**Brigham and Women’s Hospital**

**Guide for Using Controlled Substances in Animal & Basic Research**

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**Introduction**

Due to their potential for abuse, items identified by the United States Department of Justice, Drug Enforcement Administration (USDEA), and the Massachusetts Department of Public Health’s Bureau of Health Professions Licensure Drug Control Program (MADPH) as Controlled Substances are subject to extensive licensing, registration, storage, security, use, disposal, and inventory requirements. The regulations governing Controlled Substances include the following: United States Department of Justice, Drug Enforcement Administration, Controlled Substances Act, 21 C.F.R. Sections 1300 et. seq.; and Massachusetts Regulations, 105 C.M.R. 700.000 et. seq.

In general, these federal and state regulations are designed to ensure a system of security and accountability in the acquisition, use and disposal of Controlled Substances. Thus, they require license holders to document the order and receipt of Controlled Substances and to continue to document use until the time they are properly disposed of. They also call upon license holders to keep track of the individuals who are authorized to have access to the substances and the places in which the Controlled Substances are stored. Violations of the Controlled Substances laws, even when unintended, can lead to substantial civil and criminal liability.

1. **1. Responsibilities**
2. *Registrants and Authorized Individuals*

In order to ensure compliance with obligations under the Controlled Substance regulations and licenses, it is important that authorized faculty and research staff, laboratory administrators, and affected departments understand their responsibilities in connection with obtaining, preparing, handling, and using Controlled Substances. Principal investigators (PIs) shall have responsibility for managing the use of Controlled Substances in their labs. In the event that a PI is on leave or otherwise absent, he/she may legally designate another appropriate Authorized Individual to carry out the PI's duties under the Controlled Substance program by executing a written Power of Attorney. For further information on designating an Authorized Individual as your legal representative, please contact Research Operations for assistance.

PI responsibilities for Controlled Substance program oversight and management include:

* Ensuring that Controlled Substances are licensed and registered for use in their labs and stored and accounted for in the manner that is required for the particular drug classes authorized by the license holder’s registration, as indicated on the license.
* Ensuring all licenses are regularly updated (change of address, addition of new schedules, etc.)
* Restricting access only to users they authorize (Authorized Individuals)
* Providing the BWH Research Operations updated information via the Controlled Substance Info sheet
* Purchasing and dispensing Controlled Substances needed for approved research activities
* Ensuring that security and access procedures are in place in each lab
* Overseeing appropriate labeling and destruction of expired or unneeded Controlled Substances
* Ensuring that usage logs, purchase orders, inventories, disposal records and other necessary documentation are properly kept in accordance with this guide and state and federal regulations
* Reporting lost or stolen Controlled Substances immediately

*Research Operations and the Department of Environmental Affairs*

BWH Research Operations and the BWH Department of Environmental Affairs shall have primary responsibility for providing guidance to faculty, researchers, and their staffs in complying with the requirements set forth in this guide; for providing training upon request to faculty and research staff concerning obligations for handling Controlled Substances under the licenses, regulations, and any applicable BWH policies; and for working with registrants to implement any corrective actions that may be needed.

The BWH Department of Environmental Affairs shall have responsibility for conducting annual surveys of any laboratories that have licenses to use Controlled Substances and providing initial in-person training to Authorized Users at the time of initial application or as needed or upon request. The BWH Department of Environmental Affairs will provide an inspection summary report, including corrective action recommendations, to the registrant and laboratory safety officer. Periodically, the BWH Department of Environmental Affairs may be asked to provide a summary report of these surveys to BWH Research Operations. The BWH Department of Environmental Affairs shall also have responsibility for assisting PIs in the disposal of Controlled Substances. Quarterly, the BWH Department of Environmental Affairs will organize USDEA- and MADPH-approved disposal events for registrants who have expired or unwanted Controlled Substances. The disposal event information will be communicated to the research community via email and Research informational meetings, such as the quarterly LabSCENE meeting for laboratory researchers.

Research Operations may also conduct reviews of Controlled Substance programs and assist registrants or Authorized Individuals in performing self-inspections of their Controlled Substance programs. This office can also provide resources and best practices to help registrants and Authorized Individuals maintain storage areas, usage logs, inventories and other required documentation in compliance with state and federal regulations. Research Operations, in collaboration with Research Space Management, will also assist registrants with the acquisition and installation of BWH-provided Controlled Substance storage cabinets that meet the performance requirements of the USDEA for the storage of narcotics. Research Operations is also available to assist investigators when applying for their Controlled Substance registrations and renewals. BWH Research Operations will be responsible for maintaining the BWH Controlled Substance Information forms for the institution and ordering Controlled Substance storage cabinets.

*Animal Facilities*

Animal Facility Managers will assist PIs in the disposal of animals injected with Controlled Substances.

*Institutional Animal Care and Use Committee (IACUC) Inspections*

Representatives from the IACUC are required to conduct periodic inspections of any areas where animals are used or housed. Additionally, they are charged with upholding the standards of animal welfare required by the Office of Laboratory Animal Welfare (OLAW), the United States Department of Agriculture (USDA), and AAALAC International. The IACUC inspector is required to inspect Controlled Substances and records when inspecting an animal use area, as the IACUC is responsible for ensuring only pharmaceutical grade, unexpired drugs listed on an IACUC-approved protocol are used in animals. Secondary to animal welfare, the IACUC is also charged with human safety concerns and shares responsibility with other institutional entities for reporting any deviations from Controlled Substance regulations. The IACUC Administration sits within Research Operations and the staff are trained to evaluate controlled substance records compliance and make recommendations on best practices in addition to reporting noncompliance identified on their inspections to Research Operations and the Department of Environmental Affairs.

**2. Definitions**

**Authorized Individuals** are those lab personnel who handle or manage Controlled Substances in approved research. Authorized Individuals must be trained in Controlled Substance ordering, security, receipt, inventorying, and recordkeeping procedures as outlined in this Guide. Authorized Individuals are denoted as such on the state Controlled Substance registration application and the BWH Controlled Substance Info sheet.

**Controlled Substance** is a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of the Controlled Substances Act. In addition, under Massachusetts law, Controlled Substance is also defined as a **prescription** drug (termed Schedule VI) that is not otherwise included in schedules I-V. The USDEA does *not* regulate Schedule VI prescription drugs.

**Controlled Substance Schedules** identify materials containing any quantity of a substance with a stimulant, depressant, or hallucinogenic effect on the higher functions of the central nervous system, and having the tendency to promote abuse or physiological or psychological dependence, as designated in state and federal Controlled Substance schedules. Schedules I and II are the most stringently regulated, and include many widely known “street drugs,” including marijuana, heroin, LSD, GHB, and cocaine as well as such drugs as pentobarbital. Schedule III compounds include many stimulants and depressants, pain killers, and anesthetics, including ketamine and buprenorphine. Schedule IV substances cover the balance of lower-abuse potential stimulants and depressants, while Schedule V includes therapeutic drug mixtures containing very limited quantities of Controlled Substances. Each Controlled Substance has a specific drug code assigned to that particular drug. A general list of Schedule I-V Controlled Substances can be found at: https://www.deadiversion.usdoj.gov/schedules/. It should be noted that the Controlled Substance schedule list describes “parent” compounds, but isomers, salts and derivatives may also be subject to Controlled Substance regulations. The schedule list is not exhaustive and is subject to change, so the USDEA website should be consulted prior to submitting new registrations or renewals.

Schedule VI Controlled Substances under Massachusetts law include all prescription drugs, such as isoflurane, antibiotics, chemotherapies or veterinary NSAIDS (Metacam, carprofen, etc.). Non-prescription grade pharmaceuticals are *not* included in Schedule VI nor are Over-the-Counter (OTC) drugs.

**Registrants** are those persons registered pursuant to either Section 303 or Section 1008 of the Controlled Substance Act (21 C.F.R Parts 823 or 958).

**Controlled Substance Storage Cabinet** protects schedule I-V Controlled Substances from unauthorized diversion and meets or exceeds the requirements described in 21 CFR, Parts 1301.71-74. Controlled Substance Storage Cabinets provided by BWH Research Operations are Omni-Med brand economy double-locked, steel narcotics cabinets measuring 15” x 11” x 4” and weighing approximately 12 lbs. They are bolted to the wall in an area not visible to passersby.

**3. Licensing and Registration**

Controlled Substance registrations issued by the USDEA and the MADPH are required to acquire, make, possess, or use a Controlled Substance. The MADPH registration is commonly referred to as the Massachusetts Controlled Substance Registration (MCSR). Generally, licenses (i) are issued to an individual, who may authorize other individuals to operate under his/her license, (ii) are specific to drug schedules identified on the license, and further limited to specific drug codes applied for, and (iii) identify a specific location where the Controlled Substances are to be received and stored and must be amended when the location of receipt/storage changes.

*3.1 Application Process*

It is the responsibility of the Principal Investigators to obtain appropriate licenses and registrations. Research-specific licensure is required and is separate from the USDEA practitioner licensure. Members of the BWH community who participate in both clinical work and research at the hospital need to obtain both a practitioner and researcher registration. Those working in both clinical research and basic/animal research will need separate registrations to cover the separate activities. At BWH, Department Heads (Chairs) hold the clinical research MCSR for all FDA-approved drugs used in clinical research in their department when the drugs are stored in the Investigational Drug Service (research pharmacy). Individual PIs are responsible for obtaining their own clinical research MCSR for INDs. Individual PIs, or a designated Lab Manager (where operationally appropriate), must obtain research licensure from both the USDEA and the MCSR for basic and animal research. The USDEA will not grant an applicant a registration until the researcher has already obtained a MCSR although both applications may be submitted at the same time. The MCSR requires an IACUC approval letter to accompany the application. At the time of this update, the MCSR continues to require a paper application process, while the USDEA requires submission of applications via its registration website: <http://www.deadiversion.usdoj.gov/drugreg/index.html>.

Once the initial USDEA application is completed online, the USDEA registration administrator will contact the applicant by email to complete a questionnaire and provide additional information. The USDEA routinely ask for a photograph of the installed narcotics cabinet and request a phone interview or in-person site visit. Please contact Research Operations or the Department of Environmental Affairs if there are questions during this process and certainly if the USDEA will be onsite. In addition to the basic applications, those applying to use Schedule I drugs must also submit a copy of their research protocol and may require a letter of support from the institution and additional security and storage requirements for the drugs. Please notify Research Operations or the Department of Environmental Affairs of your intent to apply for a Schedule I registration.

*3.2 Applicant Qualifications*

In most cases, it will be appropriate or required to have PIs apply for the Controlled Substance registration(s). Once PIs obtain registrations for their labs, they can authorize others in their labs to access and use the materials. In some situations in which multiple PIs work together very closely in the same lab space and are operationally centralized under a single Lab Manager, it might be more appropriate for a Lab Manager to hold the license for all activity within the lab group. In these situations, the Lab Manager, with the input from the PIs in their labs or departments, can authorize others to access the materials. It is ultimately the registrant listed on the licenses who has responsibility for ensuring proper acquisition, use, maintenance, and accountability of Controlled Substances.

*3.3 BWH Controlled Substance Information Sheet*

Registration holders, or those in the process of applying for registrations, should complete and submit the BWH Controlled Substances Information Sheet to BWH Research Operations by emailing this form to the attention of Kathryn Holthaus at [kholthaus@bwh.harvard.edu](mailto:kholthaus@bwh.harvard.edu) or Angela Vail at [avail3@bwh.harvard.edu](mailto:avail3@bwh.harvard.edu). This internal form serves several purposes. First, it identifies all Controlled Substances the registrant and Authorized Individuals wish to handle. Second, it identifies all researchers, staff, and administrators designated as Authorized Individuals by the registrant to handle such substances. Third, it identifies the location where the Controlled Substances will be stored. Registrants are responsible for ensuring the Information Sheet has been submitted and is updated as needed by submitting updated versions to Research Operations as changes are made.

*3.4 Authorized Individuals*

Registrants may authorize members of their research staff or other administrators to access Controlled Substances by identifying those individuals on the BWH Controlled Substances Information Sheet. The MCSR requires the registration holder, upon application or renewal, to provide the agency with personal information pertaining to *all* Authorized Individuals. The USDEA does not have a documented process for updating this information after the application/renewal; however, conversations with the USDEA inform us that they do want to be notified of updates to Authorized Individuals. Registrants should fax the USDEA Boston Office Diversion Manager a formal, signed letter notifying them of updates at 617-557-2126 If, during the course of the year, there are additions or deletions or changes to the information provided on the BWH Controlled Substances Information Sheet, license holders must ensure that they have a record of any such changes; however, it is a best practice to make these changes on the Controlled Substance Information Sheet and resubmit it to Kathryn Holthaus to maintain a central record.

The number of Authorized Individuals should be kept to the minimum essential for efficient operation. By limiting the number of Authorized Individuals, labs can better ensure accountability. Persons previously convicted of a felony offense relating to Controlled Substances or who had an application for registration with a state or federal agency denied or who surrendered a registration for cause will not be authorized to work with these materials.

*3.5 Drug Schedules and Codes*

Upon initial application for both state and federal registrations, the Registrant must provide a list of the specific Controlled Substances to be used as well as the corresponding schedules. The USDEA also requires the drug code for each substance. Controlled Substance schedules and drug codes are listed on the USDEA website: <http://www.deadiversion.usdoj.gov/schedules/index.html>. Drug codes may also be found in Title 21 Part 1308 of the Code of Federal Regulations or by contacting the local office of the USDEA.

Except for Schedule I substances, license holders are not obligated to notify MADPH if they wish to purchase additional Controlled Substances, provided their license includes the schedule within which the new Controlled Substance falls. The USDEA must be notified whenever a new drug code within an authorized schedule is added to the license. Registrants must make these changes via the USDEA website: <https://apps.deadiversion.usdoj.gov/webforms/jsp/regapps/common/updateLogin.jsp>. In any event, license holders must provide complete, updated information about Authorized Individuals, drug codes, schedules, and licenses when they renew both their MCSR and USDEA registrations.

*3.6 Storage and Shipping Address*

Importantly, the Schedule I-V Controlled Substances must be secured at the physical address indicated on the registration application. Registrants and Authorized Individuals who conduct research in other BWH-affiliated facilities may bring Controlled Substances to these locations for use, but they must remain in the Authorized Individual’s control throughout the use and must be returned to the location indicated on the registration for storage immediately after use.

If the registration holder changes location and wishes to change the storage location indicated on his/her registration, he/she should amend the MCSR by using the same application and selecting “Amendment” AND the USDEA via an online change of registration request (<https://apps.deadiversion.usdoj.gov/webforms/jsp/regapps/common/updateLogin.jsp>) prior to relocating any Controlled Substances. As with new registration applications, the state registration change must be completed before submitting the online change of address with the USDEA. It is important to note that as soon as the USDEA change of address is approved, the controlled substances must be immediately relocated to the new address. For this reason, a new controlled substance storage cabinet should be securely mounted in the new location prior to USDEA approval, in anticipation of the move. Controlled Substances can only be moved by Registrants or Authorized Individuals and must remain on one’s person throughout the relocation process.

1. **4. Scope of Use**

Controlled Substances may only be used for duly authorized, legitimate medical or scientific research purposes to the extent permitted by the registrant’s license and registration and in conformity with state and federal statutes and regulations.

1. **5. Initial Purchase**

Once registrations have been granted from the state and federal agencies, registrants who wish to purchase Schedule I-V substances may purchase their own supply of Controlled Substances via MGB Supply Chain.

Registrants are responsible for establishing accounts with appropriate vendors of Controlled Substances.In many cases, MGB Supply Chain may already have a corporate account established with companies who supply Controlled Substances. As such, it may be helpful to contact MGB Supply Chain and inquire about a specific vendor prior to initiating an independent account. This will minimize account set-up time, but an existing MGB account does not eliminate the requirement to set up an individual account for the purchase of Controlled Substances using the registrant’s registration information.

Vendors will require:

* A copy of USDEA Registration
* A copy of State Registration (MCSR)
* DEA Form 222 (for Schedule II drugs only)

When establishing the vendor account, the "Bill To" address needs to be BWH Accounts Payable (see below). Note that the “Bill To” address is **NOT** the address listed on the USDEA registration. The USDEA registration address (where the drugs are stored) is the shipping address.

**BILL TO:**

BWH Accounts Payable  
PO Box 9127  
Charlestown, MA  02129-9127

### Once an account has been set up, registrants must complete their Purchase Requisition through MGB e-Buy. Information on completing requisitions is located on the MGB web site: <http://supplychain.partners.org/index.aspx>. Please remember, the shipping address ****must be**** the same as the address on your USDEA Registration.

### Once a Purchase Order has been generated through e-Buy, Researchers must send their Purchase Order to MGB Supply Chain (Fax: 617-623-5471). The USDEA requires a copy of the PO be maintained by the Registrant and readily accessible upon request.

### For CIII-CV Controlled Substances:

* Supply Chain will generate a PO number and place the order.

### The drugs will be shipped directly to the address listed on the USDEA registration.

### For CII Controlled Substances:

* MGB Supply Chain will send the PO back to your lab.
* You must mail the PO directly to the company along with the completed DEA Form 222. You must keep the Purchaser’s (blue) copy of the 222 where it can be easily retrieved as needed during inspections.
* Completing Official DEA 222 Forms:
  + When ordering Schedule II substances, you are responsible for filling in the number of packages, the size of the package and the name of the item.
  + Each Official Order Form must be signed and dated by a person authorized to sign a registration application.
  + When the items are received, the receipt must be documented on the purchaser’s copy (copy 3) with the actual number of packages received and the date received. Proof of receipt must be kept with the purchaser’s (blue) copy of Form 222 where it can be readily retrieved when requested.
* The drug will be shipping directly to the address listed on the USDEA registration.

**To order additional DEA 222 forms:**

Official Order Forms may be ordered by calling the USDEA Headquarters Registration Unit toll free at 1-800-882-9539 or the nearest USDEA Registration Field Office. The forms will be mailed within 10 working days. Official order forms may also be obtained by submitting a completed requisition form, DEA Form 222a, to USDEA, Registration Unit, PO Box 28083, Washington, DC 20038-8083.There is no charge for Official Order Forms. Please adequately secure all unused 222 Order Forms. As in the case of drug diversion, any theft of loss of 222 Forms must be immediately reported to the BWH Department of Environmental Affairs or Research Operations. As stipulated in 21 CFR 1305.16, all thefts of 222 Forms must also be reported to the USDEA. BWH Department of Environmental Affairs and/or Research Operations can and should assist with reports to the USDEA.

**6. Maintaining Security in the Lab**

*6.1 Schedule I-V*

Schedule I-V Controlled Substances must be stored in securely locked, substantially constructed double-locked drug cabinets or safes in locations where access is limited. This cabinet should be tamper resistant, not easily moveable, and show no display (by window or written designation) of the contents within. If the storage cabinet weighs less than 750 lbs. then it must be bolted or cemented in place, such that it cannot readily be moved. Contact the BWH Research Operations to ensure that appropriate cabinets or safes conform to the federal and state requirements. The vendor of the safes should be able to confirm the appropriateness for storage of Controlled Substances. You may also request a Controlled Substance cabinet that meets these specifications by contacting Research Operations, who will assist you with acquisition of an appropriate cabinet. There may be additional storage and security requirements based on Controlled Substance quantity and storage location; contact the Department of Environmental Affairs or Research Operations if you have questions.

All Schedule I-V Controlled Substances must be kept locked in their storage location except for the actual time required for Authorized Individuals to remove, legitimately work with, and replace the Controlled Substances. Controlled substances must not be left unattended, and when they are not being used for research, they must be securely stored in a narcotics safe. The stocks of Controlled Substances on hand should be kept to the smallest quantity needed for efficient operation to conduct the indicated research. It is strongly recommended that diluted mixtures be made in a timely manner, so that little, if any, non-diluted Schedule I-V Controlled Substances are maintained in the laboratory environment. In connection with some experiments, it may be necessary to prepare and use many doses of highly diluted Schedule I-V Controlled Substances over a relatively short period of time. In those instances, it is recommended that dilutions be prepared fresh when being administered to animals to better ensure their effectiveness and reduce additional record-keeping. All prepared dilutions must be stored in the locked cabinet when not being actively used. Any dilution prepared that will not be used the same day, must be recorded on a new page of the controlled substance logbook, such that any vial of drug has it’s own separate log page.

Controlled access to the drug cabinet is critical to establishing security for Controlled Substances. For this reason, keys and combinations to the cabinets or safes should be secure and under the control of a limited number of Authorized Individuals. Keys should not be left unattended in an unsecure location.

*6.2 Massachusetts Schedule VI*

Under Massachusetts regulation, Schedule VI prescription drugs need not be stored in safe or locked drug cabinet. Schedule VI substances can be stored together on a nearby shelf to the drug cabinet or in an unlocked cabinet but MUST NOT be stored with Schedule I-V substances, unless the license holder obtains specific permission from the USDEA to store Schedule VI prescription drugs with the substances that the USDEA regulates.

1. **7. Reporting of Loss, Destruction, Theft, or Unauthorized Use**

Thefts, suspected thefts, unauthorized uses, or other losses of any Controlled Substances must be reported immediately to BWH Department of Environmental Affairs and/or Research Operations upon discovery. The laboratory has an obligation to report the loss immediately to the state or federal authorities and must work with the Department of Environmental Affairs to do so. The MADPH and the USDEA require laboratories to report losses within one business day of discovery. DEA [Form 106](http://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html), available on USDEA’s website, is required to be used by both USDEA and the MADPH when a formal report is made, after an initial investigation.

Researchers must inform all Authorized Individuals on their license that they are required to notify BWH Department of Environmental Affairs or the Research Operations of suspected drug diversion. The reporting process is considered confidential, although all reports will be formally investigated and reported to appropriate authorities if inappropriate usage or diversion is confirmed, or if the loss cannot be accounted for within one day. The BWH Department of Environmental Affairs must assist you with reporting losses and either the Department of Environmental Affairs or Research Operations may assist you in addressing questions concerning losses of Controlled Substances.

In addition, any unauthorized persons who gain access to Controlled Substances for the purpose of diversion or theft may be reported to BWH Security and the local Police Department and may be subject to disciplinary action.

**8. Recordkeeping and Inventorying**

Registrants are required to keep records and maintain inventories in conformance with the record-keeping and inventory requirements of the Federal “Comprehensive Drug Prevention and Control Act of 1970” or any amendment thereof. A BWH Controlled Substance Usage Log template has been created to help registrants and Authorized Individuals keep track of Schedule I-V Controlled Substances. BWH Controlled Substance Usage Log sheets or equivalent, must be sequentially numbered and bound, maintained in close proximity to the cabinet and must be readily retrievable upon request. BWH has created a bound recordkeeping log and inventory book for Controlled Substances that meets these requirements and can be requested, free of charge, from the Department of Environmental Affairs. Usage Log sheets must be maintained for a minimum of two years after the complete use and disposal of Schedule I-V Controlled Substances and be readily available for inspection by the USDEA, MADPH, BWH Department of Environmental Affairs, Research Operations, the IACUC Inspection team, Inspectors from the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS), the Office of Laboratory Animal Welfare (OLAW) and/or AAALAC International. Laboratories are not required to maintain usage logs for Schedule VI Controlled Substances.

To comply with BWH and federal requirements, all laboratories that work with Schedule I-V Controlled Substances should conduct self-inspections periodically, but not less than twice annually, to ensure that the laboratory’s Controlled Substance Usage Logs match the physical inventory. The results of those self-inspections must be recorded on the BWH Controlled Substances Inventory Form or equivalent, be signed by both the Registrant and Authorized Individual who completed the inventory and be maintained by the license holder for a minimum of two years.

All records, including but not limited to: usage logs, inventories, destruction forms (DEA Form 41), ordering forms (DEA Form 222), purchase orders and shipping receipts, generated in connection with the Controlled Substances program must be maintained by the registrant for at least two years following termination of any registrations and must be readily retrievable upon request.

1. **9. Controlled Substances of Unknown Origin**

Occasionally, laboratories or animal facilities may come across Controlled Substances of an uncertain origin, sometimes referred to as “orphaned drugs.” For example, a registrant may depart the institution and another researcher may come upon the Controlled Substances that were left behind. Similarly, a researcher may come upon a Controlled Substance that was inadvertently left in an animal facility. In those circumstances, the researcher should take the following steps: (1) make sure that the Substance is secured in a registration holder’s locked safe or cabinet; and (2) contact the BWH Department of Environmental Affairs for disposal assistance and coordination. The BWH Department of Environmental Affairs will investigate the matter and, as appropriate, provide the USDEA in writing with a brief description of how the laboratory came into possession of the Controlled Substances, of the type of substance and quantity, and a proposed method of disposal for approval by the USDEA. Once the USDEA approves of the method of disposal, such orphaned drugs can be destroyed in accordance with that method.

**10. Disposal**

*10.1 Expired drugs*

When Controlled Substances expire, registrants or Authorized Individuals must mark the containers clearly as “NOT FOR USE” and store them separate (but still in the locked narcotics cabinet) from non-expired drugs. A different shelf in the storage cabinet may be labeled “NOT FOR USE-EXPIRED DRUGS,” or labs may place a bin or container in the storage cabinet with a similar label. The Department of Environmental Affairs can supply an “Expired Drug” bin which fits in the BWH supplied Controlled Substance Narcotics Cabinet, free of charge to investigators.

All expired drugs should be disposed of as soon as possible, usually at the next scheduled quarterly disposal time (process described below). Researchers should contact the BWH Department of Environmental Affairs to determine the next available disposal time so that arrangements can be made for an Authorized Individual to participate. Note that the Department of Environmental Affairs and BWH Research Operations each have the authority to require expired drug disposal within a specified time period other than that of the scheduled quarterly disposal session. It is the responsibility of the registrant to ensure that the drugs are disposed of by the deadline. If the deadline occurs before the next scheduled disposal time or if the lab misses a scheduled disposal, the registrant will be responsible for covering all costs of disposal. Corrective action may be taken for labs who fail to meet disposal requirements.

Controlled Substances consumed in a reaction incorporated into hazardous waste, or a mixture from which a Controlled Substance is not recoverable, may be disposed of through routine waste disposal procedures managed by the BWH Department of Environmental Affairs. Animal carcasses that were injected with Controlled Substances must be disposed of through the Center for Comparative Medicine (CCM).

*10.2 Fentanyl Patches*

Used fentanyl patches, a solid Controlled Substance waste, should be made irrecoverable by disposing of such waste in an organic solvent. It is appropriate to place a used fentanyl patch in the laboratory’s organic solvent waste jar for disposal along with the organic solvent. Fentanyl patches that are unused, but expired or unneeded by the lab, should be disposed of like other Controlled Substances via the quarterly disposal process described below. Please contact the Department of Environmental Affairs for questions regarding the proper disposal of fentanyl patches or any other solid Controlled Substance waste.

*10.3 Quarterly Disposal Process*

BWH has a letter on file with the USDEA which describes the quarterly controlled substance disposal process; it can be produced upon request. Registrants and their Authorized Individuals are responsible for the appropriate maintenance and disposal of Controlled Substances under their registration. BWH will not hold or take possession of Controlled Substances, even if they are expired and ready for disposal. To assist investigators in disposal, the BWH Department of Environmental Affairs will schedule and announce periodic Controlled Substance disposal events by email to the research community and include in the announcements requirements of the disposal program. The registrant or an Authorized Individual is responsible for delivering the Controlled Substances and associated paperwork to the designated drop-off location at the appropriate time. Registrants or Authorized Individuals must bring the following to the designated drop-off location: proper identification, a completed USDEA Form 41 and a photocopy of the USDEA registration. It is important that the registrant or Authorized Individual make copies of DEA Form 41 prior to leaving the lab as this form will not be returned, and a copy is required to be kept with the Controlled Substance lab record as proof of disposal. It should also be noted in the logbook that the drugs were destroyed via a USDEA Form 41 and the quarterly disposal process.

USDEA Form 41 can be obtained from the USDEA webpage: <http://www.deadiversion.usdoj.gov/21cfr_reports/surrend/index.html> and questions on completing the form can be addressed to the BWH Department of Environmental Affairs. Additional details will be announced as each disposal period is scheduled.

**11. Registrant Transfer/Departure from BWH**

Prior to a registrant departing BWH, any Controlled Substances associated with the departing PI’s registration must be destroyed before the departure. Please contact the BWH Department of Environmental Affairs to arrange for Controlled Substance disposal. Alternatively, a Controlled Substance may be transferred to another registrant whose registration includes the same drug code and schedule; however, very specific paperwork is required by the USDEA for this type of transaction. For registration or Controlled Substance transfers, please contact Research Operations for more information prior to proceeding.

**12. Shipping Procedures**

Federal law prohibits the export of Controlled Substances unless certain requirements are met, including, in most cases, export and import permits or declarations. Violators of the law risk arrest and/or fines both in the United States and the foreign country. If necessary, licensed brokers are available for transport of Controlled Substances, if regulatory approval has been granted. Contact the Department of Environmental Affairs or Research Operations for assistance in arranging for any necessary transport of Controlled Substances.

1. **13. Resources and References**

The departments identified below may be resources for questions about this Researchers’ Guide for Use of Controlled Substances:

* BWH Department of Environmental Affairs: (**617) 264-3010**
* BWH Research Operations: (617) 732-5761
* Other relevant Environmental Health & Safety Offices:
  + HIM/NRB Building: (617) 432-2762
  + Partners Research Building, 65 Landsdowne St, Cambridge: (**617) 768-8212**
* Center for Comparative Medicine (CCM Director): (617) 525-9323

For additional information about the regulatory requirements, you may consult the following websites:

Massachusetts Department of Public Health, Drug Control Program: <http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/drug-control/>.

United States Department of Justice, Drug Enforcement Administration, Controlled Substances Act: <https://www.deadiversion.usdoj.gov/drugreg/index.html>.

Copies of this Guide, forms and links mentioned throughout this guide and best practices for using Controlled Substances can be found at: <https://partnershealthcare.sharepoint.com/sites/phrmResources/c/lsea/lshsc/bb/Pages/Controlled-Substances-in-Research.aspx>