

UK Researcher Guide for the Use of DEA Controlled Substances

I. [Introduction](#)

1. [General Information-Reason for Guidelines](#)
2. [Federal Government Controlled Substance Regulations and Agencies](#)
3. [DEA District Office Contact Information](#)

II. [List of Definitions used in this Guidance Document](#)

III. [Controlled Substances-Drug Schedules](#)

1. [Schedule-I](#)
2. [Schedule-II](#)
3. [Schedule-III](#)
4. [Schedule-IV](#)
5. [Schedule-V](#)

IV. [DEA Controlled Substances Registration Requirements and General Information](#)

1. [Registration requirements for state of Kentucky](#)
2. [Separate Registrations for different business \(laboratory\) locations](#)
3. [Registration Options \(Non-Practitioner Researcher or Practitioner Researcher\)](#)
4. [Schedule-I Registrations](#)
5. [Schedule II-V Registrations](#)
6. [IACUC Protocols and DEA Registration](#)
7. [Annual Renewals](#)
8. [Changes to a Registration](#)
9. [Relinquishing a Registration](#)
10. [Relocation to another Institution](#)

V. [Responsibilities of Controlled Substance Registrants and Authorized Personnel](#)

1. [Controlled Substance licensed Registrant](#)
2. [Controlled Substance Authorized Personnel](#)

VI. [Security](#)

1. [Facility Security](#)
2. [Schedule-I Controlled Substances](#)
3. [Schedule II-V Controlled Substances](#)
4. [Tips for Securing and Storing Controlled Substances](#)
5. [Personnel Security, Background Checks & Employee Screening](#)

VII. [Controlled Substances Inventory & Record Keeping](#)

- A. [Introduction-Summary List of Required Documentation Records](#)
- B. [Acquisition/Ordering/Receipt Records of Controlled Substances](#)
- C. [Inventory Records Review](#)
- D. [Initial Inventory](#)
- E. [Biennial Inventory](#)
- F. [Ongoing/Continuous Records](#)
 1. [Individual Controlled Drug/Substance General Inventories](#)
 2. [Records of Use-Dispensing of Controlled Substances](#)
 3. [Records of Disposal/Procedures for Disposal](#)

VIII. [Purchasing Controlled Substances](#)

1. [General Information](#)
2. [Veterinary Use Only Controlled Substances and Henry-Schein, Lexington, KY.](#)
3. [DEA Form-222 for Schedule-I & Schedule-II Controlled Substances](#)

UK-Researcher Guidelines for DEA Controlled Substances (2015-v1)

4. [DEA Controlled Substance Ordering System \(CSOS\)](#)
5. [Compounding Pharmacies and Long-acting or Slow-release Buprenorphine](#)

IX. [Theft, Loss, Breakage, Spillage, In-transit Loss, Orphaned, and Registrant to Registrant Transfers of Controlled Substances](#)

1. [Theft or Loss](#)
2. [Breakage or Spillage of Controlled Substances](#)
3. [In-transit Loss](#)
4. [Orphaned Controlled Substances](#)
5. [Registrant to Registrant Transfer of Controlled Substances](#)

X. [Step-by-Step Guide for Completing a DEA-225 Research Registration](#)

- A. [DEA-225 On-Line Registration](#)
- B. [DEA-225 Application by Mail](#)
- C. [Timeline for Obtaining a Registration and Purchasing Controlled Substances](#)
- D. [Contact Information-DEA Resident District Office London, KY](#)

XI. [Appendix: Forms and Templates for Controlled Substances Inventory and Record Keeping](#)

1. [Controlled Substance Authorized Personnel Log Form](#)
2. [Controlled Substance Authorized Personnel Screening Form](#)
3. [Authorized Agent Power of Attorney \(POA\) for DEA Forms 222 and Electronic Orders](#)
4. [Controlled Substance Transfer Form](#)
5. [Biennial Controlled Substance Inventory Form](#)
6. [Example of Properly Completed DEA Form-222](#)
7. [New DEA Registration: Initial Controlled Substance Inventory Form](#)
8. [CS: Injectable Drug Formulation Acquisition and Inventory Record \(Blank Form\)](#)
9. [CS: Injectable Drug Formulation Individual Container Dispensing Record \(Blank Form\)](#)
10. [CS: Single \(1\) Dilute Injectable Drug Dispensing Record \(Blank Form\)](#)
11. [CS: Mix \(2\) Injectable Drugs Dispensing Record \(Blank Form\)](#)
12. [CS: Mix \(3\) Injectable Drugs Dispensing Record \(Blank Form\)](#)
13. [CS: Injectable Drug Formulation Acquisition and Inventory Record \(Example\)](#)
14. [CS: Injectable Drug Formulation Individual Container Dispensing Record \(Example\)](#)
15. [CS: Single \(1\) Diluted Injectable Drug Dispensing Record \(Example\)](#)
16. [CS: Mix \(2\) Injectable Drugs Dispensing Record \(Example\)](#)
17. [CS: Mix \(3\) Injectable Drugs Dispensing Record \(Example\)](#)

UK-Researcher Guidelines for DEA Controlled Substances (2015-v1)

XI. (Continued) Appendix: Forms and Templates for Controlled Substances Inventory and Record Keeping

18. [CS: Solid Formulation \(Powder/Pill/Patch\) Acquisition & Inventory Record \(Blank Form\)](#)
19. [CS: Solid Formulation \(Powder/Pill/Patch\) Individual Container Dispensing Record \(Blank Form\)](#)
20. [CS: Solid Formulation \(Powder/Pill/Patch\) Acquisition & Inventory Record \(Example\)](#)
21. [CS: Solid Formulation \(Powder/Pill/Patch\) Individual Container Dispensing Record \(Example\)](#)
22. [Example: DEA Questionnaire for New DEA Researcher Registration \(pgs. 45-47\)](#)

UK-Researcher Guidelines for DEA Controlled Substances (2015-v1)

I. Introduction-Controlled Substances Guidelines for Researcher Registrants

1. General Information-Reasons for Guideline: Controlled substances (CS) are any drugs or chemicals whose possession and use are regulated under the United States Controlled Substances Act (CSA). The U.S. Drug Enforcement Administration (DEA) administers the federal law. Controlled substances include anabolic steroids, chemicals used in the production or synthesis of controlled substances, and those with stimulant, depressant, or hallucinogenic effects on the central nervous system that can promote abuse or physiological/psychological dependence. Because of their potential for abuse, controlled substances have specific regulatory requirements for their acquisition, storage, use, and disposal.

This document has been prepared to assist UK researchers in the process of completing the **DEA-225** application form to obtain a controlled substance researcher registration and to provide guidance concerning a registrant's responsibilities for acquiring, storing, documenting inventory, and dispensing controlled substances in compliance with Federal regulations. University employees and other individuals covered by this guide must follow all applicable regulations to ensure the safe handling, and prevention of illegal diversion of controlled substances. Research uses of controlled substances include: (1) animal anesthesia, analgesia, restraint, or experimentation; (2) chemical or physical analysis including quantitation, and (3) synthetic chemistry involving the development of new drugs. This guidance is designed to ensure compliance with federal regulations and does not impose additional requirements.

Exceptions: These guidelines do not apply to controlled substances dispensed by a practitioner to a patient in the course of professional practice as authorized by his or her license. Nor does it cover teaching activities performed within a clinical environment. These activities must comply with Drug Enforcement Agency regulations applicable to practitioners and pharmacies.

2. Additional Reference Materials about Controlled Substance Regulations and Federal Agencies

Federal Government: Complete information for the current or revised DEA regulations and policies is available at the United States Department of Justice DEA Website: [DEA-Homepage](#) and [DEA Office of Diversion Control](#). Principal investigators and their staff using controlled substances should familiarize themselves with the Code of Federal Regulations ([Code of Fed Regs.](#)) regarding controlled substances that include:

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. The CSA is a federal law and each state may enact stricter laws, but at a minimum each state must enforce the CSA ([Title 21 US Code-Controlled Substance Act](#))
2. Code of Federal Regulations, 21CFR Parts 1300-1399; and 21 CFR Parts 1308 - Schedules of Controlled Substances. Outlines regulations used by the federal DEA administrators to enforce the CSA ([Title 21 CFR Parts 1300-1399](#)).

3. The DEA District Office overseeing the University of Kentucky is located in London, KY.
[DEA Detroit Division Offices](#)

150 Hal Rogers Drive
P.O. Box 5065
London, KY 40745

Diversion Number: (606) 862-4500
Diversion Fax: (606) 862-8296

UK-Researcher Guidelines for DEA Controlled Substances (2015-v1)

II. List of Definitions Used in this Document (Adapted from Univ.of Iowa Office of Animal Research: [University of Iowa OAR CSG](#)).

1. **Authorized Agent:** An individual who has the complete trust of a DEA registrant. An authorized agent can be given power of attorney authorization (POA) by a licensed researcher to oversee the ordering, dispensing and management of controlled substances in their absence. To reduce the risk of drug diversion, only 1-2 individuals in a laboratory should be provided the status of an authorized agent. Regardless of POA authorization the licensed researcher remains ultimately responsible for the management of all controlled substances acquired under their DEA registration. Only a licensed researcher and their authorized agent(s) should have access to the safe or locked cabinet where *significant* inventories of controlled substances are stored. Only authorized agents are permitted to know the licensed researcher's registration number and to order controlled substances on their behalf.
2. **Authorized Personnel:** are research staff, including graduate students and postdoctoral scholars under the direct supervision of a researcher. In addition to the researcher and authorized agent(s), authorized laboratory personnel may use controlled substances during experiments or treatments of research animals. Authorized laboratory personnel can perform these functions but without access to the safe or cabinet where *bulk* quantities of controlled substances are stored. Licensed researchers or their authorized agent(s) must take responsibility for dispensing limited quantities of controlled substances to authorized personnel for daily use and maintaining unused substances in an appropriate safe or locked cabinet for proper storage. Each licensed researcher is responsible for authorizing specific roles, and providing required training for the proper handling of controlled substances. The registrant must also screen all authorized personnel by having them complete a [DEA Authorized Personnel Screening Form](#).
3. **Controlled Substance Certificate of Registration:** The paper certificate of registration mailed to a registrant by the DEA. The paper 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 inspection. DEA Form-223 is used for registration at Federal or State institutions.
4. **Controlled Substances (CS):** are chemicals that are addictive, can be abused, and/or are illegal to possess. Therefore, the manufacture, possession, use and proper disposal of controlled substances (drugs or other drug products) are regulated by the DEA.
5. **Controlled Substance log/folder:** a notebook, file or folder where transactions of controlled substances (e.g., receipt, use, and disposal) are recorded. Examples of CS inventory and use forms are found throughout this document.
6. **Disposal:** the approved method(s) of discarding a controlled substance that is outdated, contaminated, is waste, or is no longer needed.
7. **Disposition records:** an accurate, continuous and current set of records used to track the purchase, use and disposal of controlled substances.
8. **Practitioner:** an individual registered with DEA to 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 by completing the DEA Form 225 application.
9. **Reverse Distributor:** a third party company registered with the DEA to dispose of controlled substances. Reverse distributors are authorized to receive out-of-date, damaged, or otherwise unusable or unwanted controlled substances, including unwanted bulk controlled substance samples from registered researchers.

UK-Researcher Guidelines for DEA Controlled Substances (2015-v1)

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

11. Registrant: the individual that holds a DEA registration(s) 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 may appoint a subordinate (i.e. power of attorney) to manage the controlled substances and the records; however, the registrant is ultimately solely responsible for assuring proper recordkeeping, storage, and use of controlled substances. Deficiencies or discrepancies in recordkeeping are the responsibility of the registrant.

12. 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.

III. Controlled Substance Schedules

Substances regulated under the U.S. Controlled Substances Act (CSA) are categorized into one of five schedules [DEA CSA Drug Schedules](#). The current list of drugs in each schedule is available at the DEA-Office of Diversion Control website: [DEA Diversion Control CS-schedules](#). Schedule I substances are the most restricted, and Schedule V substances the least.

All controlled substances are labeled with a “C” containing the corresponding schedule number (e.g.):



(Schedule-IV)



(Schedule-II)

The CSA defines the schedules as follows:

Schedule I. (*No Accepted Medical Use*)

Schedule I: Drugs, substances, or chemicals with no currently accepted medical use and a high potential for abuse. Schedule I substances are the most dangerous drugs of all the drug schedules with potentially severe psychological or physical dependence. Researchers requiring Schedule-I drugs must submit a **paper form** DEA-225 (PDF) application and follow the protocol found in [21 CFR 1301.18](#). You *cannot* apply online for your initial application. Some examples of Schedule I drugs are: heroin, LSD, marijuana, peyote and 3,4-methylenedioxymethamphetamine (“Ecstasy”). A separate DEA-225 registration (i.e. different from a DEA-225 research registration application for schedule II-V) is required for Schedule-I drugs.

UK-Researcher Guidelines for DEA Controlled Substances (2015-v1)

Schedules II-V. (*Accepted Medical Use*)

Schedule II. High potential for abuse; a currently accepted use in treatment in the United States, or currently accepted medical use with severe restrictions; abuse may lead to severe psychological or physical dependence. Some examples of Schedule II drugs are: cocaine, methamphetamine, methadone, hydromorphone (Dilaudid), meperidine (Demerol), oxycodone (OxyContin), fentanyl, Dexedrine, Adderall, and Ritalin. Sodium pentobarbital anesthetics (Nembutal®) and Sodium Pentobarbital based euthanasia solutions (Fatal-Plus® and Pentasol®). Schedule II drugs are ordered using a DEA-222 form.

Schedule III. Potential for abuse less than Schedule I or II substances; currently accepted medical use in treatment in the United States; abuse may lead to moderate or low physical dependence or high psychological dependence. Some examples of Schedule III drugs are: Combination products with less than 15 milligrams of hydrocodone per dosage unit (Vicodin), Products containing less than 90 milligrams of codeine per dosage unit (Tylenol with codeine), buprenorphine, ketamine, Telazol®, anabolic steroids, and testosterone. Combination phenytoin and sodium pentobarbital mixtures used for veterinary euthanasia (Beuthanasia-D®, and Euthasol®).

Schedule IV. Low potential for abuse relative to Schedule III; currently accepted medical use in treatment in the United States; abuse may lead to limited physical or psychological dependence relative to Schedule III. Examples of Schedule IV drugs are: Xanax®, Midazolam, Butorphanol, chloral hydrate, Soma®, Darvon®, Darvocet®, Valium, Ativan®, Talwin, and Ambien®.

Schedule V. Low potential for abuse relative to Schedule IV; currently accepted medical use in treatment in the United States; abuse may lead to limited physical or psychological dependence relative to Schedule IV. Schedule V drugs are generally used for antidiarrheal, antitussive, and analgesic purposes. Some examples of Schedule V drugs are: cough preparations with less than 200 milligrams of codeine per 100 milliliters (Robitussin-AC), Lomotil, Motofen, Lyrica, Parepectolin, and ephedrine.

IV. General Information: Controlled Substances Research Registration and Registrant Requirements

1) Registration Requirements for Kentucky: In Kentucky only individuals with a current federal Drug Enforcement Agency (DEA) registration can order controlled substances. At this time there is no state board of pharmacy license or registration required. Each principle investigator using controlled substances must obtain their own Federal DEA registration.

2) Separate Registrations for Different Business (Laboratory) Locations: [Title 21 CFR 1301.12](#) “A separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, imported, exported, or dispensed by a person.”

Each PI must have a DEA registration for their principal place of business (laboratory) if controlled substances are delivered, stored and administered at that location. If a PI has more than one such use location then each site must have a *separate* DEA registration. All controlled substances obtained for a specific location must be ordered using its corresponding DEA registration.

The business address and laboratory room number on the DEA registration must match the exact address where controlled substances will be delivered and stored. Vendors and package delivery companies will only ship to the location printed on the DEA Form-223 Certificate of Registration. Personnel working for delivery companies must deliver controlled substances directly to the registrant or to an *authorized agent* of the registrant at that address.

UK-Researcher Guidelines for DEA Controlled Substances (2015-v1)

3) Registration Options (Non-Practitioner Researcher and Practitioner Researcher):

Non-Practitioner Researchers must complete a DEA-225 researcher application to obtain a DEA-223 research registration for their laboratory location.

Practitioner Researchers holding a current DEA practitioner registration (for prescribing) must choose one of the following options: **(a)** Change the address on their current DEA practitioner registration to the address of their laboratory where controlled drugs are stored and administered, or **(b) Preferred option**-Obtain/complete a separate DEA 225 researcher registration application.

For practitioners with a DEA dispensing registration [Title 21 CFR 1301.13 \(e\)](#) provides guidance concerning *coincident activities* and the conduct of research or instructional activities with controlled substances. Most animal research using controlled substances in approved UK-IACUC protocols is considered a coincidental activity.

4) Schedule I Registrations: Individual registration and licensing is required for the use of Schedule I controlled substances. A separate DEA-225 registration (i.e. different from a DEA-225 practitioner or researcher registration for schedule II-V substances) is required to obtain Schedule I drugs. Researchers requiring Schedule I drugs must submit a **paper form** DEA-225 (PDF) application and follow the registration protocol found in [21 CFR 1301.18](#). You cannot *apply online* for your initial Schedule I application. Schedule I substances may not be issued to anyone other than the registrant, or used by anyone other than the registrant. If additional personnel need to use Schedule I substances, they must individually register with the DEA.

5) Schedule II-V Registrations: For new Federal registrations for Schedule II-V drugs researchers and analytical laboratory personnel must initially complete **DEA Form-225**. **Form 225-A** is completed for annual renewal applications. Because the University of Kentucky is a state institution, UK personnel are exempt from the Federal registration fee. The preferred option by the DEA is for registrants to complete applications on-line. See [Section-X](#), for “Step-by-Step” instructions to complete the on-line DEA-225 Research Registration application.

6) IACUC Protocols: When completing the on-line application the DEA does not request information about animal use protocols. However, they may request to see a copy of a protocol(s) during an on-site inspection. If a PI has more than one protocol then all protocols may be covered under the same registration.

7) Annual renewals of research registrations are due on the anniversary of the initial approval. Renewal notices are mailed by the DEA 45 days prior to the expiration date to the last address listed in the DEA’s files. The U.S. Postal Service will not forward a renewal application to a new address. Be sure to contact the DEA if you have/need to change your business or mailing address during an approval period (see also: “Changes to registration”, below). *At the anniversary date you have 30 days to renew the registration, and if not, then it will be automatically suspended.* The procedures for applying for the annual renewal are the same as the original registration (See: [Section-X](#), for guidance on completing the “DEA-225-a” Research Registration renewal). A re-inspection of the holding location is not routinely performed.

8) Changes to a Registration: If you need to make a change to an approved registration (e.g. Name Change, Schedule Change, Drug Code Change, Address Change) this can be done on-line by submitting a registration change request (See: [DEA Registration Tools](#)). *Please note that changes will become effective only after DEA approval and that a DEA field agent may contact the registrant prior to granting approval.* Once approved, a new Certificate of Registration will be mailed to the registrant. New DEA-222 order forms must also be requested if changes were made for controlled

UK-Researcher Guidelines for DEA Controlled Substances (2015-v1)

substance schedules 2 or 2N. DEA-222 order forms can be requested online at: [DEA-222 Form](#). Unused DEA-222 order forms with the old drug schedule information *must* be returned to the DEA field office. Indicate that the drug schedules were updated and the old 222 forms are being returned for destruction.

9) Relinquishing a Registration: If a registrant wishes to relinquish their registration prior to the annual renewal date then they must either complete **DEA Form-104** and send this to their local DEA field office, or contact the local DEA office directly to inform them of your intent to do so. If a registrant no longer requires the use of controlled substances or is no longer a UK employee then the registrant must dispose of the controlled substances, or transfer them to another *approved* registration (described in sections [Disposal](#) and [Transfer](#)). DEA regulations do not require any further action by DEA's Administrator to terminate a DEA registration after the submission of a voluntary surrender, and treats the submission of such a surrender form as an immediate termination of the registration. The only further action taken by DEA is the entry of the surrender into DEA's registration database. The DEA will typically request that the original certificate and any unused DEA order forms be returned to them.

10) Relocation to another Institution: If a registrant is relocating and plans to continue research at another institution, then a new registration is required for that location even if the same controlled substances will be used and for the same purpose. Contact your local DEA office to discuss all the available options in this circumstance.

V. Responsibilities of Controlled Substance Registrants and Authorized Personnel

- 1) **Controlled Substance Registrant:** Each Principal Investigator authorized to use controlled substances is responsible for understanding and complying with all regulations of the DEA regarding registration, purchase, use, and proper disposal of controlled substances used in their research. The PI retains all liabilities for loss, theft, or misuse of any controlled substance acquired through their registration. For complete information see [US DOJ DEA](#)

In summary the registrant will:

- a) Ensure compliance with all federal laws
- b) Ensure safe, secure storage of controlled substances
- c) Ensure that all employees with access to controlled substances are appropriately screened
- d) Ensure that all required records for inventory, dispensing, and disposal of controlled substances are maintained
- e) Report significant losses or theft of controlled substances to the DEA
- f) Assure legal and proper disposal of controlled substances
- g) Ensure that appropriate procedures are followed when performing a drug transfer

- 2) **Controlled Substance Authorized Personnel:** must perform research activities under the supervision of the registered PI or their authorized agent. Authorized personnel must complete the daily use forms accurately and ensure secure storage of unused chemicals and partially used vials at the end of the day.

In summary authorized personnel:

- a) Ensure safe, secure storage of controlled substances
- b) Complete DEA employee screening security questions
- c) Maintain all required records to track the use and disposal of controlled substances
- d) Promptly report any theft or significant losses of controlled substances

UK-Researcher Guidelines for DEA Controlled Substances (2015-v1)

VI. Security & Storage of Controlled Substances

DEA registrants must provide effective controls and procedures to guard against theft and diversion of controlled substances [Title 21, CFR.1301.71\(a\)](#). Efforts must be focused on physical security, entry procedures, limiting access, and appropriate record keeping to prevent diversion. Researcher and Practitioner security and storage requirements are outlined in the [DEA Practitioners Manual \(Section III – Security Requirements\)](#) and [Title 21, CFR.1301.75](#)

1. Facility Security Requirements: (See also: [DEA Controlled Substances Security Manual](#)). The following factors should be considered when evaluating a secure storage location:

- Type and form of controlled substances used.
- Quantity stored
- Location of the storage area (high or low risk crime area)
- Amount of unsupervised public access to the storage location
- Number of personnel having access to a storage location and the adequacy of their supervision.

The security of a particular drug storage area can only be deemed adequate by a DEA agent by an on-site evaluation, which may identify circumstances requiring alternative drug storage. The most typical recommendation is the purchase of a steel, wall-mountable drug cabinet, narcotics box, or safe designed for the purpose of storing controlled substances. Alternatively, a drug lock box secured in a locked drawer or cabinet may be sufficient. Locks may be combination or key type (key preferred). Combinations or keys must not be readily accessible to individuals not on the registrants “Authorized Users List”. If key locks are used, then the two locks must be keyed differently, the two keys must not be stored together (not on the same ring) and both keys must be safeguarded and not accessible to unauthorized users.

2. Schedule I: Registrants authorized to possess Schedule I agents must store these controlled substances in a safe or steel cabinet equivalent to a U.S. Government Class-V security container.

3. Schedule II through V: According to Federal law, researchers are required to store stocks of Schedule II through V controlled substances in “a securely locked, substantially constructed cabinet that is only accessible to authorized personnel”. They cannot be stored in something that can be readily picked-up and carried off. Additionally, Federal law requires that all registrants provide effective controls and procedures to guard against theft and diversion of controlled substances. All controlled substances should be kept locked in their storage locations except for the time required for authorized staff to remove, work with, and replace them.

4. Useful Tips for Securing and Storing Controlled Substances:

- Keep controlled substances in a cabinet, safe, or lockable container. Secure the safe to the floor, counter, or wall.
- Keep the cabinet in a room with a door that locks. Keep the room locked after hours or when no one is around.
- Keep the cabinet locked at all times, unlocking it only to retrieve or store the drugs.
- Limit access to the cabinet. Issue keys to as few people as possible, and only authorized users. Alternatively, keep one key in a secure location such as a wall mounted key safe (e.g. Google Search “*Images + key safe*”) and restrict access to only authorized users (the combination to most key safes can be easily changed, when/if needed). For combination lock boxes, whenever anyone who knows the combination is terminated from employment then the combination should be changed.

UK-Researcher Guidelines for DEA Controlled Substances (2015-v1)

- Some controlled drugs must be **refrigerated** (e.g. some preparations of Buprenorphine and Telazol®) for which a variety of refrigerator lock boxes are available (e.g. search Google with terms “Images + refrigerator lock box”). Ideally, the refrigerator or freezer should also be locked.

5. Personnel Security-Background Checks & Employee Screening:

A background check is conducted by the DEA when an individual applies for a controlled substance registration.

The DEA also advises all registrants and employers to assess and determine the likelihood of an employee committing a drug security breach. Screening questions have been approved by the DEA for use by non-practitioners to authorize personnel access to DEA controlled substances [21 CFR 1301.90: Employee Screening Non-Practitioners](#). Registrants must maintain the answers to these screening questions for authorized personnel in a secure place, beyond the purview of unauthorized personnel (See also, “[Authorized Personnel DEA Screening Form](#)”, and “[Controlled Substance Authorized Personnel Signature Log](#)”).

The DEA also provides the following restrictions for employment by Registrants of an agent or employee who has access to controlled substances:

- Any person who has been convicted of a felony offense related to controlled substances
- Any person who has been denied a DEA registration
- Any person who has had a DEA registration revoked
- Any person who has surrendered a DEA registration for cause

A registrant may only authorize screened personnel to use substances in Schedules II-V for approved activities. Schedule I substances cannot be issued to, or used by anyone except the registrant. If additional personnel need to use Schedule I substances, they must individually register with the DEA.

VII. Controlled Substance Inventory and Record Keeping

A. Introduction: Registrants are required to maintain records of their controlled substances in accordance to Federal law as mandated by Title 21 CFR, section 1304.22 [21 CFR 1304.22 Records & Reports of Registrants](#). ***All required records must be kept for a minimum of 2 years*** from the last transaction date recorded. Per DEA guidance, Records for Schedule I or II drugs “must be kept *separate* from all other records and be readily retrievable and available for review/inspection”. Records for Schedule III, IV, and V drugs should be kept separate and be “readily available” for review. “Readily available” means that requested records will be kept in such a manner that they can be separated from all other records in a reasonable time. The records should be kept in or near the primary work area, separate from all other records and documents, and available for inspection during working hours. In the event of an audit by the DEA you will need to produce these records. Researchers must maintain proper documentation records of controlled substance use by tracking their purchase, daily use, and disposal. The current Form-223 registration(s) must be available near where the controlled substances are stored and must be readily available for inspection by the DEA. Each registrant must maintain a complete and accurate accounting of all controlled substances, from the time they are ordered until the time they are used or disposed. The law requires maintenance of the following records: (1) Records of Receipt, (2) Records of Use (including loss or theft), (3) Records of Disposal, and (4) Biennial Inventory.

UK-Researcher Guidelines for DEA Controlled Substances (2015-v1)

The following is an extended list of required documents or documentation:

1. DEA-223 Form Certificate of Registration
2. [Authorized Agent Screening Statement\(s\)](#)
3. Acquisition and ordering invoices (signed and dated supplier invoices or packing slips)
4. [DEA-222 Forms](#) (i.e. if schedule II drugs are used, and includes: all used, voided, and unused forms)
5. Inventory forms
 - a. [Initial Inventory](#)
 - b. [Biennial Inventory](#)
 - c. [General Inventory](#) (for each controlled substance and form in use)
6. Usage and Administration Records
 - a. [Multiple dose individual drug use logs](#)
 - b. [Diluted individual drug use logs](#)
 - c. [Mixed drug use logs](#)
7. Records of [Transfer of controlled substances](#) between licensed registrants
8. Disposal Records ([DEA Form-41](#))
9. Reports of Loss or Theft ([DEA Form-106](#))
10. [Authorized Agent-Power of Attorney Designation](#)

B. Acquisition/Ordering/Receipt Records of Controlled Substances: Each registrant must maintain complete and accurate purchasing records of controlled substances for each registered location. When acquiring controlled substances the following information must be kept in the controlled substance log (see also: [“CS: Injectable Drug Formulation Acquisition and Inventory Record \(Example\)”](#)).

1. Name of the substance (e.g. Ketamine).
2. Form, concentration or weight, and quantity per container (e.g. 100 mg/ml, 10 ml vials)
3. Number of containers acquired
4. The date the controlled substance was acquired and initials of person receiving (must be the registrant or their designated authorized agent/power of attorney).
5. The name and address from where the substance was acquired (vendor)
6. For Schedule I-V controlled substances, the Registrant or Authorized Agent (if delegated by a Power of Attorney, see below in section “Purchasing”) may receive controlled substances.
7. When receiving Schedule I or II substances a signed Form 222 is used. The bottom (blue colored) page is retained for your controlled substance records. The remainder of Form 222 (i.e. top 2 pages cream & green) is remitted to the vendor for their records. This form must be maintained in the registrant’s Controlled Substance files to serve as the source document for receipt of the controlled substance(s). For additional information on use/completion of Form 222 see [“Purchasing”](#), below.
8. Special Note about ***in-transit losses*** when receiving orders of controlled substance: The supplier/distributor is responsible for in-transit losses (i.e. ***unless you sign for it***). Hence, do not sign-off on the receipt of drugs until you verify the delivered articles correspond exactly to information on the receiving invoice. This also applies to any drugs that are ***damaged or broken in transit*** (do not sign off for the damaged articles for which the responsibility for documenting the breakage, or spillage will stay with the supplier/distributor).

UK-Researcher Guidelines for DEA Controlled Substances (2015-v1)

C. Inventory Records Review: Inventory records must be maintained at the registered location for two years from the date the inventory was completed. Inventories for individual controlled drug formulations, initial site registration and biennial site registration must include the following information:

1. Name, address and DEA registration number of the registrant/licensee
2. For Initial and Biennial site inventories-the Date and Time the inventory was performed (should be at either the beginning or end of the day)
3. Signatures of the registrant/licensee or authorized agents responsible for taking the inventory
4. For each controlled substance in finished form the inventory must include:
 - Name of each controlled substance
 - Finished form of the substance (e.g., 5-mg tablet or 5-mg/ml concentration)
 - Number of units or volume of finished form in each container (e.g., 25-tablet bottle or 50-mL vial)
 - Number of containers of each finished form (e.g., 5 25-tablet bottles or 2 50-mL vials)
5. For damaged, defective or impure substances, substances awaiting disposal, substances held for quality control purposes, or substances maintained for compounding, the inventories must include:
 - Name of the substance
 - Total quantity of the substance to the nearest metric unit weight or the total number of units of finished form
 - Reason for the substance being maintained by the registrant and whether such substance is capable of use in the manufacture of any controlled substance in finished form
6. When determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, do the following:
 - If the substance is listed in schedule I or II, make an exact count or measure of the contents
 - If the substance is listed in schedules III-V, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case an exact count of the contents must be made.
 - Schedule I & II controlled substance inventories must be separated from inventory records of schedule III-V substances.

D. Initial Inventory: A separate inventory for each location must be performed on the date the registrant/licensee first engages in any activity covered by his or her state license and DEA registration. Initial inventories are usually zero. An initial inventory must be taken for any newly scheduled substance that was not previously listed on any schedule. The substance should then be accounted for on the normal annual/biennial inventories. A specific form is not required for the inventory. The following form can be used or modified for this purpose [“New DEA Registration: Initial Controlled Substance Inventory Form”](#).

E. Biennial Inventory (Required by the DEA). The DEA requires a physical inventory of all controlled substance to be conducted every two years. The inventory may be taken on any date within two years of the previous inventory date. This inventory must be kept at the registered site for two years after it is taken. It is not sent to the DEA. The following information should be included in the inventory (See also: [“Biennial Controlled Substance Inventory Form”](#)).

- Name of the substance (e.g. Ketamine)
- Form and quantity per container (e.g. 100 mg/ml, 10 ml vials)
- Number of containers on hand

UK-Researcher Guidelines for DEA Controlled Substances (2015-v1)

- Damaged, defective, expired, or impure substances awaiting disposal must be included in the inventory until the time they are disposed. **

**If impure or unusable substances are on hand (e.g. ketamine-xylazine cocktail or expired drugs), they too must be included in the inventory. List the name of the substance, the quantity, the reason it is being kept, and whether the substance could be used in the manufacture of any controlled substance.

F. Ongoing & Continuous Records:

1. Individual Controlled Drug/Substance General Inventories

A continuous general inventory is required to track the acquisition, current on-hand stocks, administration, and transfer to use logs, transfer to other registrants, and transfer for disposal of each individual formulation of a controlled substance.

- A separate general inventory log should be created for each stock of drug (e.g. Ketamine-HCl injectable, 100mg/ml, 10 ml vials) and its associated strength or container size. (see: ["CS: Acquisition & Inventory Record"](#)).
- Schedule I and II records must be separate from schedule III-V records.
- An individual controlled substance container should be transferred from a general inventory log to separate usage log for tracking doses delivered from the same container.
- Individual vials or containers should be assigned a unique inventory number or code upon receipt to assist with tracking
- Registrants/licensees may use their own form provided a substance can be tracked from acquisition to research subject, experimental endpoint, transfer, or disposal.

2. Records of Use-Dispensing of Controlled Substances

The following information must be recorded when drugs are used for teaching, research or surrendered for disposal:

- Name of individual patient/animal/cage(s) of animal(s) it was dispensed
- Date of dispensing or disposal
- Volume or quantity dispensed*
- Name or initials of dispenser
- Quantity remaining in inventory

* **Inventory Control and Labeling Containers of Diluted or Mixed Drugs:** for controlled drugs removed from their original container and diluted or combined (e.g. "ketamine/xylazine cocktail") then the new container must be labeled with a new inventory control number, the final concentration, amount in the container and expiration date. A Record of use dispensing form should then be created to log use of the cocktail (see: ["Mixed Drug Use Log"](#)).

3. Records of Disposal/Procedures for Disposal

Proper disposal of controlled substances by DEA registrants that are not used before reaching the manufacturer's expiration date, or those no longer needed must be done in a lawful manner. Flushing drugs down the sink or injecting them into a dead animal carcass is an unacceptable and unlawful practice. Foremost, if not using a DEA

UK-Researcher Guidelines for DEA Controlled Substances (2015-v1)

licensed reverse distributor, then *do not dispose of any unused controlled substances without authorization from the DEA*. For more information on this subject please see: [DEA Registrant Drug Disposal](#). To facilitate compliance with the law the University of Kentucky-Environmental Management Department (EMD) has arrangements with a DEA licensed reverse distributor to assist with the management of expired or unwanted controlled substances. As part of its service mission to the University, the EMD pays for the contractor's services, will provide coordination between faculty and the contractor and will make available its facility for the safe transfer of the substances. To get additional details on making arrangements for this service please contact Brian Butler (brianbutler@uky.edu; 859-323-5005) or the Environmental Management Department [UK-EMD](#). If a registrant does not desire to use EMD disposal then they must file a plan with the DEA using Form-41. For more information see the following: 1) [DEA Registrant Drug Disposal](#) and 2) [DEA Form-41](#) and 3) [Registrant Record of Controlled Substances Destroyed - DEA Form 411](#).

Disposal of Controlled Substances originating from Analytical/Production processes, or inter-mixed with hazardous chemical waste:

- Controlled substance waste (i.e. used, expired, partially consumed, and/or materials 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.
- Any researcher who wants to dispose of controlled substances that are mixed with hazardous chemical waste must consult with UK-EMD to ensure compliance with Research Conservation and Recovery Act (RCRA) regulations [US-EPA RCRA](#)

VIII. Purchasing Controlled Substances

1. General Information: Researchers must purchase controlled substances using their Federal DEA registration number(s). If more than one registration is held (e.g. different work site locations) then the registration number used to purchase drugs for each location must maintain site-specific correspondence. DEA regulations require a *separate* registration for *each* location where controlled substances are received, stored and utilized. Clinicians who receive or store controlled substances in their practice cannot use the same registration to order controlled substances for their laboratory if these are at different addresses/locations. Controlled substances must be purchased using a DEA registration number from a DEA approved distributor(s). All purchases must be done in compliance with DEA regulations. Orders for Schedule I and II controlled substances must be accompanied by DEA Form-222 (see additional information below).

2. Veterinary Use Only Controlled Substances and Butler-Schein Lexington, KY: Some veterinary-only use controlled substances (e.g. Tiletamine/Zolazepam [Telazol®] and euthanasia solution [Fatal-Plus®, Beuthanasia-D®, and Euthasol®]) are not available through human hospital or pharmacy distributors. In Lexington, UK researchers may purchase these substances from a veterinary distributor, most commonly Butler-Schein Animal Health. Additional information for Butler-Schein can be found at the following link: [Henry Schein Animal Health](#). The Lexington area Butler-Schein Distribution Center (859-233-1801) is located at 920 Citation Drive, Lexington, KY, 40511. To set-up a business account with Henry-Schein to source controlled substances (e.g. Buprenorphine, Ketamine, or Euthanasia solutions) it is best to contact the local Lexington office first (as opposed to National) as the personnel at the local branch are familiar with University of Kentucky's function as a research center.

3. DEA Form-222 for Schedule I & II Controlled Substances: Because Schedule I & II listed drugs have a high potential for abuse the DEA requires a special form to be used when ordering these controlled substances (e.g. Barbiturates-sodium

UK-Researcher Guidelines for DEA Controlled Substances (2015-v1)

pentobarbital [Nembutal®], Narcotics-such as oxycodone or fentanyl, and stimulants such as amphetamine, methamphetamine, or methylphenidate). This is DEA Form 222 and is only available by request from the DEA. For drugs listed under Schedules III-V, Form-222 is not necessary.

When ordering Schedule I or II CS's a completed Form-222 must be presented when placing an order with a distributor. Form-222 must be signed by the registrant of the DEA License or by a person authorized as a **power of attorney** to sign on behalf of the registrant. For information on designating a power of attorney (POA) see the following: [21 CFR §1305.05 Power of attorney](#) and [CSOS POA](#) (POA Form). Following completion of a Form-222 (in ink), the registrant submits the top copies #1 (cream) and #2 (green) to the supplier and retains the bottom copy #3 (blue). Particular attention to detail must be made when completing Form-222 as any alterations, erasures, or changes in description will be a cause for rejection. In the event an error is made then the registrant must void the form(s) and retain them in their file together with all other DEA Form-222 records. The forms are individually and consecutively numbered and all must be accounted for, thus any voided DEA-222 forms must not be discarded. It is also imperative to keep DEA-222 forms in a secure location to prevent unintended use or theft. An example of a properly completed DEA-222 form is found here ([DEA-22 Form Completed](#)).

The DEA also has a FAQ's link about Form 222 at [DEA Form 222](#). To request DEA-222 forms go to the "Request Page" at [DEA-222 Order Form Request](#) and complete the online application. Forms may also be obtained by calling the DEA Headquarters Registration Unit toll free at 1-800-882-9539. Forms are typically mailed within 3 working days.

4. DEA Controlled Substance Ordering System (CSOS): An additional option in lieu of using paper 222 forms is to inquire about enrolling in the DEA Controlled Substance Ordering System (CSOS) that allows for the secure electronic transmission of Schedule I-V controlled substance orders without the supporting paper DEA-222 form. An electronically transmitted order contains a digital version of the traditional written signature through the use of a computer file known as a "Digital Certificate". For more information see [Henry-Schein CSOS](#).

5. Compounding Pharmacies and Long-acting or Slow-release Buprenorphine** For investigators using these preparations the procedures for ordering depends on the specific product being used. For **Buprenorphine-SR™** or **Buprenorphine-SR-Lab™** sold by the compounding pharmacy ZooPharm or SR-Veterinary ([SR-Veterinary](#)) the DEA requires that it be obtained only by the prescription of a licensed veterinarian. If you need this buprenorphine formulation contact a DLAR veterinarian to obtain a prescription (on-line form faxed to SR-Veterinary Technologies). Please note that compounding pharmacies also sell other drugs and analgesic preparations. As per FDA and or DEA requirement's such drug preparations can *only* be obtained with the use of a *prescription* ordered by a licensed veterinarian. Contact a DLAR veterinarian if you have any questions about such compounded drug preparations.

Another long-acting buprenorphine-HCl preparation, **Animalgesics® for Mice** and **Animalgesics® for Rats and Mice** ([Animalgesics Labs](#)) are registered indexed products by the FDA. However, as of June 2015 these previously available products have been temporarily withdrawn from the market (first released for a short time in 2014). The company indicates a potential return of availability of these products in the fall of 2015. Because these drugs are registered for use in mice and rats and were evaluated under the FDA's Minor Use and Minor Species Animal Health Act (MUMS) when they become available they can be ***sold directly to DEA licensed registrants*** having approval to use buprenorphine-HCL (no veterinary prescription required).

****Before using any of these long-acting buprenorphine preparations DLAR veterinarians strongly recommend that you first consult with them to discuss appropriate dosing and their experience with idiosyncratic effects on different research models.**

IX. Theft, Loss, Breakage, Spillage, In-Transit Loss, Orphaned, and Registrant to Registrant Transfers of Controlled Substances

UK-Researcher Guidelines for DEA Controlled Substances (2015-v1)

1. Theft or Loss: All thefts or significant losses of controlled agents **must** be reported to the DEA immediately upon discovery of the theft or loss. The registrant shall notify the local DEA office in writing of the theft or significant loss within ***one business day of discovery***. Notification is accomplished by completing and filing a DEA Form 106, Report of Loss or Theft. The form is found on-line at [Theft or Loss of CS Form 106](#) or [Instructions for Form DEA-106](#) or may be obtained from your local DEA office. If the circumstances regarding the theft or loss need clarification before the form can be completed, the registrant can make an initial report via telephone or some other means and file the completed form as soon as the circumstances are known. Additionally, when a determination is made of probable theft or illegal diversion has occurred then the UK Police Department [UK-Police](#) should also be notified.

2. Breakage or Spillage of controlled substances: Breakage of controlled substances does **not** constitute a "loss" of controlled substances. When there is breakage, damage, spillage or some other form of destruction, any ***recoverable*** controlled substances must be disposed of according to DEA requirements. Damaged goods may be disposed of through a "reverse distributor" or by a DEA approved process. The DEA recommends that any registrant seeking to dispose of controlled substances first contact the nearest DEA Diversion Field Office for disposal instructions. In no case should drugs be forwarded to the DEA unless the registrant has received prior approval from the DEA. If the breakage or spillage is **not** recoverable, the registrant must document the circumstances of the breakage in their inventory records. Two individuals who witnessed the breakage must sign the inventory records indicating what they witnessed. The submission of a **DEA Form 41, Registrants Inventory of Drugs Surrendered** is not required for non-recoverable controlled substances.

3. In-Transit Loss: When a controlled substance shipment/order is received it should be immediately inspected for damage and the items received verified to correspond to the quantities/amounts listed on the receiving invoice. The supplier/distributor is responsible for any in-transit losses (*i.e. unless you sign for it*). Therefore, do not sign-off on a receipt of drugs until you verify the delivered articles correspond to information on the receiving invoice. This also applies to any drugs that are damaged or broken in-transit. Similarly do not sign off for any *damaged articles* so that the responsibility for documenting the breakage, spillage, damage stays with the supplier/distributor.

4. Orphaned Controlled Substances: When a controlled substance is found but the "owner" is not known (e.g. a PI who has retired or left the university, or a substance(s) purchased prior to being classified as a controlled agent) then it is classified as "orphaned". In these circumstances an official from the responsible department must take temporary possession of the "orphaned" controlled substance(s) and then notify the DEA to determine an appropriate disposition/disposal plan. For any such orphaned substances the following information should first be ascertained prior to contacting the DEA: (a) DEA Registration number (if available); (b) the location where the drugs were found (lab number, building); (c) name of the controlled substance(s); (d) content of each individual container; (e) number of containers; and (f) size of each container. An approved disposal plan can then be determined by the DEA.

5. Transfer of controlled substances between principal investigators/registrants is generally discouraged. However, if done then such transfers ***can only be performed if both investigators have an active DEA license that covers the drug(s) being transferred***. Such transfers require proper record keeping that includes the completion of a DEA-222 form for the transfer of Schedule-II substances. Prior to such transfers it is recommended that the local DEA office be contacted to ensure that all required documentation is obtained.

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 their controlled substances to non-licensed researchers or other PIs. To do otherwise is considered a diversion of controlled substances and a violation of DEA rules and regulations. Each PI who needs to use controlled substances in his/her research is required to register with the DEA for a specific research location.

UK-Researcher Guidelines for DEA Controlled Substances (2015-v1)

The Following are some general Guidelines and Procedures that must be followed to correctly make a controlled substance transfer between current licensed registrants. Only researchers with active DEA registrations for their laboratories can transfer small amounts of controlled substances to each other. However, the cumulative annual quantity transferred must be kept to less than 5% of a registrant's inventory or annual usage to comply with Federal regulations. If the 5% annual total is exceeded then a separate DEA distributor registration (\$1,500) must be acquired.

The Following Procedures should be done to Lawfully Complete such Transactions:

- 1) Transfers can only be completed between current approved DEA registrants located on the Lexington UK campus.
- 2) Each registrant must have a valid, current DEA registration covering the controlled substance schedule that will be transferred.
- 3) A ["Controlled Substance Transfer Form"](#) must be completed to document the transfer. This form serves the same function of an invoice and must be maintained in the records of the Receiver and Supplier. The following information is required:
 - Date of the Distribution or Transfer.
 - Name, Address and DEA registration number of receiver.
 - Name, Address and DEA registration number of supplier.
 - Name, concentration, and quantity of the controlled substance transferred.
- 3) A DEA-222 form must be used for the transfer of Schedule I or II substances. The Receiver gives copies 1 & 2 to the Supplier. The Supplier retains Copy-1 and must submit Copy-2 to the local DEA office. The receiving registrant must complete Copy-3 and retain it in their DEA-222 form records.
- 4) All transferred drugs must then be appropriately debited from the suppliers inventory/dispensing records, or entered into the receiving registrants master Inventory Log for each transferred controlled substance(s).

UK-Researcher Guidelines for DEA Controlled Substances (2015-v1)

X. Step-by-Step Guide for Completing a DEA-225 Research Registration Application.

To obtain controlled substances an individual must first register with the DEA and obtain a license. There are two ways to obtain a license: apply online or by mail.

(A). **DEA-225 On-Line Registration**– The fastest way to obtain a DEA License is to register online. You will need a Tax ID number and/or Social Security Number.

(1) Log on to: <http://www.deadiversion.usdoj.gov/index.html>

(2) Click on tab “New Application”

(3) Read the directions in the new window. **Do not worry about the following sections:**

a) “**Section 3. State License(s)**” It is mandatory to provide State medical and/or controlled substance licenses/registrations. Failure to provide VALID and ACTIVE state licenses will be cause to declare the application as defective and it will be withdrawn **WITHOUT refund**”, and b) “**Section 5. Payment:** Payment, via this on-line application, must be made with a Visa or MasterCard, American Express, or Discover. **Application fees are not refundable.**” The reasons are explained later.

(4) When completed reading and having the other requested information select “**Form 225**” in “**Select Your Business Category**”

Select Your Business Category	
<input type="checkbox"/> Form 224 -	Practitioners(MD,DO,DDS,DMD,DVM,DPM), Mid Level Practitioners (NP, PA, OD, etc.), Pharmacies, Hospitals/Clinics, Teaching Institutions
<input type="checkbox"/> Form 225 -	Manufacturers, Import/Export, Distributors, Researchers, Dog Handlers, Labs
<input checked="" type="checkbox"/> Form 510 -	Chemical: Manufacturers, Import/Export, Distributors
<input type="checkbox"/> Form 363 -	Treatment Clinics

(5) For “**Select One Business Activity**”, choose “**RESEARCHER (II-V) (\$244/1 yrs)**” from the drop down menu.

Next click “**Begin**”. The online application is divided into six sections.

UK-Researcher Guidelines for DEA Controlled Substances (2015-v1)

Section 1. General Information (Page-1): Complete requested information for: name, address, social security number or tax ID, and phone number. Click “**Next**”. Complete (Page-2), NOTE –on this page you will be given an option to apply for Fee Exemption. Only University of Kentucky researchers may opt for fee exemption (other private enterprises/businesses may not). Check the box, and then click “**Next**”. This will bring up the following screen. Complete as indicated below:

1. Personal Information (Page 3 - Fee Exempt Details)

Please provide the Name, Title, and phone number of the Certifying Official (applicants must not certify themselves).

* Name of Fee Exempt Institution (Must be a Federal, State, or County Agency)

University of Kentucky

* Certifying Official Name (other than applicant)

Your Department Chair

* Certifying Official Title

Their Title

* Certifying Official Phone Number

() - Ex.

By checking the following box, the applicant states that the certifying official listed above has consented to be named on this application for the purpose of certifying the applicant's Fee Exempt status.



I have read the above, and agree.

Fields with a () are required.*

<-Previous

Next->

-Cancel-

Section 2. Activity - Business Activity and Drug Schedule information. Check what drug schedule(s) you will be working under. If you will be using a Schedule II drug (e.g. pentobarbital) you will also need to check the box requesting order forms (i.e. “**DEA Form 222 - Official Order Forms**”). Lists of each Controlled Substances Schedules are available by clicking on “[See Schedules](#)” [Office of Diversion Control CS Schedules](#)

UK-Researcher Guidelines for DEA Controlled Substances (2015-v1)

The following is a list of commonly requested controlled substances

Drug	DEA #	Schedule	Narcotic	Other Names
Amphetamine	1100	II	N	Dexedrine, Adderal
Buprenorphine	9064	III	Y	Buprenex, Suboxone
Butorphanol	9720	IV	N	Torbutrol, Torbugesic
Diazepam	2765	IV	N	Valium
Fentanyl	9801	II	Y	Duragesic, Sublimaze
Ketamine	7285	III	N	Ketaset
Midazolam	2884	IV	N	Versed
Pentobarbital	2270	II	N	Nembutal & Fatal-Plus
Pentobarbital + Phenytoin (euthanasia)	2271	III	N	Euthasol, Pentasol, SomnaSol, Beuthanasia-D
Testosterone	4000	III	N	Android-T, Androlan
Tiletamine/zolazepam	7295	III	N	Telazol

Note: *Xylazine, Acepromazine, Propofol, Isoflurane, Sevoflurane, & Desflurane are not controlled substances.*

Section 3. State License(s) - Information pertaining to current and pending state controlled substance licenses/registrations. Kentucky currently does **not** require a state controlled substance license, *so most researchers can do nothing and simply click and go on to the next section* (if you have an MD, Veterinary, other prescribing license then you can enter this information). However, you must have a separate DEA research registration (for research animal use), that is *separate* from a practitioner DEA prescribing registration.

Section 4. Background Information - Information pertaining to controlled substances in the applicant's background. Answer the 4 questions, then click “**Next**”. The next page prompts you to select Drug Codes for the Schedules you selected in Section2. *Researchers requesting Schedule II-V are only required to report drug codes for Schedule II substances which they manufacture or import, so most can simply click and go on to the next section.*

Section 5. Payment – Since the University of Kentucky is considered a governmental agency, researchers are exempt from paying the application fee. Do not fill anything in and simply click “**Next**”.

Section 6. Confirmation - Confirm the entered information, make corrections if needed, and electronically submit the application and a submission confirmation will be presented. Applicants will be able to print copies for their records. When finished, click to complete the application process.

UK-Researcher Guidelines for DEA Controlled Substances (2015-v1)

(B). DEA-225 Application by Mail – You may apply by mail if you wish to pay by check or if you do not want to apply online.

1. Download the Application from the DEA Applications website: [DEA Form 225](#)

2. Paper forms should be mailed to:

Drug Enforcement Administration
Registration Section/ODR
P.O. Box 2639
Springfield, VA 22152-2639

3. The average processing time for a new DEA registration is four to six weeks provided that the application is complete. To avoid delay in the processing of your application, be sure to check the following before submitting the application to DEA: a) Complete the application in its entirety; b) Sign and date the application; c) Mail the application to the address printed on the form.

4. The following are short directions for completing responses for each section:

- **Section 1. Applicant Identification** – Complete this section, including Tax ID number or SSN.
- **Section 2. Business Activity** – Most researchers should check “Researcher w/Sched II – V.”
- **Section 3. A. Drug Schedules** – Check the drug schedule(s) you will be working under. If you will be using a Schedule II drug (e.g. pentobarbital or Nembutal) then you will need to check the box requesting DEA-222 order forms. **B.** To be completed by manufacturers only. **C.** Researchers requesting Schedule II-V are only required to report drug codes for Schedule II substances that they manufacture or import, so most can go on to the next section.
- **Section 4. State License(s)** – Information pertaining to current and pending state controlled substance licenses/registrations. Kentucky does not require a state controlled substance license, so most researchers can go on to the next section.
- **Section 5. Liability** – Answer all 4 questions in this section.
- **Section 6. Exemption** – This Exemption only applies to federal, state, or local institutions or officials and requires a Certifying Official to verify the status of the applicant. Since University of Kentucky is considered a governmental agency, you may check the box and fill in the Business or Facility Name (University of Kentucky). The Certifying Official is your Department Chair (complete this information as described above for on-line applications).
- **Section 7. Method of Payment** – You may skip this section as University of Kentucky researchers are exempt from paying the application fee.

(C). Timeline for Obtaining a Registration & Purchasing Controlled Substances

1. Timeframe for obtaining a DEA researcher registration. While the online application process only requires a few minutes, it may take several months to coordinate a visit with the DEA. After the inspection it may take several months more before your DEA license is actually issued. Given these variables, it is reasonable to expect that the entire licensing process may take 2 to 6 months.

2. Meeting with the DEA. Once the DEA District Office receives your application they will contact you to arrange a meeting or phone interview. You may also receive a questionnaire (see: [“DEA Researcher Registration Questionnaire-2013”](#)). In the authors experience and via consultation with other researcher registrants the

UK-Researcher Guidelines for DEA Controlled Substances (2015-v1)

questionnaire typically follows/covers these questions, but is not “standardized”. The purpose of the meeting and for completing the questionnaire is to familiarize you with the responsibilities of holding a DEA controlled substance registration, and for the DEA to obtain information about your research, the individuals involved, an estimate of the amount of each agent you plan to use, and how you plan to source the controlled substances. Other items addressed on both the registration questionnaire and laboratory inspection include:

- Identifying the vendor(s) from which controlled substances will be obtained (i.e. name, address, phone number, and registration number of the vendor/supplier).
- Review the procedures for the delivery and receipt of controlled substances (i.e. the controlled drugs must be hand-delivered to the person responsible for the order, or person designated by the registrant as a responsible person).
- Review the documentation and recordkeeping procedures for controlled substance inventory, dispensing, and disposal in the registered location.
- To inspect the storage location for your controlled drugs. If your storage location is ready for inspection during the on-site meeting then the DEA agent can inspect it that day. If not, then the DEA agent may have to return at a later date to perform the inspection, which can delay your approval. Because each building, or laboratory is unique with respect to secure storage considerations it may be of benefit to inquire with colleagues holding DEA registrations in your area about the storage recommendations they were given during their DEA agent inspection.

(D) Contact Information-DEA Resident District Office London, KY

The DEA Resident District Office overseeing the University of Kentucky is located in London, KY.

[Diversion Field Contact Search](#)

150 Hal Rogers Drive

P.O. Box 5065

London, KY 40745

Diversion Number: (606) 862-4500

Diversion Fax: (606) 862-8296

Controlled Substance Authorized Personnel Log

Individuals on this list have been granted access to controlled substances for the listed DEA registration. All individuals granted access have completed the Controlled Substance Authorized Personnel Screening Form. Individuals who no longer have access to controlled substances are crossed off the list and the date their access was removed recorded.

Registrant: _____

DEA Registration # _____

Address on DEA #223 Certificate of Registration: _____

Name (Last, First)	Responsibilities delegated ¹	Signature	Initials	Date Access Granted	Date Access Removed

¹ **Authorized Personnel**: Research personnel under the direct supervision of a researcher using controlled substances during experiments or treatments of research animals.

¹ **Authorized Agent**: An individual who has been authorized to oversee the ordering, dispensing and management of controlled substances by provision of Power of Attorney (POA) authorization.

Controlled Substance Authorized Personnel Screening Form

The DEA requires that any person who will have access to controlled substances as a result of employment at the University of Kentucky answer the following questions ([CFR 1301.90](#)). The need to know this information is to help assess the likelihood of an individual to commit a breach of controlled substance security. Information revealed in this questionnaire will not necessarily preclude your employment, but will be considered as an overall evaluation of your qualifications for being granted access to controlled substances. All responses to this questionnaire are held in strict confidence.

Question #1: Within the past five years, have you been convicted of a felony, or, within the past two years, any misdemeanor, or, are you presently charged with committing a criminal offense? If yes, furnish the details of conviction, offense, location, date and sentence. Do not include traffic violations, juvenile offenses or military convictions, except by general court martial.

Yes _____ No _____

Q #1: If the answer is **YES**, then provide brief details of the conviction, offense, date and sentence:

Question #2: In the past 3 years, have you knowingly used narcotics, amphetamines, or barbiturates other than those prescribed to you by a physician?

Yes _____ No _____

Q #2: If the answer is **YES**, then provide details:

Question #3: Have you ever had an application for registration with the DEA denied, revoked, or surrendered for cause?

Yes _____ No _____

Q#3: If the answer is **YES**, then provide details:

Name (print) _____ Signature _____ Date _____

Registrant (print) _____ Signature _____ Date _____

Authorized Agent Power of Attorney for DEA Forms 222 and Electronic Orders

(Name of registrant) _____

(Address of registrant) _____

(DEA registration number) _____

I, _____ (name of person granting power), the undersigned, who am authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act or Controlled Substances Import and Export Act, have made, constituted, and appointed, and by these presents, do make, constitute, and appoint _____ (name of attorney-in-fact), my true and lawful attorney for me in my name, place, and stead, to execute applications for Forms 222 and to sign orders for Schedule I and II controlled substances, whether these orders be on Form 222 or electronic, in accordance with 21 U.S.C. 828 and Part 1305 of Title 21 of the Code of Federal Regulations. I hereby ratify and confirm all that said attorney must lawfully do or cause to be done by virtue hereof.

(Signature of person granting power)

I, _____ (name of attorney-in-fact), hereby affirm that I am the person named herein as attorney-in-fact and that the signature affixed hereto is my signature.

(Signature of attorney-in-fact)

Witnesses:

1. _____ (Signature of witness)

2. _____ (Signature of witness)

Signed and dated on _____ (current date).

Notice of Revocation – to be completed only when Power of Attorney is revoked

The foregoing power of attorney is hereby revoked by the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act or the Controlled Substances Import and Export Act. Written notice of this revocation has been given to the attorney-in-fact _____ this same day.

(Signature of person revoking power)

Witnesses:

1. _____ (Signature of witness)

2. _____ (Signature of witness)

Signed and dated on _____ (current date).

Controlled Substance Transfer Form

Date: _____

Supplier¹ Name: _____ Supplier DEA #: _____

Receiver¹ Name: _____ Supplier DEA #: _____

The following transfer of controlled substance(s) was made between the above licensed DEA registrants. Each registrant certifies to hold approval on their respective DEA registration to possess the schedule of the listed transferred controlled substance(s).

The named **supplier** attests that this transfer does not exceed their individual five percent (5%) annual limit of transfer of any of the listed controlled substance(s).

Controlled Substance	Conc.	Container Size	Amount in Container	Manufacturer	Supplier Inv.#*	Receiver Inv.#*	DEA Sched. (I-V ²)

²DEA Schedule I or II also requires the use of a DEA Form 222.

Supplier Registrant or Authorized POA signature

Date

Receiver Registrant or Authorized POA signature

Date

¹Both the supplier (person transferring) and receiver (person receiving) should assure that their CS-general inventory records for each transferred controlled substance(s) is appropriately reconciled to document the transfer(s).

²DEA Schedule I or II also requires the use of a DEA Form-222.

Biennial Controlled Substance Inventory Form

A separate Initial Inventory is required for each registered location. Do not submit a copy of the biennial inventory to the DEA unless requested. Schedule I and II drugs must be separated from all other drugs or placed on a separate form.

Date: _____

DEA Registrant (Print Name): _____

DEA Registration Number: _____

DEA Registrant Address: _____

(As appears on DEA Form 223)

Inventory Performed by: _____

Print Name

Signature

Inventory Witness: _____

Print Name

Signature

☐ Inventory completed-start of business day

☐ Inventory completed-end of business day

No. ¹	Drug Name ²	Concentration or Form ⁷	CS Schedule	DEA # (4 digit)	Unopened Containers ³		Opened Containers ^{4,5,6}		
					Qty.	Container Size	Qty.	Container Size	Remaining amount
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									
12									

(1) Cross out any unused line(s). Keep the biennial inventory record at the licensed-registered location. (2) Schedule I and II drugs must be separated from all other drugs or placed on a separate form. (3) Unopened containers of same substance, manufacturer, volume, and concentration can be listed together. (4) List open containers as separate line items. (5) Measure in weight (powder or crystals) or volume (liquids) or number of units (tablets or capsules). (6) For opened containers: If the substance is listed in Schedule I or II, make an exact count or measure of the contents. (7) Finished form refers to the strength and form of the item as commercially prepared.

Example: Properly Completed DEA Form 222

See Reverse of PURCHASERS Copy for Instructions				No order form may be issued for Schedule I and II substances unless a completed application form has been received, (21 CFR 1305.04).												OMB APPROVAL No. 1117-0010												
TO: (Name of Supplier) #1				STREET ADDRESS: #2																								
CITY and STATE #3				DATE #4				TO BE FILLED IN BY SUPPLIER																				
								SUPPLIERS DEA REGISTRATION NO. #10																				
L I N E N O	TO BE FILLED IN BY PURCHASER																National Drug Code #11								Packages Shipped #12		Date Shipped #13	
	No. of Packages #5		Size of Package #6		Name of Item #7																							
	1	1	50 ml	Sodium Pentobarbital 50mg/ml vial																								
	2	5	1 ml	Hydromorphone 1mg/ml ampule																								
	3	5	4 ml	Cocaine 4% topical solution																								
	4	1	10/box	Morphine 10mg/ml (1.0 ml ampule)																								
	5	1	1 g	Amphetamine powder																								
	6	2	10 patches	Fentanyl 50mcg patch																								
	7	1	10/50ml	Sodium Pentobarbital 10 vials, 50mg/ml																								
	8																											
	9																											
	10																											
7 ◀ NO. OF LINES COMPLETED #8				SIGNATURE OF REGISTRANT #9																								
Date Issued PRE-PRINTED BY DEA				DEA Registration No. PRE-PRINTED BY DEA				Name and Address of Registrant PRE-PRINTED ON FORM BY DEA (Name and address as printed on DEA Certificate of Registration- Form 223)																				
Schedules PRE-PRINTED BY DEA																												
Registered as a RESEARCHER				Order Form Number PRE-PRINTED BY DEA																								

1) The Purchaser completes: #1 - #9 (No cross outs, “write-overs” or initials are allowed). Write “VOID” across any forms with errors and retain.

#5 No. of Packages: Indicate the number of individual containers - enter 1 for each vial or container. For boxes or multiple vial packages enter 1 for each box or package

#6 Size of Package: Indicate the amount, quantity per box, or size of individual vials or container (e.g. ml, g).

#7 Name of controlled substance item and concentration or strength. Description must fit on one line. **Example:** Morphine 25mg/ml 2ml vial

2) Copy #1 (brown) and #2 (green) remain attached with carbon intact and are sent to supplier.

3) Supplier completes: #10 - #13 (DEA registration number, NDC number, packages shipped, and date shipped). Supplier mails Copy #2 to DEA.

4) Purchaser retains and completes Copy #3 (blue) and completes Packages received and date received sections when the CS order is received.

New DEA Registration: Initial Controlled Substance Inventory

1 (A separate inventory must be completed for each new registered location).

Date: _____

DEA Registrant (name): _____

DEA Research Registration#: _____

Inventory Performed By: _____

Printed name
Signature

Inventory Witnessed By: _____

Printed name
Signature

Inventory Completed: ☐ Start of day ☐ End of day

[illegible]

* Schedule (I and II) drugs must be inventoried separately from all other drugs (i.e. Schedules III-V) or placed on a separate form.

Page _____ of _____

¹ At the time of issue of a new DEA registration the registrant must perform an initial inventory (actual physical count) of all controlled substances currently in their possession. If no stocks of controlled substances are on hand, then the registrant should make a record showing a zero inventory. Keep the initial inventory record at the licensed-registered location. The DEA does not require you to submit a copy of the initial inventory to their office, unless specifically requested.

Controlled Substance: Injectable Formulation

Acquisition and Inventory Record

Drug: _____ **Concentration (mg/ml):** _____ **Volume (ml):** _____ **CS-Schedule** _____

[illegible]

1. **Note:** To ensure a comprehensive record, file a copy of the invoice or shipping document in the CS folder. Ensure the date of receipt is recorded on the invoice or shipping document. For DEA Schedule I or II drugs attach the applicable DEA-222 form or invoice to requisition, as appropriate.

Controlled Substance: Injectable Drug Formulation

Individual Container Dispensing Record

[illegible]

Controlled Substance: Single (1) Dilute Injectable Drug Dispensing Record

Drug: _____

Drug/Vehicle	Stock Conc. (mg/ml)	Amt (ml)	Lab Inv ID# (Manufacturer)	Lot #:
1)				
2)				
	Total:		Final Concentration (mg/ml) =	

Lab Inv #: _____ Date Mixed: _____ Container Size: _____ Expiry: _____

[illegible]

Controlled Substance: Mix (2) Injectable Drugs Dispensing Record

Drug Mixture: _____

Drug/Vehicle	Stock Conc. (mg/ml)	Amt. (ml)	Mixed Final Conc. (mg/ml)	Lab Inventory ID# Manufacturer)	Lot #:
1)					
2)					
3)					
	Total:				

Inventory #: _____ **Issue Date:** _____ **Container Size:** _____ **Expiry:** _____

[illegible]

Controlled Substance: Mix (3) Injectable Drugs Dispensing Record

Drug Mixture: _____

Drug/Vehicle	Stock Conc. (mg/ml)	Amt. (ml)	Mixed Final Conc. (mg/ml)	Lab Inv. ID# (Manufacturer)	Lot #:
1)					
2)					
3)					
4)					
	Total:				

Inventory #: _____ **Issue Date:** _____ **Container Size:** _____ **Expiry:** _____

[illegible]

Controlled Substance: Injectable Drug Acquisition and Inventory Record

Drug: Ketamine-HCL Injectable

Concentration (mg/ml): 100 mg/ml

Volume (ml): 10

DEA Schedule: III

[illegible]

1. **Note:** To ensure a comprehensive record, file a copy of the invoice or shipping document in the CS folder. Ensure the date of receipt is recorded on the invoice or shipping document. For DEA Schedule I or II drugs attach the applicable DEA-222 form or invoice to requisition, as appropriate.

Controlled Substance-Injectable Drug Formulation Individual Container Dispensing Record

[illegible]

Controlled Substance: Single (1) Injectable Drug Dispensing Record

Drug: Dilute Buprenorphine-HCl (0.015 mg/ml)

Drug/Vehicle	Stock Conc. (mg/ml)	Amt (ml)	Lab Inv ID# (Manufacturer)	Lot #:
1) Buprenorphine-HCL	0.3	1.00	BUP-001 (Reckitt-Benckiser)	L-1456-V
2) 0.9% Sterile Saline	n/a	9.00	Baxter	QR-345-L
	Total:	10.00	Final Concentration (mg/ml) = 0.03	

Lab Inv #: Bup-Dil-001

Date Mixed: 15-Mar-14

Container Size: 10.0 ml

Expiry: 16-Apr-14

[illegible]

Controlled Substance: Mix (2) Injectable Drugs Dispensing Record

Drug Mixture: Ketamine-Xylazine Cocktail (10.0 mg/ml Ketamine + 1.0 mg/ml Xylazine)

Drug/Vehicle	Stock Conc. (mg/ml)	Amt. (ml)	Mixed Final Conc. (mg/ml)	Lab Inv. ID# (Manufacturer)	Lot #:
1) Ketamine-HCL	100.0	1.00	10.0	KET-001 (Fort Dodge)	L-1456-V
2) Xylazine	20.0	0.50	1.0	XYL-001 (Akorn)	LA02813
3) Sterile Water	n/a	8.50	n/a	Baxter	QR-345-L
	Total:	10.00			

Inventory #: KX-001

Issue Date: 03-Jan-2014

Container Size: 10.0 ml

Expiry: 04-Feb-2014

[illegible]

Controlled Substance: Mix (3) Injectable Drugs Dispensing Record

Drug Mixture: Ket-Xylazine-Acepromazine Inj. (7.0 mg/ml Ket. + 1.0 mg/ml Xyl. + 0.15 mg/ml Aceprom.)

Drug/Vehicle	Stock Conc. (mg/ml)	Amt. (ml)	Mixed Final Conc. (mg/ml)	Lab Inv ID# (Manufacturer)	Lot #:
1) Ketamine-HCL inj	100.0	0.70	7.00	KET-001 (Fort Dodge)	L-1456-V
2) Xylazine Injextable	20.0	0.50	1.00	XYL-001 (Akorn)	LA02813
3) Acepromazine	10.0	0.15	0.15	ACE-001 (Boehringer-Ingelheim)	AH00AH4
4) Sterile Water	n/a	8.65	n/a	Baxter	QR-345-L
	Total:	10.00			

Inventory #: KXA-001

Issue Date: 03-Jan-2014

Container Size: 10.0 ml

Expiry: 04-Feb-2014

[illegible]

Controlled Substance Solid Formulation (Powder/Pill/Patch) Acquisition and Inventory Record

[illegible]

Controlled Substance Solid Formulation (Powder/Pill/Patch) Individual Container Dispensing Record

Drug: _____

Manufacturer: _____		Lot #: _____	Expiry: _____
Lab Inv.ID #: _____	Issue Date: _____		Container Size: _____

[illegible]

Controlled Substance Solid Formulation (Powder/Pill/Patch) Acquisition and Inventory Record

[illegible]

Controlled Substance Solid Formulation (Powder/Pill/Patch) Individual Container Dispensing Record

Drug: *Buprenorphine Sublingual Tablets (2 mg/tablet)*

Manufacturer: <u>Roxane Labs</u>		Lot #: <u>BL-1976</u>	Expiry: <u>Jun-2018</u>
Lab Inv.ID #: <u>B-Tab-02</u>	Issue Date: <u>15-Feb-2015</u>		Container Size: <u>20 tablets</u>

[illegible]

DEA Researcher Registration Questionnaire (example of one DEA form-circa 2013)

Name of Project: _____

[illegible]

Name of Applicant: _____

Credentials of Project Personnel: _____

PERSONS RESPONSIBLE FOR CONTROLLED SUBSTANCES

[illegible]

PERSON RESPONSIBLE FOR RECORD KEEPING: (NAME/DOB/SSN):

CONTROLLED SUBSTANCES INVOLVED:

SUBSTANCE NAME	SCHEDULE	DRUG CODE	AMOUNT REQUIRED

SECURITY: PERSONS WHO WILL HAVE ACCESS TO CONTROLLED SUBSTANCES

NAME	DOB	SSN	TITLE/POSITION

PERSON WITH OVERALL RESPONSIBILITY FOR SECURITY: (NAME/DOB/SSN):

SECURITY ARRANGEMENTS (SAFE/LOCKER/ALARM/ETC) & SECURITY SYSTEM ACCESS:

WHERE ARE CONTROLLED SUBSTANCES ORDERED FROM (SOURCE OF SUPPLY/ADDRESS/PHONE NUMBER)?

REMARKS/COMMENTS:
