



Controlled Substances in Research Program

PROGRAM STATEMENT

The University of Texas at Austin (UT Austin) is committed to complying with federal and state regulations involving controlled substances and controlled items. UT Austin recognizes that registration and compliance related to controlled substances are between the federal Drug Enforcement Agency (DEA) and the purchaser/user. The Principal Investigator/DEA Registrant has the ultimate responsibility for ensuring proper acquisition, use, maintenance, security, accountability, and disposal of controlled substances.

REASON FOR PROGRAM

To assist researchers in complying with all applicable federal and state regulations and UT Austin requirements. The Controlled Substances in Research Policy (HOP 7-1510), this program, and the Controlled Substances in Research training (OH 221) identify the responsibilities and requirements of the Principal Investigator/DEA Registrant and their authorized laboratory personnel when possessing and/or working with controlled substances at UT Austin.

The DEA strictly regulates controlled substances and certain listed chemicals used in the manufacturing of controlled substances. Due to their abuse potential, controlled substances are subject to registration, storage, security, use, and disposal requirements. In addition, certain precursor chemicals and laboratory apparatus, collectively known as controlled items, are subject to specific regulations as agreed to in a Memorandum of Understanding (MOU) between the Texas Department of Public Safety (DPS) and the Texas Higher Education Coordinating Board (THECB).

SCOPE AND AUDIENCE

The Controlled Substances in Research Program applies to all employees, students, University affiliates, and visitors. This program applies to controlled substances used in research, including human and animal research.

This program provides guidance to researchers to assist in properly managing registration, procurement, use, recordkeeping, storage, security, and disposal of controlled substances used in research. The information provided is not intended to cover all aspects of the applicable regulations governing controlled substances. Further information on requirements for managing controlled substances can be found on the DEA Diversion Control Division website and in Title 21 of the Code of Federal Regulations, Chapter II. This program complements the Researcher's Manual published by the DEA. Researchers may contact EHS for guidance on specific questions related to the use of controlled substances in research.

RELATED UT AUSTIN DOCUMENTS

UT Austin Handbook of Operating Procedures – [Controlled Substances in Research Policy](#)

UT Austin Handbook of Operating Procedures – [Environmental Health and Safety Policy](#)

[UT Austin Lab Safety Manual](#)

DEFINITIONS

| Term | Definition |
|------------------------------------|---|
| Access | direct access to stored controlled substances; has the combination/key to the safe, lock box, cabinet, etc. where controlled substances are stored; granted only by the PI/Registrant |
| Authorized Designee | individual authorized by the PI/Registrant to have access to the secure storage cabinet/safe; responsible for issuing and managing controlled substances; kept to the minimum essential for operation (e.g., 1-2/lab); must be a UT Austin employee |
| Certificate of Registration | DEA Form 223; issued by the DEA to the PI/Registrant authorizing the specified business activity and handling of specified schedules of controlled substances and/or specified controlled substances; lists the registration number and the expiration date of the registration |
| Controlled Items | regulated precursor chemicals and laboratory apparatus as defined in the Texas Controlled Substances Act ; chemical laboratory apparatus are any item of equipment designed, made, or adapted to manufacture a controlled substance or a controlled substance analogue; requirements outlined in the MOU between DPS and THECB |
| Controlled Substances | compounds containing any quantity of a substance with a stimulant, depressant, or hallucinogenic effect on the higher functions of the central nervous system, and have the tendency to promote abuse or physiological or psychological dependence, as designated under the federal Controlled Substances Act (CSA) |
| Diversion Listed Chemicals | using a controlled substance that was obtained legitimately for illegitimate uses chemicals that, in addition to legitimate uses, are used in illicit manufacturing of a controlled substance; list I and II chemicals, as designated under the federal Controlled Substances Act (CSA) |
| Non-Employee | any individual without a paid employee appointment at UT Austin, including students without employee appointments and volunteers |
| Non-Retrieveable | for the purpose of destruction (21 CFR 1300.05(b)): the condition or state to which a controlled substance shall be rendered following a process that permanently alters that controlled substance's physical or chemical condition or state through irreversible means; unavailable and unusable for all practical purposes; cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue |
| On Hand Permitted User | in the possession of or under the control of the PI/Registrant individual authorized by the PI to work with limited quantities of controlled substances; no access to the secure storage cabinet/safe |
| Principal Investigator | individual registered with the DEA to conduct research with controlled substances; ultimately responsible for controlled substances management; must be the PI of the lab; referred to as PI/Registrant throughout this document |

(PI)/DEA

Registrant

**Readily
Retrievable** ([21 CFR 1300.01](#)): records kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time, and/or records kept in such a manner that certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records

**Reverse
Distributor** third-party entity registered with the DEA to handle returns and disposal of controlled substances; authorized to receive expired, damaged, or otherwise unwanted controlled substances from PIs/Registrants with a current DEA Certificate of Registration

RESPONSIBILITIES

All employees, students, University affiliates, and visitors are responsible for full compliance with applicable state, federal, and University regulations and requirements governing controlled substances, listed chemicals, and controlled items management. PIs/Registrants have the ultimate responsibility for ensuring proper acquisition, use, maintenance, security, accountability, and disposal of controlled substances obtained under their DEA controlled substances registration. The PI/Registrant is responsible and liable for any loss, theft, or misuse of any controlled substance acquired through their registration.

An employee who has knowledge of controlled substance diversion by another employee at UT Austin is obligated to report such activities to the UT Police Department (UTPD). Reported activities are treated as confidential by UT Austin and reasonable steps are taken to protect the confidentiality and identity of the employee providing the information. Failure to report the diversion of a controlled substance will be considered in determining the feasibility of allowing an employee to work in a research space where controlled substances are used.

Principal Investigator (PI)/DEA Registrant (Registrant):

- Adhering to all federal and state regulatory requirements while working with controlled substances;
- Adhering to all requirements, established by HOP 7-1510 and this program, pertaining to proper reporting of information and usage of controlled substances;
- Obtaining and keeping current a DEA controlled substances registration;
- Notifying EHS of intent to use controlled substances prior to obtaining a DEA registration;
- Notifying EHS, UTPD, and the DEA (as applicable) of theft, loss, or unauthorized use immediately upon discovery;
- Completing required background check;
- Establishing and maintaining effective controls and procedures to prevent unauthorized access, theft, or diversion;
- Completing required controlled substances training;

- Meeting with EHS to perform controlled substances inspections and providing access to records as needed to complete the inspection;
- Providing a copy of their current registration certificate to EHS prior to ordering controlled substances, and upon renewal thereafter;
- Ensuring all records, including but not limited to, current DEA registration, inventory records, and personnel records, are complete, current, and available upon request for inspection;
- Notifying DEA of significant changes, including but not limited to, change in storage location;
- Ensuring all unused controlled substances are disposed of promptly and prior to termination of employment and/or registration; and
- Notifying EHS of any DEA visits/audits/inspections relating to controlled substances.

Authorized Designees:

- Adhering to all procedures and program elements;
- Informing PI/Registrant and EHS of theft, loss, or unauthorized use immediately upon discovery;
- Completing required background check; and
- Completing required controlled substances training.

Permitted Users:

- Adhering to all procedures and program elements;
- Informing PI/Registrant and EHS of theft, loss, or unauthorized use immediately upon discovery; and
- Completing required controlled substances training.

Environmental Health and Safety (EHS):

- Assisting PIs/Registrants in complying with applicable regulations and requirements by implementing and maintaining the Controlled Substances in Research Program;
- Providing training on regulations and requirements;
- Performing regular controlled substances inspections;
- Reviewing controlled substances self-evaluations and following-up as needed;
- Notifying PIs in advance of their registration renewal date; and
- Acting as the designated Controlled Substances in Research Program Administrator/Coordinator.

Human Resources (HR):

- Notifying the Office of the Vice President for Legal Affairs and the Office of the Vice President for Research, Scholarship, and Creative Endeavors of employees convicted of drug-related offenses when conducting background checks for controlled substance access.

Office of the Vice President for Legal Affairs (OVPLA) and Office of the Vice President for Research, Scholarship, and Creative Endeavors (OVPR):

- Making the determination whether an employee's access to controlled substances should be denied when notified by HR that the employee has been convicted of drug-related offenses.
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REQUIREMENTS

Controlled substances possessed, kept, or otherwise stored in a manner or location not in compliance with applicable laws, regulations, and requirements are subject to seizure by and forfeiture to law enforcement officials. Failure to comply with federal and state regulations may result in personal, civil, and/or criminal liability. In addition, non-compliance with applicable requirements may result in a suspension of purchasing privileges and disciplinary actions.

Registration ([21 CFR 1301](#))

PIs must obtain a DEA Certificate of Registration (DEA Form 223) and provide a copy of this certificate to EHS prior to purchasing and working with controlled substances at UT Austin. Notify EHS before applying for registration with the DEA.

- As of September 1, 2016, the State of Texas no longer requires a controlled substance registration with the Texas Department of Public Safety (DPS). Therefore, there is no separate state registration for research use of controlled substances.
- As employees of UT Austin, PIs may certify that they are government employees in order to receive a fee exemption. The fee exemption restricts the use of the Certificate of Registration to official government or university duties only. The UT Austin Certifying Official for this purpose is the Director of Environmental Health and Safety.
- Separate registrations are required for each group of independent business activities, except as provided under coincident activities allowed per [21 CFR 1301.13\(e\)](#).
 - Research with Schedule I controlled substances requires a separate registration from both Practitioner (Schedule II-V) and Researcher (Schedule II-V) registrations.
 - Though it is not recommended, practitioners with a Schedule II-V Certificate of Registration may conduct research and instructional activities with those controlled substances for which registration was granted to the extent allowed in [21 CFR 1301.13\(e\)\(1\)](#).
 - Research must be conducted at the same address (building) as the location listed on the Practitioner's Certificate of Registration. There may be additional restrictions on the storage location of controlled substances used for research. Contact the DEA to discuss each specific situation.

- The registered storage location (i.e., the business address listed on the Certificate of Registration) must reflect the location where drugs are actually stored.
 - Only one storage location is permitted on each registration. Separate registrations are required for separate locations.
 - If the storage location changes, even temporarily, the registration must be updated. The DEA will issue an updated Certificate of Registration with the same expiration date.
- All activity associated with the controlled substance must be conducted at the same general physical location (e.g., within the same building and/or within a complex of interconnected buildings with the same address) as the registered storage location. If controlled substances are used outside of the registered storage location, they must be returned to the secure storage in the registered storage location at the end of the day.
- Registrations for Schedule I controlled substances require additional information:
 - Specific drug code numbers. Any changes to the substances used in these schedules must be submitted to and approved by the DEA prior to purchasing and working with these controlled substances.
 - A research protocol as outlined in [21 CFR 1301.18](#). Any changes to the research conducted with these substances (e.g., increase in the quantity used for an approved research project or conducting research beyond the variations provide in the approved protocol) must be submitted to and approved by the DEA prior to implementing the changes.
 - For human subject research: Institutional Review Board (IRB) approval for clinical studies and an approved active Notice of Claimed Investigational Exemption for a New Drug (IND) number for clinical studies.
 - For animal research: Institutional Animal Care and Use Committee (IACUC) approval for animal studies.
 - Research protocols and human/animal research supporting documentation can be uploaded at the time of application.

The current Certificate of Registration must be stored at the registered location in a readily retrievable manner and accessible upon request for inspection by the DEA, EHS, and other authorized agencies or other official oversight authority. When modifications of registration are submitted and approved, the DEA issues updated Certificates of Registration. Maintain the updated certificate with the old certificate until expiration.

The DEA sends renewal notifications via email to PIs/Registrants approximately 60 calendar days prior to their registration expiration date. PIs/Registrants are responsible for maintaining a current email address in application portal on DEA's website.

Once the Certificate of Registration is obtained, provide a copy to EHS initially, and annually thereafter (once the renewed Certificate of Registration is received). If copies of current Certificates of Registration are not submitted to EHS upon request, the request will be escalated.

EHS Registration Notification Process:

- EHS notifies the PI/Registrant and their identified contact(s) via email in advance of their registration renewal date.
- EHS sends reminders to the PI/Registrant and their identified contact(s) after the expiration date.
 - 1 month after expiration – EHS emails the PI/Registrant and their identified contact(s) and calls the PI/Registrant.
 - 2 months after expiration – EHS calls the PI/Registrant and notifies the EHS IACUC and IRB representatives, if applicable.
 - If no response within 2 weeks, EHS escalates to the Department Chair, Associate Dean, and OVPR, as needed.

Personnel Access (including Background Checks)

PIs/Registrants may authorize personnel to have access to and/or work with controlled substances. Non-employees, including students without paid employee appointments, must not have access to controlled substances and must not be left unsupervised at any time when working with controlled substances.

Additionally, per [21 CFR 1301.76\(a\)](#), PIs/Registrants must not give access to any person who:

- has been convicted of a felony offense relating to controlled substances;
- has had an application for registration with the DEA denied;
- has had a DEA registration revoked; or
- has surrendered a DEA registration for cause.

Authorized Designees are personnel authorized by the PI/ Registrant to have access to controlled substances and carry out other functions except ordering controlled substances or transferring controlled substances for purposes other than disposal (i.e., issuing controlled substances for use by Permitted Users). Authorized Designees:

- Must be kept to the minimum number essential for operation.
- Must complete a background check and controlled substances training prior to being granted access to controlled substances.

Permitted Users are personnel authorized by the PI/Registrant to work with, but not have access to, controlled substances. Permitted Users:

- Must complete controlled substances training prior to working with controlled substances.
- Are not required to complete a background check.

PIs/Registrants must maintain current, written records of all Authorized Designees and Permitted Users. Update records immediately when personnel leave and no longer have access to or permission to work with controlled substances. Notify EHS (submit updated forms) each time access to and/or permission to work with controlled substances changes.

- Authorized Designee Signature Logs (CS Form A) must minimally include:
 - PI/Registrant Name and EID
 - Drug Storage Location (bldg./room)

- Name, EID, Job Title, Signature, and Initials of each Authorized Designee
- Date access was granted and revoked (if applicable) – must be initialed by the PI/Registrant
- Permitted Users Lists (CS Form B) must minimally include:
 - PI/Registrant Name and EID
 - Drug Storage Location (bldg./room)
 - Name, EID, Job Title, and Initials of each Permitted User
 - Date permission was granted and revoked (if applicable) – must be initialed by the PI/Registrant
- All personnel records must be stored at the registered location in a readily retrievable manner and accessible upon request for inspection by the DEA, EHS, and other authorized agencies or other official oversight authority.
- Personnel Records for the DEA: Upon initial application for registration, the DEA may request information about anyone who will have access to controlled substances. PIs/Registrants must maintain a current list of who has access (Authorized Designees). This list must be provided to the DEA if requested during a DEA regulatory inspection, but the DEA does not need to know every time access changes. Notify the DEA of those who no longer have access only if there was a diversion/loss/theft issue at the same time.

Requirements for those granted access to controlled substances (PIs/Registrants and their Authorized Designees):

- **Background Checks** ([21 CFR 1301.93](#)) that include drug-related offenses must be conducted for each employee prior to being granted access to controlled substances. Background checks must be performed in relation to the employee's current relevant job duties (i.e., handling controlled substances).
 - PIs/Registrants must request background checks through HR. When submitting this request, PIs/Registrants must notify HR that there are additional offense types relevant to this specific position for HR to review.
 - If an employee's existing background check was not performed in relation to their current relevant job duties (i.e., handling controlled substances), a new background check that includes review of offenses relevant to this specific position must be completed prior to being granted access to controlled substances.
 - PIs/Registrants should contact HR for information regarding an employee's background check, including the date of the check, the type of check performed, and whether all drug-related offenses (not just felonies) were reviewed.
 - Upon review of the information received in an employee's background check conducted for controlled substance access, HR will notify the OVPLA and the OVPR of employees convicted of drug-related offenses. The OVPLA and the OVPR will together make the determination whether the employee's access to controlled substances should be denied.

Training

All personnel using controlled substances, including PIs/Registrants, Authorized Designees, and Permitted Users, must complete required training prior to being granted access to and/or working with controlled substances. Individuals must understand all applicable state, federal, and University requirements and lab-specific procedures, including:

- Receiving
- Recordkeeping
- Storage and Security
- Disposal
- Lost/Theft/Unauthorized Use

Required Training:

- Controlled Substances in Research (OH 221) training – required initially and every 3 years thereafter
- Lab-specific procedures for working with controlled substances (OH 102) – required initially and whenever there is a significant change in procedures and/or materials used
 - Document lab-specific procedures training on an OH 102 Laboratory Site-Specific Training Record; list working with controlled substances under the Additional Site-Specific Topics section

Recordkeeping ([21 CFR 1304](#))

PIs/Registrants must maintain complete, current, and accurate records of all controlled substances, from purchase, receipt, or acquisition, to their use, distribution, or disposal. Maintaining a complete audit trail provides accountability of all controlled substances to help reduce the potential for diversion.

Required records include:

- 1) **Purchasing and Receiving** – executed official order forms (DEA Forms 222) or the electronic equivalent and unexecuted official order forms (DEA Forms 222) for Schedules I and II; receipts and/or invoices for Schedules III, IV, and V; transfer forms for acquisitions from other registrants; and record of receipt documenting each purchase or other acquisition
- 2) **Usage Logs** – separate log for each container, including all dilutions/mixtures prepared by lab personnel, but not used by the end of the same business day; record an entry every time these substances are used and when transferred, disposed of, spilled, or lost
- 3) **Inventories** – initial and biennial inventories (or more often as needed) of all controlled substances in possession at the time of the inventory, dated as beginning or close of business
- 4) **Distribution and Disposal** – records of all distributions (i.e., transfers to other registrants, returns to vendors, distributions to reverse distributors for disposal); all associated paperwork – including transfer forms for distributions to other registrants and any executed DEA Forms 222, invoices, reports, records of receipt, shipping documents, and/or records of destruction (DEA Forms 41) for disposal through reverse distributors and returns to vendors
- 5) **Theft, Loss, or Unauthorized Use** – records of any theft, suspected theft, unauthorized use, or other losses (including in-transit losses and unacceptable discrepancies) – including Reports of

Theft or Loss of Controlled Substances (DEA Forms 106) and any correspondence with the DEA; records of minor inventory discrepancies; records of breakage and spillage – may include Registrant Record of Controlled Substances Destroyed (DEA Form 41), if applicable; record of occurrences of theft, loss, or unauthorized use, any discrepancies in recordkeeping and any breakage/spillage; incident reports, if applicable

At a minimum, all records must be:

- Stored in a readily retrievable manner.
 - Controlled substance records must be kept separately from all other records and documents in a dedicated binder or folder.
 - Records for controlled substances listed in Schedules I and II must be kept completely separate from records for controlled substances listed in Schedules III, IV, and V in their own dedicated binder or folder.
- Stored at the registered location.
 - A PI/Registrant who wishes to maintain at a location other than the registered location records (e.g., invoices or packing slips stored in a central billing office) must notify the DEA per [21 CFR 1304.04\(a\)\(1\)](#) and adhere to the conditions outlined in [21 CFR 1304.04\(b\)](#).
 - Executed order forms (DEA Forms 222) and inventories must be maintained at the registered location.
 - Recommended: If packing slips are stored elsewhere, keep a copy at the registered location.
- Kept separate for each registration number and for each registered location.
- Available for inspection by the DEA, EHS, and other authorized agencies or other official oversight authority during regular work hours.
- Maintained for a period of at least two years from the date of the last recorded transaction.

Electronic Records:

PIs/Registrants are not required to notify the DEA or obtain approval to maintain records on an in-house computer system. If records are kept electronically, they must be:

- Stored in such a manner that they can be separated out from all other records in a reasonable time. Keep records in their own dedicated folder so they are readily retrievable from other records.
- Accessible at the registered location. The PI/Registrant is responsible for providing access to any equipment required to view records at the registered location.
 - If inventories are stored electronically, a current, printed version must be kept at the registered location.

For Schedule I and II controlled substances, electronic copies of DEA Forms 222 are deemed to be readily retrievable if they are stored separately in their own dedicated folder and accessible at the registered location.

Contents of Records:

At a minimum, all records must contain the name of the controlled substance, the concentration/strength and form, and the container size/type and original amount. Some record types require additional information as detailed in each of the record type sections.

In order to maintain complete records, each container of controlled substance must be labeled with a unique lab inventory control number. This number must be documented on all records for each container. Additionally, all dilutions/mixtures created must be labeled with their own unique number. Any dilutions/mixtures completely used by the end of the same business day in which they were created do not require separate inventory control numbers.

The use of codes, symbols, or foreign languages in identifying a controlled substance or person in any controlled substance record is prohibited.

Purchasing and Receiving ([21 CFR 1305](#); [21 CFR 1304.21](#); [21 CFR 1304.22](#))

Only PIs/Registrants may order controlled substances. ProCards cannot be used to order controlled substances. Schedule I and II controlled substances must be ordered with an official paper order form (DEA Form 222), or the electronic equivalent. A DEA Form 222 is also required for each distribution or transfer of a Schedule I or II controlled substance unless exempted (i.e., required for transfers to/from other registrants and distributions to reverse distributors for disposal). Schedule III, IV, and V controlled substances cannot be ordered with an official paper order form (DEA Form 222).

The supplier may request a copy of the PI's/Registrant's current DEA Certificate of Registration before the order will be prepared and shipped. Controlled substances will be delivered directly to the address indicated on the Certificate of Registration or DEA Form 222 (for Schedule I and II).

Schedule I and II orders - DEA Form 222 Requirements ([21 CFR 1305](#); additional information is available in the [Researcher's Manual](#) published by the DEA):

- DEA Forms 222 are issued by the DEA once registration is granted. Limits on the number of forms furnished are determined by business activity. Additional single-sheet forms must be requested from the DEA.
 - As of October 31, 2021, the DEA implemented the mandatory use of single-sheet DEA Forms 222. Unused triplicate DEA Forms 222 are no longer accepted and must be returned to the DEA Registration Section. Retain copies of executed, unaccepted, and voided triplicate forms for two years. Lost and stolen triplicate forms must be reported per 21 CFR 1305.20(f).
- All DEA Forms 222 must be kept secure.
- Even if other records are maintained elsewhere (with DEA approval), executed order forms (DEA Forms 222) must be retained at the registered location printed on the form. DEA Forms 222 must be maintained separately from all other records.
- PIs/Registrants must account for all issued DEA Forms 222, including voided, unexecuted, and executed forms. DEA Forms 222 must not be discarded. Unused forms must be returned to the DEA Registration Section if no longer needed.

- Strongly recommended: Keep a log of DEA Forms 222 received (CS Form E) and verify periodically (e.g., annually) to maintain accountability.
- Forms have an order form number and are issued with the name, address, and registration number of the registrant, the authorized activity, and the schedules of the registrant. Errors must be reported. This information CANNOT be altered or changed by the registrant. If the name or address as shown on the purchaser's registration changes, the purchaser must return all unused DEA Forms 222 to the DEA Registration Section.
- The controlled substances must be shipped only to the purchaser and the location printed by the DEA on the Form 222.
- Purchasers must make a copy (paper or electronic) of the original DEA Form 222 for their records and then submit the original to the supplier.
- If the order is not filled or voided for any reason, the DEA Form 222 must be retained with appropriate documentation (e.g., statement of the reason the form was not accepted). The purchaser may cancel and/or a supplier may void all or part of an order on a DEA Form 222 as outlined in [21 CFR 1305.19](#).
- Any used or unused DEA Forms 222 that are lost or stolen must be reported immediately upon discovery to the local DEA Field Office. If the order form number is not known, the PI/Registrant must submit date or approximate date of issuance. Additionally, if any unfilled DEA Forms 222 are lost, the PI/Registrant must follow the procedures outlined in [21 CFR 1305.16\(a\)](#).
 - If any unused DEA Form 222 reported stolen or lost is subsequently recovered or found, the DEA must be immediately notified.
- Electronic orders may be submitted via the [DEA's Controlled Substance Ordering System \(CSOS\)](#), which allows for secure electronic transmission of controlled substance orders without the supporting paper DEA Form 222. If a purchaser determines that an unfilled electronic order has been lost before or after receipt, the purchaser must follow the procedures outlined in [21 CFR 1305.26](#).

Tracking and Receiving Packages ([21 CFR 1304.21](#); [21 CFR 1304.22](#)):

PIs/Registrants or their Authorized Designee are responsible for tracking the controlled substance package once ordered. Only the PI/Registrant or their Authorized Designee should sign for the package.

As soon as the package is received, verify the contents, comparing the invoice and packing slip. Sign and date the packing slip signifying that all is correct. For Schedule I and II orders, immediately document the actual number of commercial or bulk containers received and the date received on the retained copy of the DEA Form 222.

If there are any discrepancies, contact the supplier and document any changes. Include emails or other correspondence to indicate the discrepancy and resolution. Any in-transit losses of controlled substances must be reported to the DEA (see Theft, Loss, and Unauthorized Use for details).

Upon receipt, each container of controlled substance must be labeled with a unique lab inventory control number. This number will be documented on all records for each container in order to maintain a complete audit trail of all controlled substances. All dilutions/mixtures prepared by lab personnel, but not used by the end of the same business day, must be labeled with their own unique number.

Keep all purchasing and receiving documents for at least two years, including:

- Copies of executed DEA Forms 222 (Schedules I and II only) – with date and quantity received
- Purchase orders (if available)
- Receipts and/or invoices
- Verified/signed packing slips

All receipts of controlled substances (including purchases from vendors and transfers from other registrants) must be documented in the Record of Receipt. Attach all purchasing and receiving documents to the Record of Receipt.

Records of Receipt (CS Form F) must minimally include:

- **PI/Registrant Name** – the DEA Registrant’s name as it appears on the Certificate of Registration
- **PI/Registrant DEA Registration Number** – the DEA Registrant’s registration number as it appears on the Certificate of Registration
- **Drug Storage Location** – the building/room number where the controlled substance is stored
- **Drug Name** – the name of the controlled substance
- **Drug Schedule** – the assigned DEA schedule of the controlled substance
- **Date Received** – the date the controlled substance was received (not the invoice date)
- **Invoice/Transfer Form Number** – the number listed on the associated invoice, transfer form, and/or DEA Form 222 (for Schedule I and II)
- **Lab Inventory Control Number** – the unique number assigned by the lab to each container of controlled substances and recorded on all records for this container (new number required for dilutions/mixtures except for materials completely used by the end of the same business day)
- **Drug Concentration/Strength and Form** – the concentration/strength of each finished form of controlled substance (e.g., 10 mg tablet, 10 mg/mL, 100% - if pure powder); the physical form of the controlled substance (i.e., liquid, powder, crystals, tablets, capsules)
- **Container Size/Type** – the number of units or volume of finished form the container holds and the type of container (e.g., 100-tablet bottle or 3-mL vial); record amount in volume (liquids), weight (powder or crystals), or number of units (tablets or capsules)
- **Amount per Container** – the number of units or volume of finished form in the container when received from the supplier (e.g., 85 tablets or 2 mL); if the container is not full upon receipt, this may differ from the container size; record amount in volume (liquids), weight (powder or crystals), or number of units (tablets or capsules)
- **Expiration Date** – the expiration date of the controlled substance; if no expiration date, refer to the manufacturer’s recommendations for shelf life (typically up to three years for most stable organic compounds and one year if stability is unknown)
- **Received By** – the printed (written or typewritten) name and signed initials of the individual who received the controlled substance; the received by person must be the PI/Registrant or their Authorized Designee

- **Received From** – the name of the supplier (e.g., vendor or PI/Registrant) the controlled substance was received from as written on the associated invoice, transfer form, and/or DEA Form 222 (for Schedule I and II); the supplier's address must be listed on the attached invoice, packing slip, transfer form, and/or DEA Form 222

Usage Logs ([21 CFR 1304.22](#))

Usage Logs are used to record the daily use of all controlled substances. The physical amount in each container must match the usage log at all times. Keep usage logs secured.

A separate usage log must be maintained for each container of controlled substances. An entry must be recorded every time these substances are used and when transferred, disposed of, spilled, or lost. Each error must be struck-through once and initialed by the PI/Registrant or their Authorized Designee.

Usage Logs (CS Form G) must minimally include (:

- **PI/Registrant Name** – the DEA Registrant's name as it appears on the Certificate of Registration
- **PI/Registrant DEA Registration Number** – the DEA Registrant's registration number as it appears on the Certificate of Registration
- **Drug Name** – the name of the controlled substance
- **Lab Inventory Control Number** – the unique number assigned by the lab to each container of controlled substances and recorded on all records for this container (new number required for dilutions/mixtures except for materials completely used by the end of the same business day)
- **Expiration Date** – the expiration date of the controlled substance; if no expiration date, refer to the manufacturer's recommendations for shelf life (typically up to three years for most stable organic compounds and one year if stability is unknown)
- **Date Received** – the date the container was received
- **Drug Storage Location** – the building/room number where the controlled substance is stored
- **Drug Concentration/Strength** – the concentration/strength of each finished form of controlled substance (e.g., 10 mg tablet, 10 mg/mL, 100% - if pure powder)
- **Drug Form** – the physical form of the controlled substance (i.e., liquid, powder, crystals, tablets, capsules)
- **Container Size/Type** – the number of units or volume of finished form the container holds and the type of container (e.g., 100-tablet bottle or 3-mL vial); record amount in volume (liquids), weight (powder or crystals), or number of units (tablets or capsules)
- **Original Amount** – the initial number of units or volume of finished form in the container when received from the supplier (e.g., 85 tablets or 2 mL); if the container is not full upon receipt, this may differ from the container size; record amount in volume (liquids), weight (powder or crystals), or number of units (tablets or capsules)
- **Date** – the date each time the controlled substance is used

- **Issued By** – the printed (written or typewritten) name and signed initials of the individual who withdrew the controlled substance; the issued by person must be the PI/Registrant or their Authorized Designee
- **Issued To** – the printed (written or typewritten) name and signed initials of the individual using the controlled substance; the issued to person must be on the PI’s/Registrant’s current Authorized Designee or Permitted User lists
- **Purpose of Use** – the research project/experiment the controlled substance was used for; the controlled substance’s application in the research; whether the controlled substance was used to prepare a diluted stock solution or mixture (e.g., ketamine/xylazine cocktail) (record new container’s lab inventory control number in this field); whether the controlled substance was transferred (including to a reverse distributor), disposed of, spilled, or lost; when the empty container is disposed of in the trash
 - When preparing a diluted stock solution or mixture, label the new container with a unique lab inventory control number and include this number in “Purpose of Use” field; record the use of the dilution/mixture on a separate “Dilution/Mixture Usage Log” (dilutions/mixtures completely used by the end of the same business day do not require a new inventory control number/usage log)
 - If there is a theft, unauthorized used, spill, or other loss of controlled substances, include the incident form number in the “Purpose of Use” field; record the explanation of what happened in the theft, loss, or unauthorized use records
- **Amount Withdrawn** – the amount withdrawn each time the controlled substance is used (e.g., 2 tablets or 0.5 mL); record amount in volume (liquids), weight (powder or crystals), or number of units (tablets or capsules)
- **Amount Remaining** – the amount remaining each time the controlled substance is used (e.g., 83 tablets or 1.5 mL); record amount in volume (liquids), weight (powder or crystals), or number of units (tablets or capsules)
- **Amount Wasted** – the amount withdrawn but not used (e.g., 0.1 mL); must be disposed of in a manner that renders it non-retrievable; record amount in volume (liquids), weight (powder or crystals), or number of units (tablets or capsules)
- **Witness Initials** – the initials of the two individuals witnessing the wasting

Dilution/Mixture Usage Logs:

When controlled substances are withdrawn from their original (stock) container and diluted (e.g., in saline/water) or mixed with other chemicals (e.g., ketamine-xylazine cocktail), additional records must be kept for each container not completely used by the end of the same business day.

Each container of diluted/mixed controlled substances must:

- Be assigned a unique lab inventory control number.
- Be labeled with:
 - **Drug Dilution/Mixture Name** – the name of the diluted controlled substance (if diluted in saline/water; e.g., Dilute Buprenorphine) or the name of the mixture (if mixed with other chemicals; e.g., Ketamine-Xylazine Cocktail);

- **Lab Inventory Control Number** – the unique number assigned by the lab to each container of controlled substances and recorded on all records for this container; must be separate number from the stock container; and
- **Expiration Date** – the expiration date of the dilution/mixture; if used in animals, the expiration date must be one month from the date of preparation, even if it is earlier than the manufacturer’s drug expiration date
- Be securely stored in the same manner as all other controlled substances.
- Be recorded on a separate dilution/mixture usage log.

Dilution/Mixture Usage Logs (CS Form H) must minimally include:

- **PI/Registrant Name** – the DEA Registrant’s name as it appears on the Certificate of Registration
- **PI/Registrant DEA Registration Number** – the DEA Registrant’s registration number as it appears on the Certificate of Registration
- **Drug Dilution/Mixture Name** – the name of the diluted controlled substance (if diluted in saline/water; e.g., Dilute Buprenorphine) or the name of the mixture (if mixed with other chemicals; e.g., Ketamine-Xylazine Cocktail)
- **Lab Inventory Control Number** – the unique number assigned by the lab to each container of controlled substances and recorded on all records for this container; must be separate number from the stock container (new number not required for dilutions/mixtures completely used by the end of the same business day)
- **Expiration Date** – the expiration date of the dilution/mixture; if no expiration date, refer to the manufacturer’s recommendations for shelf life (typically up to three years for most stable organic compounds and one year if stability is unknown)
 - If used in animals, the expiration date must be one month from the date of preparation, even if it is earlier than the manufacturer’s drug expiration date. Any exceptions must be approved by the Institutional Animal Care and Use Committee (IACUC).
- **Date Prepared** – the date the dilution/mixture was prepared and added to the container
- **Drug Storage Location** – the bldg./room number where the dilution/mixture is stored
- **Drug Concentration/Strength** – the final concentration/strength of each controlled substance in the dilution/mixture (e.g., 1 mg/mL)
- **Drug Form** – the physical form of the dilution/mixture (i.e., liquid, powder)
- **Container Size/Type** – the number of units or volume of dilution/mixture the container holds and the type of container (e.g., 15-mL tube); record amount in volume (liquids) or weight (powder)
- **Original Amount** – the initial number of units or volume of dilution/mixture in the container when prepared (e.g., 5 mL); record amount in volume (liquids) or weight (powder)
- **Dilution/Mixture Details:**
 - **Dilution/Mixture Components** – the name of each component in the dilution/mixture

- **Lab Inventory Control Number** – the unique number of each stock container of controlled substance; if component is not a controlled substance (e.g., water), record “N/A”
- **Stock Concentration** – the concentration/strength of the stock container of controlled substance; if component is not a controlled substance (e.g., water), record “N/A”
- **Amount** – the amount of each component used to prepare the dilution/mixture
- **Total** – the total amount of dilution/mixture prepared
- **Final Concentration in Dilution/Mixture** – the final concentration of each component in the dilution/mixture
- **Date** – the date each time the dilution/mixture is used
- **Issued By** – the printed (written or typewritten) name and signed initials of the individual who withdrew the dilution/mixture; the issued by person must be the PI/Registrant or their Authorized Designee
- **Issued To** – the printed (written or typewritten) name and signed initials of the individual using the dilution/mixture; the issued to person must be on the PI’s/Registrant’s current Authorized Designee or Permitted User lists
- **Purpose of Use** – the research project/experiment the dilution/mixture was used for; the controlled substance’s application in the research; whether the dilution/mixture was transferred (including to a reverse distributor), disposed of, spilled, or lost; when the empty container is disposed of in the trash
 - If there is a theft, unauthorized used, spill, or other loss of controlled substances, include the incident form number in the “Purpose of Use” field; record the explanation of what happened in the theft, loss, or unauthorized use records
- **Amount Withdrawn** – the amount withdrawn each time the dilution/mixture is used (e.g., 0.5 mL); record amount in volume (liquids) or weight (powder)
- **Amount Remaining** – the amount remaining each time the dilution/mixture is used (e.g., 4.5 mL); record amount in volume (liquids) or weight (powder)
- **Amount Wasted** – the amount withdrawn but not used (e.g., 0.1 mL); must be disposed of in a manner that renders it non-retrievable; record amount in volume (liquids), weight (powder or crystals), or number of units (tablets or capsules)
- **Witness Initials** – the initials of the two individuals witnessing the wasting

Initial and Biennial Inventories (21 CFR 1304.11)

Inventories of all controlled substances in the PI’s/Registrant’s possession must be completed initially and at least every two years thereafter. Ensure that the inventory can be reconciled to the records of receipt, usage, and distribution/disposal at all times. Keep initial and biennial inventories secured; if stored electronically, keep a current, printed version at the registered location.

Inventories of controlled substances must be completed:

- **Initially** – the initial inventory must be completed initially when the PI/Registrant is issued their Certificate of Registration. In the event that the PI/Registrant does not possess any controlled substances when commencing business, the initial inventory must be completed showing a zero inventory.
- **Biennially** – after the initial inventory is taken, a new inventory must be completed at least every two years. In the event that the PI/Registrant does not possess any controlled substances when the biennial inventory is due, the biennial inventory must be completed showing a zero inventory.
 - Strongly recommended: Complete the inventory more frequently (e.g., annually).
- **As applicable for newly controlled substances** – a new inventory must be completed if the PI/Registrant possesses a substance that was not previously on any schedule. The inventory, including all stocks of the substance possessed by the PI/Registrant, must be completed on the effective date of the ruling adding the substance to the schedule.
- Complete a new inventory if controlled substances are moved to a new storage location.

When inventories are conducted:

- The record must be a complete and accurate list of all stocks and forms of controlled substances in the PI's/Registrant's possession, including samples, dilutions/mixtures, and stored materials.
- An actual physical count of all Schedule I-V controlled substances must be performed.
 - For Schedule I and II: Make an exact count or measure of the contents.
 - For Schedules III, IV, and 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 is required.
- The count must be completed either at the beginning of business (before the first use of the day) or at the close of business (after last use of the day); the time must be documented on the inventory form.
- Two people must be physically present to oversee the count; the person conducting the count and the witness must be documented on the inventory form.
- Separate records must be completed for each registered location and each independent activity registered.
- Separate records must be completed for controlled substances listed in Schedules I and II and controlled substances listed in Schedules III, IV, and V.
 - Confirm that the actual physical count matches the usage log. **Immediately report inventory discrepancies to EHS.** If no discrepancies are found, inventories do not need to be submitted to the DEA or EHS.
- The record must be kept available for two years after completely using, transferring, or disposing of any controlled substance listed.

Inventories (CS Form J) must minimally include:

- **PI/Registrant Name** – the DEA Registrant's name as it appears on the Certificate of Registration

- **PI/Registrant DEA Registration Number** – the DEA Registrant’s registration number as it appears on the Certificate of Registration
- **PI/Registrant Address** – the DEA Registrant’s address as it appears on the Certificate of Registration; must include information indicating the specific building and room number where the drugs are stored
- **Drug Storage Location** – the building/room number where the controlled substance is stored
- **Time Completed (Beginning of Business/Close of Business)** – the time the inventory was taken on the inventory date; must either be beginning of business (before the first use of the day) or close of business (after last use of the day)
- **Inventory Date** – the date the inventory was taken
- **Initial or Biennial Inventory** – the type of inventory completed
- **Inventory Performed By** – the printed name and signature of the individual who actually did the physical count
- **Inventory Witness** – the printed name and signature of the individual who witnessed and confirmed the physical count
- **Drug Name** – the name of the controlled substance
- **Drug Schedule** – the assigned DEA schedule of the controlled substance
- **Lab Inventory Control Number** – the unique number assigned by the lab to each container of controlled substances and recorded on all records for this container (new number required for dilutions/mixtures except for materials completely used by the end of the same business day)
- **Drug Concentration/Strength** – the concentration/strength of each finished form of controlled substance (e.g., 10 mg tablet, 10 mg/mL, 100% - if pure powder)
- **Drug Form** – the physical form of the controlled substance (i.e., liquid, powder, crystals, tablets, capsules)
- **Container Size/Type** – the number of units or volume of finished form the container holds and the type of container (e.g., 100-tablet bottle or 3-mL vial); record amount in volume (liquids), weight (powder or crystals), or number of units (tablets or capsules)
- **Original Amount** – the initial number of units or volume of finished form in the container when received from the supplier (e.g., 85 tablets or 2 mL); if the container is not full upon receipt, this may differ from the container size; record amount in volume (liquids), weight (powder or crystals), or number of units (tablets or capsules)
- **Amount Remaining** – the amount remaining in the container at the time the inventory was taken (e.g., 83 tablets or 1.5 mL); record amount in volume (liquids), weight (powder or crystals), or number of units (tablets or capsules)
- **Reason Maintained (if not in use)** – the reason a controlled substance is being maintained if it is damaged, defective, expired, or otherwise not in use and whether the controlled substance is capable of use in the manufacture of any controlled substance

Storage and Security (21 CFR 1301.71; 21 CFR 1301.75)

PIs/Registrants must provide effective controls and procedures to guard against theft and diversion of controlled substances. When evaluating a secure storage location, the following factors must be considered:

- Type and form of controlled substances used;
- Quantity of controlled substances stored;
- Location of the storage 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; and
- Procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel.

The security of a particular drug storage area can only be deemed adequate by the DEA. PIs/Registrants can contact their local DEA Field Office with questions regarding proposed controlled substance storage. The local DEA Field Office may conduct an on-site inspection as part of the registration approval process, which may identify circumstances requiring alternative storage solutions.

Storage and security procedures must minimally include:

- **General Security** – all controlled substances (including expired substances and dilutions/mixtures) must be secured at all times.
 - Keep controlled substances locked in the secure storage cabinet/safe or under the direct control of authorized personnel for the actual time required to remove, legitimately work with, and replace them.
 - Expired controlled substances must be clearly labeled as being expired and must remain in the secure storage cabinet/safe until they are packaged and consigned for disposal.
 - Never leave controlled substances unattended.
 - Keep the inventory (stocks) of controlled substances to the smallest quantity needed.
 - Schedule I only – if there will be any changes to the storage and security procedures, a supplemental protocol must be submitted to and approved by the DEA prior to implementing the changes.
- **Personnel Access** – keep the number of individuals authorized to handle controlled substances to an absolute minimum essential for operation.
 - Only the PI/Registrant and their Authorized Designees may access the secure storage cabinet/safe.
 - Permitted Users may only handle controlled substances that were issued to them by the PI/Registrant or their Authorized Designee.
 - Non-employees must not be left unsupervised at any time when working with controlled substances.
 - Recommended: Designate a backup person for safe access (i.e., someone who can access the safe if the PI/Registrant is not available).

- **Storage Location** – the registered storage location (i.e., room in which the storage cabinet/safe is located) must be secured.
 - Must have limited access during work hours.
 - The door to the storage location must be locked at all times when unoccupied.
 - The number of personnel with access to the storage location should be minimized.
 - When it is necessary for non-authorized individuals to enter the storage location, the PI/Registrant must ensure adequate observation by authorized personnel.
- **Storage Cabinets/Safes** – all controlled substances must be stored in a securely locked, substantially constructed cabinet or safe.
 - Must be kept locked at all times.
 - Must not be easily broken into and must be secure enough to show when entry is forced.
 - Must not be readily moveable. If the cabinet/safe weighs less than 750 pounds, it must be bolted to the floor, mounted on the wall, or stored inside of a locked cabinet that is secured to the floor or wall.
 - Must not have a glass panel as the panels could be easily broken and allow passersby to view the contents of the cabinet.
 - **Drawers:** Must be inaccessible from the upper or lower drawers in the stack. If possible, use the top drawer of the stack for storage. Cabinetry encasing the drawer must be secured to the wall or floor or weigh more than 750 pounds.
 - **Padlocks and Hinges:** Mounting screws or bolts must be inaccessible when the door is closed and locked.
 - **Cold Storage:** A lock box must be used inside of a locked refrigerator/freezer.
 - **Separation of Items:**
 - Schedule I and II controlled substances must be kept separate from Schedule III-V. Storage on a separate shelf of the same cabinet/safe is permitted.
 - Cabinets/safes must not be shared with other PIs/Registrants that have separate DEA Registrations.
 - Expired controlled substances must be separated from non-expired containers of controlled substances.
 - Other items, including non-controlled drugs and other chemicals, must not be kept in the same cabinet/safe as the controlled substances.
 - Recommended: Use a steel, wall-mountable drug cabinet, narcotics box, or safe designed for the purpose of storing controlled substances. Depending on the factors described above, a lock box secured in a locked drawer or cabinet may be sufficient.
- **Keys/Combination Codes** – keys and combination codes must be kept secure.
 - Keys and combination codes must not be stored near the cabinet/safe.

- Keys and combination codes must not be readily accessible to individuals not listed in the PI's/Registrant's record of Authorized Designees.
- Whenever anyone with access is terminated from employment, retrieve all keys and change all combination codes. Record the Date Access Revoked on the Authorized Designee Signature Log.
- Recommended: Keep one key in a secure location, such as a wall-mounted key safe, and restrict access to only Authorized Designees. The combination to most key safes can be easily changed when needed.

Distributions ([21 CFR 1304.22](#))

All distributions of controlled substances (including disposal through reverse distribution and transfers to other registrants) must be documented in the Record of Distribution. Attach all distribution documents (invoices, destruction reports, transfer forms, and DEA Forms 222, where applicable) to the Record of Distribution.

A DEA Form 222 is required for each distribution or transfer of a Schedule I or II controlled substance unless exempted (i.e., required for distributions to reverse distributors for disposal and transfers to other registrants). The supplying PI/Registrant must make and submit a copy of the original DEA Form 222 to the DEA Registration Section.

Records of Distribution (CS Form K) must minimally include:

- **PI/Registrant Name** – the DEA Registrant's name as it appears on the Certificate of Registration
- **PI/Registrant DEA Registration Number** – the DEA Registrant's registration number as it appears on the Certificate of Registration
- **Drug Storage Location** – the building/room number where the controlled substance is stored
- **Drug Name** – the name of the controlled substance
- **Drug Schedule** – the assigned DEA schedule of the controlled substance
- **Date Distributed** – the date the controlled substance was distributed (i.e., removed from the cabinet/safe and given/sent to the recipient)
- **Invoice/Transfer Form Number** – the number listed on the associated invoice, transfer form, and/or DEA Form 222 (for Schedule I and II)
- **Lab Inventory Control Number** – the unique number assigned by the lab to each container of controlled substances and recorded on all records for this container (new number required for dilutions/mixtures except for materials completely used by the end of the same business day)
- **Drug Concentration/Strength and Form** – the concentration/strength of each finished form of controlled substance (e.g., 10 mg tablet, 10 mg/mL, 100% - if pure powder); the physical form of the controlled substance (i.e., liquid, powder, crystals, tablets, capsules)
- **Container Size/Type** – the number of units or volume of finished form the container holds and the type of container (e.g., 100-tablet bottle or 3-mL vial); record amount in volume (liquids), weight (powder or crystals), or number of units (tablets or capsules)

- **Amount per Container** – the number of units or volume of finished form in the container when distributed to the recipient (e.g., 85 tablets or 2 mL); if the container is not full upon distribution, this may differ from the container size; record amount in volume (liquids), weight (powder or crystals), or number of units (tablets or capsules)
- **Expiration Date** – the expiration date of the controlled substance; if no expiration date, refer to the manufacturer’s recommendations for shelf life (typically up to three years for most stable organic compounds and one year if stability is unknown)
- **Distributed By** – the printed (written or typewritten) name and signed initials of the individual who distributed the controlled substance; the distributed by person must be the PI/Registrant or their Authorized Designee
- **Distributed To** – the name of the recipient (e.g., reverse distributor or PI/Registrant) the controlled substance was distributed to as written on the associated invoice, transfer form, and/or DEA Form 222 (for Schedule I and II); the recipient’s address must be listed on the attached invoice, destruction reports, transfer form, and/or DEA Form 222

Transfers and Shipping ([21 CFR 1301.74](#); [21 CFR 1301.76](#))

Controlled substances may not be sold, furnished, or transferred except as permitted by federal, state, and University requirements. PIs/Registrants must not distribute, transfer, or share their controlled substances to unregistered PIs/researchers, as it is considered a diversion of controlled substances and noncompliance with federal, state, and University requirements. Each PI needing to use controlled substances in their research must register with the DEA for their specific research location.

The supplier (PI/Registrant transferring the controlled substance) is responsible for confirming that the recipient has a current DEA Certificate of Registration for the specific controlled substance transferred. Schedule I and II registrations are issued for specific drug codes, and the supplier can be fined for transferring to an individual that does not have a current registration for the specific schedule/drug code.

Transfers of controlled substances between PIs/Registrants must be:

- Completed by the PI/Registrant.
- Witnessed by EHS.
- Documented on a registrant-to-registrant transfer form that is signed by both the supplier and the recipient. A copy of the signed form must be kept by both the supplier and the recipient.
 - For transfers of Schedule I and II controlled substances, DEA Forms 222 must be used in lieu of the registrant-to-registrant transfer form.
 - The DEA Form 222 must be completed by the PI/Registrant receiving the controlled substance(s).
 - The receiving PI/Registrant must make a copy of the original DEA Form 222 for their records, then submit the original to the supplying PI/Registrant.
 - The supplying PI/Registrant must make and submit a copy of the original DEA Form 222 to the DEA Registration Section.

- Recorded immediately in both the supplier’s distribution records and the recipient’s receiving records.
 - The supplier must document the removal of the controlled substance(s) from their inventory in their Record of Distribution (CS Form K; record requirements outlined in Distributions).
 - The recipient must document the addition of the controlled substance(s) to their inventory in their Record of Receipt (CS Form F; record requirements outlined in Purchasing and Receiving).
- Packaged securely in secondary containment during transport when transferred between buildings on campus.

Registrant-to-Registrant Transfer Forms (CS Form L) must minimally include:

- **Supplier’s Information:**
 - **PI/Registrant Name, DEA Registration Number, and Address** – the supplying DEA Registrant’s name, registration number, and address as it appears on the Certificate of Registration
 - **Drug Storage Location** – the building/room number where the controlled substance was stored
 - **PI/Registrant Signature and Date Signed** – the information of the individual actually completing the transfer; must be the PI/Registrant
- **Recipient’s Information:**
 - **PI/Registrant Name, DEA Registration Number, and Address** – the receiving DEA Registrant’s name, registration number, and address as it appears on the Certificate of Registration
 - **Drug Storage Location** – the building/room number where the controlled substance will be stored
 - **PI/Registrant Signature and Date Signed** – the information of the individual actually completing the transfer; must be the PI/Registrant
- **Date Transferred** – the date the controlled substance was transferred
- **Reason for Transfer** – the reason the controlled substance was transferred
- **Transfer Form Number** – the unique number assigned to this transfer form; to be recorded on the supplier’s distribution record and on the recipient’s receiving record
- **EHS Witness Printed Name, EHS Witness Signature, and Date Signed** – the information of the EHS employee witnessing the transfer
- **Information for Each Container:**
 - **Drug Name** – the name of the controlled substance
 - **Drug Schedule** – the assigned DEA schedule of the controlled substance
 - **Manufacturer and Lot Number** – the manufacturer and lot number of the controlled substance, if known

- **Drug Concentration/Strength** – the concentration/ strength of each finished form of controlled substance (e.g., 10 mg tablet, 10 mg/mL, 100% - if pure powder)
- **Drug Form** – the physical form of the controlled substance (i.e., liquid, powder, crystals, tablets, capsules)
- **Number of Containers** – the number of containers of controlled substance; if any other fields are not an exact match, record the container(s) on a separate line
- **Container Size/Type** – the number of units or volume of finished form the container holds and the type of container (e.g., 100-tablet bottle or 3-mL vial); record amount in volume (liquids), weight (powder or crystals), or number of units (tablets or capsules)
- **Amount per Container** – the number of units or volume of finished form in the container when transferred (e.g., 85 tablets or 2 mL); if the container is not full upon transfer, this may differ from the container size; record amount in volume (liquids), weight (powder or crystals), or number of units (tablets or capsules)
- **Expiration Date** – the expiration date of the controlled substance, if available; or the manufacturer’s recommended shelf life

Transfers Outside of UT Austin:

In addition to the transfer requirements above, sending controlled substances to or receiving controlled substances from a PI/Registrant outside of UT Austin requires a [Material Transfer Agreement \(MTA\)](#), except when being shipped for disposal or returned to the owner of the material (e.g. for sponsored trials). Additional approvals may be required.

Shipping ([21 CFR 1301.74](#); [21 CFR 1301.76](#)):

When shipping controlled substances, PIs/Registrants are responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses. In addition, PIs/Registrants must employ precautions to guard against in-transit losses, including:

- Ensuring that the outer packaging does not indicate that contents are controlled substances (i.e., the package should be nondescript and should not include any markings or other information that might indicate that the package contains controlled substances).
- Packaging each container of controlled substance in a manner to prevent leakage if the package/container were damaged during transport (i.e., the package should be water- and spill-proof, tamper-evident, tear-resistant, and sealable – triple packaging method).
- Ensuring tracking of the package to verify whether it reached the destination (see below).

Any in-transit losses of controlled substances must be reported to the DEA. If an in-transit loss occurs, the supplier is responsible for reporting the loss unless the shipment arrives at the destination and the recipient signs for or takes custody of the shipment. At this point, the recipient becomes responsible for reporting any loss of controlled substances.

Contact EHS prior to shipping any controlled substances to ensure they are not otherwise regulated for transport.

Disposal (21 CFR 1317.05)

All controlled substances, including those that are used, expired, partially consumed, and/or generated from synthetic or analytical processes, are regulated by the DEA and must be disposed of in a manner that renders them non-retrievable. The PI/Registrant must dispose of all waste containing controlled substances in compliance with applicable regulations including, but not limited to, federal and state requirements.

All expired, damaged, or unwanted controlled substances must be disposed of through a DEA-registered reverse distributor. Controlled substances injected into research animals or consumed in a reaction must go into a hazardous waste stream for disposal through UT Austin's Hazardous Materials Management program. EHS must grant approval prior to generation of all other wastes containing controlled substances as they may be subject to additional regulations. Wastes containing infectious materials, RCRA hazardous materials, raw compounding chemicals, or other sharps or biohazardous materials cannot be sent to a reverse distributor for disposal. In no case may controlled substances be disposed of by any other means (i.e., controlled substances cannot be "sewered", poured down the sink, or flushed).

Expired controlled substances, including those with no expiration date that have reached the end of their shelf-life, should be disposed of within 90 days. The shelf-life is commonly obtained from the manufacturer, and for most stable organic compounds it is up to three years. If stability is unknown, the drug should not be used beyond one year. When used in animals, all dilutions and mixtures of drugs removed from the manufacturer's primary packaging must be discarded after one month from the date of preparation, even if it is earlier than the manufacturer's drug expiration date; any exceptions must be approved by the Institutional Animal Care and Use Committee (IACUC).

All controlled substances, including expired substances and dilutions/mixtures, must remain in the secure storage cabinet/safe until they are packaged and consigned for disposal.

All disposal records, including any executed DEA Forms 222, invoices, reports, records of receipt, shipping documents, and/or records of destruction (DEA Forms 41) for disposal through reverse distributors, must be maintained with the PI's/Registrant's records to provide accountability for the disposal of these controlled substances.

Disposal Through a Reverse Distributor:

- Controlled substances must be sent to an entity registered with the DEA to handle returns and disposal of controlled substances (known as a reverse distributor). The local DEA Field Office can provide a current list of DEA-registered reverse distributors.
- Controlled substances must be promptly delivered to a reverse distributor's registered location by common or contract carrier pick-up or by reverse distributor pick-up at the registrant's registered location
- DEA-registered reverse distributors will only accept controlled substances from PIs/Registrants with a current DEA Certificate of Registration.
- Transfer of the controlled substance to the DEA-registered reverse distributor must be documented in the Record of Distribution. A DEA Form 41 (Registrant Record of Controlled

Substances Destroyed) should not be used to record the transfer of controlled substances between the PI/Registrant and the reverse distributor.

- When Schedule I and II controlled substances are transferred to a DEA-registered reverse distributor for disposal, the reverse distributor must issue a DEA Form 222 (or the electronic equivalent) to the PI/Registrant; the PI/Registrant is the supplier.
- The PI/Registrant must maintain copies of all reverse distribution documents, including but not limited to: inventories submitted to the reverse distributor and all invoices, reports, and records of destruction supplied by the reverse distributor.
- The DEA-registered reverse distributor must destroy or cause the destruction of any controlled substance received for the purpose of destruction no later than 30 calendar days after receipt.
- The DEA-registered reverse distributor who destroys the controlled substances is responsible for submitting a DEA Form 41 to the DEA when the controlled substances have been destroyed.

Disposal Through the DEA ([21 CFR 1317.05\(a\)\(4\)](#)):

In some cases, it may be necessary to contact the local DEA Field Office to request assistance with controlled substances disposal. The PI/Registrant must receive approval from the DEA prior to transferring any controlled substance to the DEA for disposal. If controlled substances are transferred to the DEA, they will provide a record of receipt.

Empty Controlled Substance Containers:

Controlled substance containers that are void of content or where any remaining material cannot be withdrawn from the container using reasonable means are considered empty. For liquids, the container is empty when the material cannot be drawn out with a syringe. For solids, the container is empty when the material cannot be scraped out with a spatula.

Empty containers can be disposed of by defacing the container labels then discarding in non-regulated waste (i.e., the trash, or glass waste, if applicable). Record the disposal of the empty container on the Usage Log.

- If a container is not empty, but the Usage Log shows zero amount remaining, document the discrepancy and dispose of the container with controlled substances waste (i.e., through a reverse distributor).
- If a container is empty, but the Usage Log shows any amount remaining, document the discrepancy, then deface the label and discard in non-regulated waste. Record the disposal of the empty container on the Usage Log.

On-Site Destruction:

UT Austin currently does not have any approved methods for on-site destruction. If unintentional on-site destruction occurs (e.g., non-recoverable breakage or spillage), it must be documented on a Registrant Record of Controlled Substances Destroyed (DEA Form 41).

Abandoned (Orphaned) Controlled Substances

PIs/Registrants are strictly prohibited from abandoning controlled substances. Any PI/Registrant who abandons controlled substances is considered noncompliant with federal, state, and university requirements and will be subject to personal, civil, and/or criminal liability.

Occasionally, abandoned controlled substances (sometimes called “orphaned” controlled substances) are found. This typically occurs during lab and/or office cleanouts if the PI/Registrant left the university without appropriately disposing of or transferring all controlled substances or if the materials were purchased before they were scheduled as controlled substances.

If abandoned controlled substances are found, an official from the responsible college/department must take temporary possession of the controlled substance(s), ensure proper storage prior to destruction, and be available to transfer the controlled substance(s) to the DEA. The college/department must contact EHS and provide the following information:

- PI's/Registrant's name (if known)
- DEA Registration number (if available)
- Location where the controlled substance was found (building and room number)
- Name of the controlled substance
- Number of containers
- Size of each container
- Approximate amount left in each container (if visible)

EHS will contact the local DEA Field Office to coordinate the destruction of the abandoned controlled substance(s).

Theft, Loss, and Unauthorized Use (Including Inventory Discrepancies) ([21 CFR 1301.76\(b\)](#))

Theft, suspected theft, unauthorized use, or other losses (including in-transit losses and unacceptable discrepancies) of any controlled substance must be reported to the UT Police Department (UTPD) and EHS immediately upon discovery (no later than the end of the work day). Unacceptable discrepancies are any difference in the amount on hand and the amount documented that cannot reasonably be explained by normal loss (e.g., measurement error).

Additionally, PIs/Registrants must notify the local DEA Field Office in writing within one business day of the discovery of theft or significant loss of any controlled substance. The PI/Registrant must also complete, and submit to the local DEA Field Office, a Report of Theft or Loss of Controlled Substances (DEA Form 106) once the circumstances surrounding the theft or significant loss are clear, no later than 45 days after the discovery of the theft or loss. Keep copies of notifications to the DEA.

PIs/Registrants are responsible for using their best judgement to identify what is considered a significant loss and to take appropriate action. When determining whether a loss is significant, PIs/Registrants should consider, among others, the following factors:

- The actual quantity of controlled substances lost in relation to the type of business (e.g., an insignificant loss for a hospital or manufacturer may comparatively be considered a significant loss for a researcher).

- Note: The loss of a small quantity of controlled substances, repeated over a period of time, may indicate a significant problem.
- The specific controlled substances lost.
- Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances.
- A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses.
- Whether the specific controlled substances are likely candidates for diversion.
- Local trends and other indicators of the diversion potential of the missing controlled substances.

If there is a question as to whether a theft has occurred or a loss is significant, the PI/Registrant should err on the side of caution and report it to the DEA, UTPD, and EHS.

Report of Theft or Loss of Controlled Substances (DEA Form 106):

The DEA Form 106 is used to document the actual circumstances of the theft or significant loss and the quantities of controlled substances involved. The DEA Form 106 is not used to report an accidental spillage or miscounts or adjustments to the inventory involving clerical errors.

The DEA Form 106 must include the following information:

- Name and address of the PI/Registrant
- DEA registration number of the PI/Registrant
- Date of theft or loss (or when discovered if not known)
- Name and telephone number of local police department (if notified)
- Type of theft or loss (e.g., break-in, robbery, loss in-transit)
- List of identifying marks or symbols (if any) used by the researcher on the labels of the containers
- A listing of controlled substances missing, including the strength, dosage form, and size of container (in milliliters if liquid form) or corresponding National Drug Code numbers
 - In order to better track controlled substances reported as lost or stolen, the DEA uses of the National Drug Code (NDC) number. The NDC number identifies the manufacturer, product, dosage form, and package size. Entry of the NDC number in the online reporting form will prompt the system to auto-populate additional fields such as the name of the product, dosage form, dosage strength, and quantity per container.

If, after the initial notification to DEA, the investigation of the theft or loss determines no such theft or loss of controlled substances occurred, a DEA Form 106 does not need to be submitted. However, for complete and accurate records, the PI/Registrant must notify DEA in writing to resolve the initial report and explain why a DEA Form 106 was not submitted regarding the incident.

In-Transit Losses ([21 CFR 1301.74\(c\)](#); [21 CFR 1301.76\(b\)](#)):

Any in-transit losses of controlled substances must be reported to the DEA by completing and submitting a DEA Form 106.

- The supplier is responsible for reporting the in-transit loss of controlled substances when:
 - All or part of an in-transit shipment of controlled substances fails to reach its intended destination.
 - The purchaser/recipient does not take custody of the shipment.
- The purchaser/recipient is responsible for reporting the in-transit loss of controlled substances after they have signed for or taken custody of a shipment.

All occurrences of theft, loss, or unauthorized use must be documented in the Record of Theft, Loss, or Unauthorized Use. Copies of DEA correspondence (initial notification, DEA Forms 106, DEA Forms 41, etc.) and Theft, Loss, or Unauthorized Use Incident Reports must be kept with this record. Any losses determined to be not significant must still be documented in order to identify patterns of losses over time. This includes discrepancies in recordkeeping and any breakage/spillage.

Records of Theft, Loss, or Unauthorized Use (CS Form M) must minimally include:

- **PI/Registrant Name** – the DEA Registrant’s name as it appears on the Certificate of Registration
- **PI/Registrant DEA Registration Number** – the DEA Registrant’s registration number as it appears on the Certificate of Registration
- **Drug Storage Location** – the building/room number where the controlled substance is stored
- **Drug Name** – the name of the controlled substance
- **Drug Schedule** – the assigned DEA schedule of the controlled substance
- **Date of Theft/Loss** – the date of the theft/loss; if unknown, the date the theft/loss was discovered
- **Type of Theft/Loss** – the type of theft or loss (break-in/burglary, employee theft (or suspected), hijacking of transport vehicle, packaging discrepancy, robbery, customer theft (or non-employee), loss in-transit, disaster (fire, weather, etc.), other unauthorized use, breakage/spillage)
- **Incident Form Number** – the unique number assigned by the lab to this incident
- **Lab Inventory Control Number** – the unique number assigned by the lab to each container of controlled substances and recorded on all records for this container
- **Drug Concentration/Strength and Form** – the concentration/ strength of each finished form of controlled substance (e.g., 10 mg tablet, 10 mg/mL, 100% - if pure powder); the physical form of the controlled substance (i.e., liquid, powder, crystals, tablets, capsules)
- **Container Size/Type** – the number of units or volume of finished form the container holds and the type of container (e.g., 100-tablet bottle or 3-mL vial)
- **Amount Lost** – the amount lost from each controlled substance container (e.g., 83 tablets or 1.5 mL)
- **Discovered By** – the printed (written or typewritten) name and signed initials of the individual who discovered the theft/loss

- **Reported To** – the agencies/departments notified of the theft/loss (e.g., DEA, EHS, UTPD, local PD other than UTPD)

A Theft, Loss, or Unauthorized Use Incident Report must be completed for all thefts, losses, unauthorized uses, and breakage/spillage of controlled substances. This is an internal form separate from any forms submitted to the DEA. Attach copies of any related DEA Forms to the incident report.

Incident reports are not required for minor inventory discrepancies.

Theft, Loss, or Unauthorized Use Incident Reports (CS Form N) must minimally include: (See CS Form N: Instructions for specific field definitions)

- Name and DEA registration number of the PI/Registrant
- Type of theft or loss (e.g., break-in, robbery, loss in-transit, unauthorized use, breakage/spillage)
- Incident form number – unique number assigned by the lab to this incident
- Date of theft or loss (or when discovered if not known)
- Drug storage location
- Who discovered the loss and who completed the incident report
- Who was notified (DEA /EHS/UTPD/local police department other than UTPD), how they were notified (including phone numbers, if applicable), whether there was a specific contact, and whether any forms were completed/submitted (e.g., DEA Form 106 or DEA Form 41)
- Detailed Description of the incident and corrective measures taken (if any) (not required if DEA Form 106 used)
- A listing of controlled substances missing, including the strength, dosage form, size of container (in milliliters if liquid form) or corresponding National Drug Code numbers, and any identifying marks or symbols used by the researcher on the labels of the containers (not required if DEA Form 106 or DEA Form 41 used)

Inventory Discrepancies:

All inventory discrepancies must be documented to identify patterns of losses over time. An unacceptable discrepancy must be reported to the DEA, UTPD, and EHS as outlined above. Minor inventory discrepancies that are not due to theft or significant loss do not need to be reported to the DEA, UTPD, or EHS and should not be documented on a DEA Form 106. The PI/Registrant is responsible for determining what is a minor inventory discrepancy (e.g., normal loss through measurement error) versus an unacceptable discrepancy.

PIs/Registrants should not disregard any unexplained shortage of controlled substances. If there are consistent minor inventory discrepancies, the PI/Registrant should investigate the source of the discrepancies and consider modifying procedures and/or retraining staff to prevent further discrepancies. If a continuing pattern of loss of seemingly insignificant quantities is detected, it should be considered significant and subsequently reported.

Minor inventory discrepancies must be documented in the Usage Log and on the Record of Theft, Loss, or Unauthorized Use. A Theft, Loss, or Unauthorized Use Incident Report is not required for minor inventory discrepancies.

- For minor inventory discrepancies with an excess of controlled substance (i.e., a container is not empty, but the Usage Log shows zero amount remaining), document the discrepancy and dispose of the container with controlled substances waste (i.e., through a reverse distributor).
- For minor inventory discrepancies with an insignificant loss of controlled substance (i.e., a container is empty, but the Usage Log shows any amount remaining), document the discrepancy, then deface the label and discard in non-regulated waste. Record the disposal of the empty container on the Usage Log.

Breakage and Spillage:

The witnessed (i.e., clearly observed) breakage or spillage of a controlled substance does not constitute a loss of controlled substances because the PI/Registrant can account for the controlled substances. These types of incidents do not require notification to DEA.

For all breakage and spillage, document the incident in the Record of Theft, Loss, or Unauthorized Use and complete a Theft, Loss, or Unauthorized Use Incident Report. Record the breakage or spillage in the Usage Log and reference the Incident Form Number from the Theft, Loss, or Unauthorized Use Incident Report. If the controlled substances are still recoverable, they must be disposed of through a DEA-registered reverse distributor. If the controlled substances are not recoverable, document the nonrecoverable breakage or spillage on a Registrant Record of Controlled Substances Destroyed (DEA Form 41) in order to maintain complete and accurate records. The DEA Form 41 must be signed by two individuals who can testify that a breakage or spillage occurred.

All materials used in the clean-up must be submitted for disposal through UT Austin's Hazardous Materials Management program. Put the materials in a sealable, leak-resistant container and submit as spill debris, with the contaminant (e.g., the controlled substance) indicated in parentheses.

Self-Evaluations (CS Form O)

PIs/Registrants are required to complete a Controlled Substances Self-Evaluation annually. It is a self-check to ensure compliance with applicable regulations, including registration information; authorized personnel; maintenance, adequacy, and accuracy of required records; and adequacy of security measures. The forms, indicating corrective actions taken, must be kept by the PI/Registrant for a minimum of one year. An electronic copy of the completed form must be sent to EHS Lab Safety at ehs-labstaff@austin.utexas.edu. If a PI/Registrant does not complete an annual self-evaluation, it will be noted as a deficiency during EHS lab inspections.

EHS Inspections (EHS Controlled Substances Inspection Form and EHS Controlled Substances Inspection Guide in Forms and Tools – link to EHS website)

PIs/Registrants are responsible for monitoring the security, recordkeeping, inventory, handling, and disposal of controlled substances in their possession. EHS assists in this process by conducting regular controlled substances inspections to ensure compliance with all applicable regulations and requirements. These inspections may be announced or unannounced.

PIs/Registrants and their Authorized Designee(s) will be notified in advance of announced controlled substances inspections. Unannounced controlled substances inspections may occur at any time and can

be based upon random selection, changes in regulations and requirements, and/or prior inspection discrepancies and deficiencies. All inspections will be conducted by trained EHS personnel.

EHS controlled substances inspections may include:

- Physical inspection of the storage and security of controlled substances
- Thorough review of controlled substance records to ensure:
 - A complete audit trail of all containers of controlled substances;
 - All controlled substances currently in possession can be reconciled to the records; and
 - Personnel records and training are up-to-date
- Review of prior inspection discrepancies and deficiencies, including items noted on the annual Controlled Substances Self-Evaluation

When EHS requests to schedule a controlled substances inspection, the PI/Registrant or their Authorized Designee must respond and be available to meet within a reasonable timeframe. The PI/Registrant or their Authorized Designee must be present during the inspection to provide access to the records and storage area and to answer any associated questions.

Controlled substances inspection results are communicated to the PI/Registrant and their Authorized Designee(s). Inspection deficiencies must be addressed within the specified time frame, which varies depending on the severity of the findings. Higher severity items requiring prompt remediation include findings such as: unsecured controlled substances, no usage logs, or no personnel records. Uncorrected deficiencies will be escalated, resulting in notifications to the PI's Department Chair and Associate Dean.

DEA Visits ([21 CFR 1316 A](#))

The DEA may conduct controlled substance audits and inspections at any time. Pre-registration inspections are typically scheduled, but regular post-registration inspections and audits due to notification of theft, loss, or unauthorized use may be announced or unannounced. The DEA will have two investigators present for all audits and inspections. They will perform an audit of all controlled substances in possession and review security, access, and all required records. The PI/Registrant must provide access to the controlled substances and all relevant records. Pre-registration inspections are intended to review protocols, security, and access.

PIs/Registrants should ensure that all lab personnel know who to contact in case of an audit or inspection. When the DEA arrives for an inspection, they will provide a written notice of inspection (DEA Form 82) and obtain written informed consent. If a PI/Registrant refuses to consent to an inspection, the DEA will return with an administrative inspection warrant. If a PI/Registrant persistently impedes the execution of the warrant, the PI/Registrant may be arrested.

During the visit, the DEA may ask lab personnel about the controlled substance program and their responsibilities. PIs/Registrants should ensure that all lab personnel have had awareness level, site-specific training regarding controlled substances.

Notify EHS of all DEA visits. If these visits are announced, EHS may be able to attend. If the visit is unannounced, notify EHS after the visit concludes.

Termination of Employment or Registration ([21 CFR 1301.52](#))

PIs/Registrants must promptly notify the local DEA Field Office and EHS when planning to leave the university or cancel a registration. Notify EHS at least 90 days prior to leaving the university or rescinding the registration.

PIs/Registrants are responsible for making arrangements for any remaining inventory before terminating employment or canceling a registration. All controlled substances must be spent, disposed of, or transferred to another registered individual prior to departure or registration termination. For disposal through a DEA-registered reverse distributor, PIs/Registrants must have a current DEA Certificate of Registration. EHS is not permitted to take custody of controlled substances.

PIs/Registrants are responsible for notifying EHS when all controlled substances have been removed from the controlled substances storage area and disposed of or transferred. EHS will provide the Decommissioning of Controlled Substances Work in Research Labs Form (CS Form P) to the PI/Registrant. Once this form is signed by the PI/Registrant, EHS will schedule an on-site visit to verify that there are no longer any controlled substances present in the storage area and complete the decommissioning form. The PI/Registrant and EHS must keep a copy of the completed form for at least two years beyond expiration of the registration for that location.

All unused DEA Forms 222 (schedule I and II only) and the DEA Certificate of Registration must be returned to the DEA Registration Section.

PIs/Registrants are strictly prohibited from abandoning controlled substances. Any PI/Registrant who abandons controlled substances is considered noncompliant with federal, state, and university requirements and will be subject to personal, civil, and/or criminal liability. Upon departure, EHS will ensure the DEA is notified of the PI's/Registrant's employment termination and whether any controlled substances were abandoned. If the PI/Registrant provides EHS with a copy of the written notice to the DEA and has properly disposed of or transferred all controlled substances, EHS will not send a separate notification to the DEA.

Listed Chemicals ([21 CFR 1309](#); [21 CFR 1310](#))

Listed chemicals include both List I and List II chemicals, as designated under the federal Controlled Substances Act (CSA). In addition to legitimate uses, these chemicals are used in illicit manufacturing of controlled substances. The sale and distribution of listed chemicals are regulated by the DEA to prevent illegitimate use, but they are not considered controlled substances and do not require controlled substance registration to purchase and use.

Researchers that purchase List I chemicals must only dispose of them as hazardous waste through UT Austin's Hazardous Materials Management program and not distribute them to other users. When purchasing a List I chemical, vendors must confirm the researcher will be the end user and will not redistribute this chemical. Vendor confirmation forms may be called "Intended Use Declaration", "DEA Listed Chemical", "Authorized Purchaser", or something similar. Department Chairs are responsible for signing the section certifying that the purchaser is authorized to buy and receive the chemical.

Listed chemicals must be handled as hazardous chemicals, including proper storage by hazard class, maintenance in the lab's chemical inventory, and disposal through UT Austin's Hazardous Materials Management program. Do not store listed chemicals with controlled substances. If research use of a listed chemical generates one or more controlled substances, controlled substances requirements must be implemented and followed. Contact EHS immediately.

Controlled Items

Controlled items include both regulated precursor chemicals and laboratory apparatus as defined in the [Texas Controlled Substances Act](#). Similar to the DEA listed chemicals, these precursor chemicals are used in the illicit manufacturing of controlled substances in addition to legitimate uses. Regulated chemical laboratory apparatus include any item of equipment designed, made, or adapted to manufacture a controlled substance or a controlled substance analogue.

At UT Austin, controlled items are subject to specific requirements as agreed to in a [Memorandum of Understanding \(MOU\) between the Texas Department of Public Safety \(DPS\) and the Texas Higher Education Coordinating Board \(THECB\)](#). Any person with specific authority to purchase or accept controlled items must bear full responsibility for establishing security measures regarding their purchase, acceptance, use, and ultimate disposal.

In order to comply with the MOU between DPS and THECB, PIs and their lab personnel must:

- Maintain purchase, transfer, and inventory records of controlled items
 - Do not send controlled items to Surplus Property
- Report loss, pilferage, theft, or an inventory discrepancy that cannot be reasonable explained by accidental or normal loss to UTPD and EHS immediately and submit a written [RSD-905 form](#) to the DPS no later than three business days after the date of discovery
 - Be aware of unauthorized personnel in the laboratory
 - Be alert and attentive to disappearance of controlled items
- Permit any DPS representative to conduct audits and inspections of all records made in accordance with the MOU at any reasonable time
- Maintain physical security of items and store in accordance with manufacturer recommendations
 - Establish specific locations where controlled items are utilized and/or stored
 - Lock all doors/windows when the room is not occupied
 - Establish key control and restrict room access to authorized personnel
 - Establish procedures to assure proper use of controlled items in laboratories and storerooms
 - Do not store these regulated chemicals with controlled substances

PROGRAM EVALUATION

A periodic evaluation of the program will be performed by EHS with feedback from PIs/Registrants and/or their Authorized Designees. Comments related to this program can be submitted to EHS at ehs-labstaff@austin.utexas.edu.

FORMS AND TOOLS (all forms available on the [EHS Controlled Substances Website](#))

Template Forms

CS Form A – Authorized Designee Signature Log
CS Form B – Permitted User List
CS Form C – Reserved
CS Form D – Reserved

CS Form E – Record of DEA Form 222 Use
CS Form F – Record of Receipt
CS Form G – Usage Log
CS Form H – Dilution-Mixture Usage Log
CS Form I – Reserved
CS Form J – Initial/Biennial Inventory Form
CS Form K – Record of Distribution
CS Form L – Registrant-to-Registrant Transfer Form
CS Form M – Record of Theft, Loss, or Unauthorized Use
CS Form N – Theft, Loss, or Unauthorized Use Incident Report
CS Form O – Controlled Substances Self-Evaluation Form

CS Form P – Decommissioning Controlled Substances Work in Research Labs Form

Guides and References

EHS Controlled Substances Inspection Form
EHS Controlled Substances Inspection Guide

RELATED INFORMATION

[DEA Diversion Control Division](#)

[Resources](#) (Controlled Substance Schedules and Listed Chemicals, Regulations: 21 CFR Chapter II, 21 USC Chapter 13)

[Registration](#)

[DEA Forms & Applications](#) – Forms (41, 106, 222, 225, 225a)

[DEA Researcher’s Manual](#)

[Department of Public Safety \(DPS\) and Texas Higher Education Coordinating Board \(THECB\) Controlled Substance Memorandum of Understanding \(MOU\)](#)

Texas DPS Regulatory Services – [Precursor Chemical and Laboratory Apparatus](#)

REVISION HISTORY

| Revision Date | Material Changed | Changed By |
|---------------|----------------------|-------------------|
| 5/27/2022 | Document created | Laura Schultheiss |
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