- 2.1 *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.
- 2.2 Code of Federal Regulations, 21CFR Parts 1300-1399; and 21 CFR Parts 1308 - Schedules of Controlled Substances.
- 2.3 State of Iowa Administrative Code, Chapter 657; and Iowa Controlled Substances ACT (CSA), Chapter IC124.
- 2.4 Code of Federal Regulations, 40 CFR Parts 260, 261 and 264.

3.0 Applicability

- 3.1 Controlled substances must be used only in research locations and situations described in DEA and IBPE registrations. The researcher must address specific aspects of controlled substance utilization as stated in the research project justification.
- 3.2 Typical examples of research situations for the use of controlled substances include: (a) animal anesthesia, analgesia, restraint, or experimentation; (b) analysis including quantitation and/or characterization; and (c) synthetic chemistry involving development of new drugs.
- 3.3 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

- 4.1 Each Principal Investigator (PI, defined as a "Researcher" in DEA registration application) who is authorized to use controlled substances is responsible to understand and comply with all applicable rules and regulations by the Federal Drug Enforcement Agency (DEA) and the State of Iowa - Iowa Board of Pharmacy Examiners (IBPE) for registration, purchase, use, and proper disposal of controlled substances in his/her research work. The PI retains all liabilities for loss, theft, or misuse of any controlled substance acquired through his/her registration.
- 4.2 Researchers must purchase the controlled substances using Federal DEA registration numbers and DEA/IBPE approved distributors.
- 4.3. The use of controlled substances is approved for individual researchers and only for the research location(s) described in their 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.

- 4.4 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 Appendices B1-B5).
- 4.5 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.
- 4.6 Used, expired, unwanted, or partially consumed controlled substances container(s) must be disposed of through DEA-registered reverse distributors only.
- 4.7 Controlled substances waste (used, expired, partially consumed, and generated from synthetic or analytical processes) is regulated by DEA. Researchers must treat the controlled substance wastes separately and **must not treat** them as a hazardous waste, biological waste or regulated medical waste. Researchers must be aware that the disposal of a mixed waste containing controlled substance(s) and other hazardous chemicals will be expensive and will take a longer lead time for DEA/IBPE approval. Reverse distributors must be contacted for proper disposal of controlled substance waste and the above described mixed waste. The researchers wanting to dispose of controlled substances that are mixed with hazardous chemical waste must consult with EHS to ensure compliance with RCRA regulations.
- 4.8 The EHS office is not registered with either DEA or IBPE as a reverse distributor and does not hold an institutional license for storing the controlled substances. It is against DEA regulations for EHS to accept, store or dispose of the controlled substances. However, researchers may contact EHS for specific questions related to registration, purchase, storage and security, and disposal.

5.0 Definition/Abbreviation

- 5.1 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, dispensing and manage 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 conduct due diligence credential checks for their staff. Therefore, each licensed researcher is responsible for checking their staffs' credentials, authorizing specific roles, and providing required training for proper handling of controlled substances.
- 5.2 **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 must take responsibility 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.

- 5.3 **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			
<p>The Controlled Substance Act of 1970 reads in part as follows: Sec. 304. (a) A registration pursuant to section 303 to manufacture, distribute, or dispense a controlled substance may be suspended or revoked by the Attorney General upon a finding that the registrant</p> <p>(1) has materially falsified any application pursuant to or required by the title or title III; (2) has been convicted of a felony under this title or title III or any other law of the United States, or any State, relating to any substance defined in this title as a controlled substance or (3) has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the manufacturing, distributing, or dispensing of controlled substances.</p> <p>FORM DEA 223 (5/78)</p>	DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	EEE PAID
	AB1234567	MM/DD/YY	\$XX.XX
	SCHEDULES	BUSINESS ACTIVITY	DATE ISSUED
1, 2, 3, 3N, 4, 5	RESEARCHER	MM/DD/YY	
<p>YOUR INSTITUTION 1 MAIN STREET TOWN, STATE XXXXX</p>			
THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION OR BUSINESS ACTIVITY			

- 5.4 **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 at DEA website at <http://www.dea diversion.usdoj.gov/21cfr/cfr/2108cfrt.htm>. The same information can also be found in DEA orange book, <http://www.dea diversion.usdoj.gov/schedules/orangebook/orangebook.pdf>.
- 5.5 **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.
- 5.6 **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.
- 5.7 **Disposal:** the approved method of discarding a controlled substance that is outdated, redundant, contaminated, is waste, or is no longer needed.
- 5.8 **Disposition records:** an accurate, continuous and current record used to track the purchase, use and disposal of controlled substances.
- 5.9 **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.
- 5.10 **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.
- 5.11 **Licenses:** There are 11 classes of licenses (registrations). The most significant classes for registration as researcher are highlighted below.

License Class	License Description
Class 1:	Manufacturer
Class 1a:	Manufacturer (Out-of-State)
Class 2:	Distributor
Class 2a:	Distributor (Out-of-State)
Class 3:	Institutional Dispenser
Class 3a:	Institutional Dispenser Limited
Class 4:	Researcher (Schedules II-V) (Individual and Institutional)
Class 5:	Instructional Activities (Schedules II-V)
Class 7:	Research and Instructional Activities (Schedule I) (Individual and Institutional)
Class 8:	Analytical Laboratory
Class 9:	Importer
Class 9a:	Importer Broker
Class 10:	Exporter
Class 10a:	Exporter Broker
Class 11:	Pharmacy - Automated Dispensing System

- 5.12 **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](#).
- 5.13 **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.
- 5.14 **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.
- 5.15 **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.
- 5.16 **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.
- 5.17 (Licensed) **Researcher:** throughout this document, ‘licensed researcher’ refers only to the **Principal Investigators (PIs) who possess a “Researcher” class license through the DEA and IBPE.**

6.0 Registration

- 6.1 Each researcher (PI) who intends to use DEA controlled substances in their 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.
- 6.2 State of Iowa Registration: The Iowa initial registration and renewal forms can be downloaded as a pdf file at the IBPE website: http://www.state.ia.us/ibpe/application_forms.html. The State of Iowa requires that a renewal registration is completed biennially.

The State of Iowa controlled substance registration must be acquired prior to application for a DEA permit. Anticipate several weeks for processing of the Iowa application. Once the Iowa license is acquired, the DEA registration process can be initiated.

- 6.3 DEA Registration: the registration application for DEA must be completed online. The online application is preferred by DEA because the online process alerts the registrant about missing information and errors (if any) and 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. The following DEA links are very useful during the registration process.
http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm.
<http://www.deadiversion.usdoj.gov/drugreg/index.html>
http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms.htm.
<http://www.deadiversion.usdoj.gov/drugreg/index.html#1>
- 6.4 If needed, a [hardcopy of the application](#) for controlled substance registration may be downloaded as a pdf file. Completed application must be mailed to:
- Drug Enforcement Administration
 Registration Section/ODR
 P.O. Box 2639
 Springfield, VA 22152-2639**
- 6.5 DEA Renewal application: A DEA registration is required to be renewed annually. Licensed researchers and analytical laboratories must fill out DEA Form 225a (departments or units with instructional activities fill out DEA Form 224a).
http://www.deadiversion.usdoj.gov/drugreg/reg_apps/pdf_apps.htm
<http://www.deadiversion.usdoj.gov/drugreg/index.html#1>
- 6.6 Requirements for handling controlled substances, per CSA, are summarized below.

	Schedule II	Schedule III & IV	Schedule V
Registration	Required	Required	Required
Ordering	Licensed Researcher	Licensed Researcher	Licensed Researcher
Purchasing Receiving Records (Example forms in Appendix B)	Order Forms (DEA Form-222) Signature and Date	Invoice Signature and Date	Invoice Signature and Date
Daily Use	Spiral or Bound Logbook is Recommended	Spiral or Bound Logbook is Recommended	Spiral or Bound Logbook is Recommended
Distribution Between Registrants	Order Forms (DEA Form-222)	Invoices	Invoices
Inventory (Example forms in Appendix B)	Initially, and updated every 2 years	Initially, and updated every 2 years	Initially, and updated every 2 years
Security	Locked Drawer/Cabinet or Safe	Locked Drawer/Cabinet or Safe	Locked Drawer/Cabinet or Safe

Theft or Significant Loss	Report and Complete the DEA Form 106 and Iowa Form 46 .	Report and Complete the DEA Form 106 and Iowa Form 46 .	Report and Complete the DEA Form 106 and Iowa Form 46 .
Disposal	By Reverse Distributor	By Reverse Distributor	By Reverse Distributor
Disposal Records Maintenance	At least 2 Years after Disposal	At least 2 Years after Disposal	At least 2 Years after Disposal

7.0 Storage and Security

- 7.1 Upon acquisition, controlled substances must be stored in a securely locked, substantially constructed cabinet, located where access is limited to authorized individuals only. While laboratory rooms have controlled access, either by keys or a keycard, access to the secure safe/cabinet must be kept to a minimum. It is recommended that only 1-2 individuals should have this level of access, and they need to be the individuals listed as the PI's authorized agents. The general security requirements are available at http://www.dea diversion.usdoj.gov/21cfr/cfr/1301/1301_71.htm.
- 7.2 Controlled substances must be maintained behind a minimum of two (2) locks. The storage of the controlled substances can be within: (a) a locked cabinet in a locked room and the 'locked room' must always be locked when it is not occupied by either the registrant or an authorized user; or (b) a locked inner cabinet in a locked cabinet.
- 7.3 Locks may be cipher locks (combination locks) or key locks. If key locks are used, then (a) the two locks must be keyed differently; (b) two keys must not be stored together (i.e., not on the same key ring); (c) both keys must be safeguarded, and not in public sight; and (d) individuals with access to the keys must be approved by the licensed researcher.

8.0 Background Check/ Screening of Employees

- 8.1 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.
- 8.2 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.dea diversion.usdoj.gov/21cfr/cfr/1301/1301_90.htm
<http://www.dea diversion.usdoj.gov/pubs/manuals/sec/index.html>
[www.hreo.ku.edu/files/.../DEA Lab Bkgrnd Check Process.doc](http://www.hreo.ku.edu/files/.../DEA_Lab_Bkgrnd_Check_Process.doc)
- 8.3 For any questions related to security screenings for University employees, please contact the following University of Iowa administrative officers:
[Judie Hermsen](#), Director of UI Administrative Services in Central Human Resources; phone 335.3553
[James Jorgensen](#), Deputy Counsel in the Office of the General Counsel; phone 335.0400.
- 8.4 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

- 9.1 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. Utmost care must be taken when filling out the Official Order Form 222. A Form 222 that shows any alteration, erasure or change 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 [properly completed DEA Form 222](#) can be viewed at the University of Michigan EHS website.

9.2 A [list of distributors](#) can be downloaded from the DEA website. The list below is provided for planning purposes only.

Burns Veterinary Supply	Fort Dodge Laboratories	JA Webster	Vortech Pharmaceutical
3400 West Lake Ave.	800 5 th Street, Northwest	86 Leominster Road	6851 Chase Road
Glenview	Fort Dodge	Sterling	Dearborn
IL 60025	IA 50501-0518	MA 01564-2198	MI 48126
1-800-922-8767	1-800-685-5656	1-800-225-7911	1-800-521-4686
Butler Schein, Inc.	Butler Schein, Inc.	Sigma-Aldrich, Inc.	Diamondback Drugs
135 Duryea Road	3820 Twin Creeks Dr.	3050 Spruce Street	7901 East McDowell Road
Melville, NY 11747	Columbus, OH 43204	St. Louis, MO 63103	Scottsdale, Arizona 85257
1-800-483-8329	1-800-552-8387	1-800-325-3010	1-866-578-4420

10.0 Schedules of Controlled Substances

10.1 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>

<p>Schedule I A drug or other substance that has a high potential for abuse and which currently has no accepted medical use in the United States. There is a lack of accepted safety regarding the use of the drug or other substance, by patients under medical supervision.</p>	For authorized research only. Examples are: heroin, marijuana, LSD, and certain fentanyl analogs.
<p>Schedule II A drug or other substance that has a high potential for abuse and currently has an accepted medical use (or with severe restrictions) in the United States. Abuse of the drug or other substances may lead to severe psychological or physical dependence.</p>	Controlled substances consist of certain narcotic, stimulant, and depressant drugs. Some examples of CII narcotics are: opium, morphine, codeine, hydromorphone, methadone, meperidine, cocaine, oxycodone, anileridine, and oxymorphone.
<p>Schedule II N</p>	Non-narcotic drugs with a high potential for abuse, such as amphetamines, phenmetrazine, methylphenidate; and short-acting barbiturates. Methamphetamine, phenmetrazine, methylphenidate; the depressants amobarbital, pentobarbital, secobarbital; and fentanyl etorphine hydrochloride, and phencyclidine (PCP).

<p>Schedule III A drug or other substance that has a high potential for abuse and currently has an accepted medical use (or with severe restrictions) in the United States. Abuse of the drug or other substances may lead to severe psychological or physical dependence.</p>	<p>These include preparations containing limited quantities of certain narcotic drugs, and other nonnarcotic drugs such as derivatives of barbituric acid.</p>
<p>Schedule III N</p>	<p>Includes central nervous system depressants, such as glutethimide, methyprylon, and barbiturates not listed in other Schedules. Also includes anorectant agents not included in other Schedules.</p>
<p>Schedule IV A drug or other substance that has a low potential for abuse relative to the drugs or other substances in Schedule III. The drug or other substance is currently accepted for medical use in the United States. Abuse of the drug or other substance may lead to limited physical dependence</p>	<p>Includes narcotics in combination with other non-narcotic drugs, antidiarrheals, mild CNS depressants, mild CNS stimulants, and tranquilizers. They include such drugs as: barbital, phenobarbital, methylphenobarbital, and chloral hydrate.</p>
<p>Schedule V A drug or other substance that has a low potential for abuse relative to the drugs or other substances in Schedule IV. The drug or other substance currently has an accepted medical use in the United States. Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule IV.</p>	<p>Includes narcotic cough syrups and ephedrine, pseudoephedrine, and phenylpropanolamine products. Buprenorphine is also a Schedule V drug.</p>

11.0 Disposal

- 11.1 The disposal of controlled substances is the final action necessary to ensure proper management of controlled substances.
- 11.2 EHS is not approved by either DEA or IBPE for receiving controlled substances for storage, distribution or disposal of bulk/neat substances, or blending wastes containing controlled substances. Therefore, EHS will not receive or store waste containing controlled substances for disposal. 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.
- 11.3 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.
- 11.4 A licensed researcher must dispose of outdated, damaged, or otherwise unusable or unwanted controlled substances by transferring them to a “reverse distributor” registrant; only reverse distributors are authorized to receive such materials from licensed researchers. The fee associated with this service is the responsibility of the registrant.
- 11.5 Any animal waste that contains controlled substances that is generated under a UI –IACUC Animal Care Protocol must be destroyed by a member of the IBPE or an approved agent of IBPE. The destruction must be witnessed by the licensed researcher. An “Inventory of Drugs Destroyed or Surrendered” ([Form 41](#)) must be completed and signed by an agent of IBPE. Disposal information must include: (a) DEA registration number, (b) controlled substance name, (c) vendor, (d) quantity (controlled substance content of each unit described in container, number of containers and size of the containers), and (e) user name and campus address, including the room number where the substance was being used. One copy will be made available to IBPE

and one copy must be retained by the licensed researcher. Please contact Jim Wolfe, Compliance Monitor of the controlled substances at james.wolf@iowa.gov.

- 11.6 As required by the [DEA](#), any controlled substance transfers must only be made after obtaining approval from DEA. Schedule I and II controlled substances must be transferred for reverse distribution using [DEA Form 222](#) only. Schedule III–V compounds may be transferred to reverse distributors via invoice. The registrant must maintain copies of the records documenting the transfer and disposal of controlled substances for a period of at least two years after disposal of a controlled substance.
- 11.7 Examples of [reverse distributors](#) used by the University of Iowa licensed researchers include:

Distributor	Address
Clean Harbors (Chemical packing Services)	42 Longwater Drive Norwell, MA 02061-9149 1-800-282-0058 www.cleanharbors.com
National Pharmaceutical Returns, Inc.	4164 NW Urbandale Drive Urbandale, IA 050322 1-800-470-7725 http://www.npreturns.com/
EXP Pharmaceutical Services Corp.	48021 Warm Springs Boulevard Fremont, CA 94539 1-510-476-0909, Ext. 429 http://www.expworld.com/

12.0 Handling Orphan Controlled Substances

- 12.1 “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 been left by a retiring researcher, 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 in conjunction with IBPE to notify DEA and ensure it is properly destroyed.
- 12.2 When disposal of orphan controlled substances is necessary, the temporary custodian must contact the DEA regional office and IBPE to submit [surrender forms](#) and to receive approval for proper disposal. Upon the receipt of approval, the department must then contact reverse distributors for proper collection and disposal of controlled substances.
- 12.3 The department may also contact EHS (Jim Pyrz, 335-4625) for assistance and provide the following information: (a) DEA Registration number (if available); (b) location where the Orphan was found (lab number, building, and originating department); (c) name of the controlled substance; (d) controlled substance content in each individual container; (e) number of containers; (f) size of each container.
- 12.4 EHS is not permitted to take possession of orphan controlled substances while waiting for DEA approval for disposal.

13.0 Transportation

- 13.1 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.

- 13.2 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 Appendix B4: Record of Controlled Substances Dispensation/Use).
- 13.3 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.
- 13.4 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 222s or invoices (the same way it was purchased).

14.0 Recordkeeping

- 14.1 The controlled substances tracking requirements are available at http://www.deadiversion.usdoj.gov/21cfr/cfr/1304/1304_22.htm.
- 14.2 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.
- 14.3 Basic record keeping includes:
- 14.3.1 Records of receipt
 - 14.3.2 Records of use (including loss or theft)
 - 14.3.3 Records of disposal of controlled substances
 - 14.3.4 Biennial inventory
- 14.4 The following information will be kept in the receiving log:
- 14.4.1 The date the substance was received at the storage location
 - 14.4.2 The substance name assigned by the manufacturer
 - 14.4.3 The manufacturer of the substance or vendor
 - 14.4.4 The quantity and strength of the substance added to the storage area
- 14.5 Name of individual adding product to the inventory
- 14.4 Dispensing controlled substances: whenever drugs are dispensed either for teaching purposes, research or surrendered for disposal the following information must be logged.
- 14.4.1 Date used or disposal of waste
 - 14.4.2 Quantity dispensed for aliquots, dilution
 - 14.4.3 Strength dispensed (concentration and volume)
 - 14.4.4 Name of person (authorized user)
 - 14.4.5 Quantity remaining in inventory
- 14.6 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.

- 14.7 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.
- 14.7.1 These inventories and records should be kept at the location where the licensed activity is conducted, and must be readily available for inspections.
 - 14.7.2 Chemical inventories of controlled substances are up-to-date and discrepancies reconciled at least annually.
 - 14.7.3 All records of inventories and logs of controlled substances shall be kept a minimum of two years and be available for inspections and copying by a member of DEA or IBPE.
 - 14.7.4 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

- 15.1.1 Registrants Inventory of Drugs Surrendered (for Disposal or Transfer) ([DEA Form 41](#))
http://www.deadiversion.usdoj.gov/21cfr_reports/surrend/41_blank.pdf
- 15.1.2 Report of Theft or Loss of Controlled Substances ([DEA Form 106](#))
http://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html
- 15.1.3 U.S. Official Order Form for Controlled Substances ([DEA Form 222](#))
<https://www.deadiversion.usdoj.gov/webforms/orderFormsRequest.jsp>
- 15.1.4 Application for Online Registration ([DEA Form 225](#))
http://www.deadiversion.usdoj.gov/drugreg/reg_apps/225/225_instruct.htm
http://www.deadiversion.usdoj.gov/drugreg/reg_apps/225/225_form.pdf
- 15.1.5 Renewal Application for Online DEA Registration ([DEA Form 225a](#))
<http://www.deadiversion.usdoj.gov/drugreg/index.html>
http://www.deadiversion.usdoj.gov/drugreg/reg_apps/pdf_apps.htm

15.2 IBPE Forms:

- 15.2.1 [Address Change](#) Form for Download from IBPE.
<http://www.iowa.gov/ibpe/pdf/48.pdf>
- 15.2.2 Iowa [Quarterly Report](#) of Compliance Form from IBPE.
<http://www.iowa.gov/ibpe/pdf/qrptcomplnc.pdf>
- 15.2.3 [Iowa – Report of Theft or Loss](#) Form from IBPE.
<http://www.iowa.gov/ibpe/pdf/46.pdf>
- 15.2.4 [Iowa – CSA New Application](#) Form from IBPE.
http://www.iowa.gov/ibpe/pdf/csa_new.pdf
- 15.2.5 [Iowa – CSA Renewal](#) Application Form from IBPE.
http://www.iowa.gov/ibpe/pdf/csa_renewchange.pdf

16.0 References

- 16.1 Controlled Substances Security Manual - An Informational Outline of the Controlled Substances Act of 1970, Drug Enforcement Administration, Revised May, 1991.
<http://www.dea.gov/diversion/usdoj/pubs/manuals/sec/security.pdf>
- 16.2 Practitioner's Manual - An Informational Outline of the Controlled Substances Act, Drug Enforcement Administration 2006. http://www.dea.gov/diversion/usdoj/pubs/manuals/pract/pract_manual012508.pdf
- 16.3 Lists of Scheduling Actions Controlled Substances Regulated Chemicals. Orange Book. U.S. Department of Justice, Drug Enforcement Administration, Office of Diversion Control Drug & Chemical Evaluation Section. July 2011. <http://www.dea.gov/diversion/usdoj/schedules/orangebook/orangebook.pdf>
- 16.4 Environmental Health and Safety Standard Operating Procedure (SOP) for the Disposal of Controlled Substances for the Department of Public Safety–Police Division. Iowa State University, Ames, Iowa. 2007.
- 16.5 Teaching with Controlled Substances. Iowa State University, Ames, Iowa.
<http://www.ehs.iastate.edu/publications/policies/contrsubpol.pdf>
- 16.6 Rules for Controlled Substances. Northern Iowa University, Cedar Falls, Iowa.
www.vpaf.uni.edu/ehso/documents/rules_controlled_substances.doc
- 16.7 Policy and Procedures for Research Use of Controlled Substances at Emory University. October 2006.
- 16.8 Policy on the Use of Controlled Substances in Research. Yale University, October 2009.
- 16.9 NIH Policy Manual 1345 - Handling and Safeguarding of Controlled Substances for Nonhuman Use. August 2008. <http://oma.od.nih.gov/manualchapters/management/1345/>
- 16.10 Research Use of Controlled Substances Program. Cornell University, July 2011.
- 16.11 Controlled Substances. <http://www.purdue.edu/rem/eh/DEA.htm>
- 16.12 Disposal of expired, excess, and unwanted controlled substances.
http://www.dehs.umn.edu/hazwaste_consуб_dispos.htm and
<http://www.research.umn.edu/riop/controlsubst.htm>
- 16.13 Controlled Substances in Research Policies. <http://www.ucuca.umich.edu/csubs.htm>
- 16.14 Guidelines for the Ordering and Use of Prescription Drugs and Devices and Controlled Substances for Non-Clinical Laboratory Research. University of Pittsburgh.
<http://www.rcco.pitt.edu/ControlledDrugs/Guidelines/GuidelinesControlledDrugs.pdf>
- 16.15 Controlled Substances Program. North Carolina State University EH&S, April 2008.
http://www.ncsu.edu/ehs/www99/right/handsMan/Controlled_substances.pdf
- 16.16 Wayne State University Controlled Substances Program. http://www.oehs.wayne.edu/controlled-substances/WSU_Controlled_Substances_Program.php.
- 16.17 University of Illinois at Urbana-Champaign DEA Controlled Substances Guidance Document.
<http://www.drugs.illinois.edu/css/guidesplans/dea/>
- 16.18 Stefan Wawzyniecki. Emphasizing the “Control” in Controlled Substances. Journal of Chemical Health & Safety **11**, 6-9, July/August, 2004.

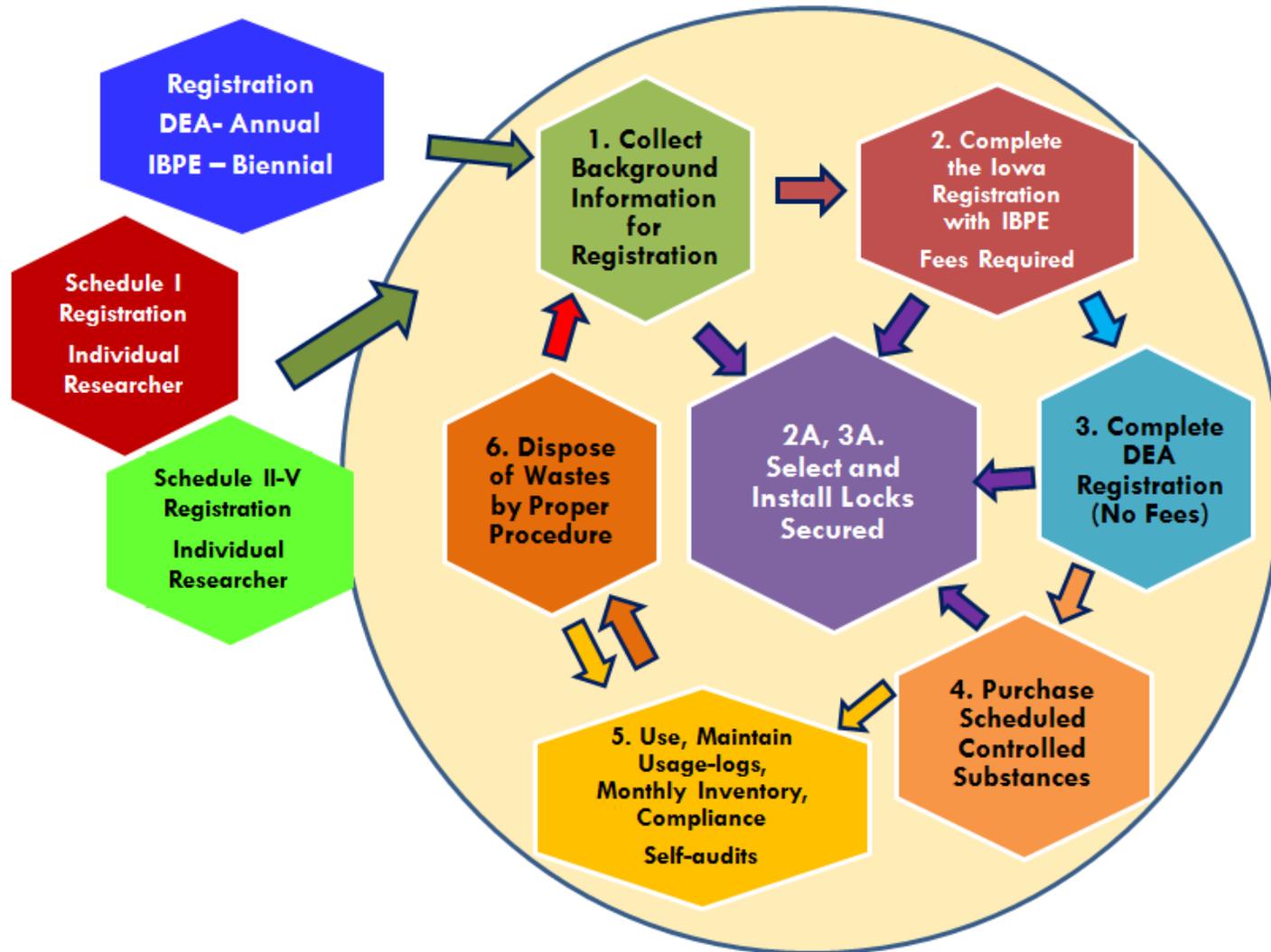
Appendix A1:

Pre-planning Activities

Once your application is submitted to the IBPE, there are a number of activities you need to complete in preparation for your site inspection and to obtain approval to receive and work with controlled substances. The activities include:

1. Write a brief description of the research that will be conducted (typically 100 words or less), a list of controlled substances that will be used to conduct research/testing, and the approximate quantities that will be used per year.
2. Identify the primary responsible person that supervises use of controlled substances at the facility. The "Responsible Person" is the principal investigator (known as 'Researcher' and 'Registrant' in the DEA registration) and has a faculty-rank appointment (i.e., faculty or administrative professional such as laboratory director). This person is ultimately responsible for obtaining approval to use a controlled substance, and is responsible for the safe use, secure storage, and recordkeeping requirements of that controlled substance. The responsible person certifies that the legally required records of receipts and disbursements of the controlled substances listed on the application will be maintained for inspection, and security measures will meet those required by federal and state law.
3. Determine the type of safe/cabinet where you plan to secure the controlled substances and the exact location in which they will be stored:
 - Cabinet/safety must be capable to be securely locked and is substantially constructed, where access is limited to only authorized agents.
 - Location of room where cabinet/safe is located (name of the building and room number).
4. Identify the supplier and vendors from whom controlled substances for the research will be obtained (name, address, phone number, and registration number of the supplier)
5. Develop laboratory policies and procedures for use and disposal of outdated/unwanted controlled substances.
6. Develop and document procedures for delivery and receipt of controlled substances. The items must be hand-delivered to the person responsible for the order or an individual designated by the responsible person.
7. Develop recordkeeping procedures and maintain records for every controlled substance brought into the registered location. Recordkeeping is required at the site of storage for controlled substances. See Appendices B1-B5 for examples of the types of records that are required.

Appendix A2: Elements of Controlled Substances Management in Research Labs



Appendix B1: Controlled Substance Authorized Users Signature Log (Example)

For security, the number of individuals who have access to controlled substances should be limited.
List the names, titles, initials and signatures of all persons designated by the Registrant as Authorized Users for this Location.

PI (Registrant) Name: _____ **Location(s) of Use:** _____

Protocols (Name and Number): _____

Controlled Substances Used in Research: _____

(List Bulk Materials and Schedule) _____

Veterinary Drugs Used in Research: _____

(List Injectable Solutions and Schedule) _____

Full Name of Authorized User (Print Full Name)	Job Title (or Project Role)	Legal Signature of Authorized User	Authorized User Initial	PI (Registrant) Initial and Date

I hereby certify that I have designated the persons listed above as Authorized Users for this location.

Registrant Signature: _____

Appendix B2: Record of Controlled Substance Purchases (Example)

Note: To ensure a comprehensive record, file a copy of the invoice or shipping document in the controlled substances folder. Ensure the date of receipt is recorded on the invoice or shipping document.

Registrant Name: _____

Registration Number: _____

Product Name	Amount Purchased	Date Received	Company Purchased From	Schedule No.	DEA Number	Invoice or Shipping Document Number

