

1. Purpose

This Controlled Substances Program (CSP) establishes KSU requirements for the acquisition, storage, use, transfer, inventory, disposal, and oversight of DEA-regulated controlled substances used in research, teaching, and veterinary activities at the University.

2. Scope

This program applies to all KSU personnel and students who handle controlled substances in any KSU owned, leased, or operated facilities.

3. Regulatory Framework and Authority

The CSP is based on the following federal and state laws:

- 21 CFR Parts 1300–1308 (DEA regulations)
- Controlled Substances Act (CSA)
- Drug Enforcement Administration (DEA) policies and guidance
- DEA Diversion Control Division requirements
- Georgia State Board of Pharmacy regulations
- Federal funding requirements, including NIH and NSF compliance expectations

4. Responsibilities

A. Environmental Health and Safety Department (EHS)

EHS serves as the central authority responsible for:

- Oversight of all DEA compliance related to research and instructional uses
- Reviewing and approving PI registration requests
- Maintaining institutional records
- Conducting audits and training
- Outlining corrective actions
- Reporting significant losses, thefts, or regulatory violations
- Interacting directly with DEA or State authorities

B. Principal Investigator (PI)

The PI is responsible for:

- Obtaining approval from his/her Department Chair and EHS to apply for licenses to store and use controlled substances in research on campus through submitting an internal CSP form
- Obtaining and maintaining any required state licenses and federal DEA licenses, and following all requirements of the license(s)
- Providing the registration(s), once obtained, to EHS

- Identifying appropriately controlled space and ensuring proper, secure storage of all controlled substances
- Performing initial, biennial, and perpetual inventories
- Reporting any thefts, losses, or inventory discrepancies to EHS and DEA (form 106)
- Maintaining access control records and ensuring EHS retains updated access control records

C. Department Chair

The Department Chair is responsible for:

- Reviewing and approving/denying the PI's request to apply for license(s) to store and use controlled substances in research on campus

5. Definitions

Controlled Substance: Substances regulated under federal law. Controlled substances are divided into five schedules based on (1) its potential for abuse; (2) scientific evidence of its pharmacological effect, if known; (3) the state of current scientific knowledge regarding the drug or substance; (4) its history and current pattern of abuse; (5) the scope, duration, and significance of abuse; (6) what, if any, risk there is to the public health; (7) its psychic or physiological dependence liability; and (8) where the substance is an immediate precursor of a substance already controlled under the Controlled Substances Act.

Controlled Substance Schedules:

- Schedule I Controlled Substances: High potential for abuse; no currently accepted medical use in treatment in the United States, and may not be prescribed, administered, or dispensed for medical use.
- Schedule II Controlled Substances: High potential for abuse which may lead to severe psychological or physical dependence, and have a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.
- Schedule III Controlled Substances: Potential for abuse lower than substances in schedules I or II, have a currently accepted medical use in treatment in the United States, and abuse may lead to moderate or low physical dependence or high psychological dependence.
- Schedule IV Controlled Substances: Low potential for abuse relative to substances in schedule III, have a currently accepted medical use in treatment in the United States, and abuse may lead to limited physical dependence or psychological dependence relative to substances in schedule III.
- Schedule V Controlled Substances: Low potential for abuse relative to substances listed in schedule IV, have a currently accepted medical use in treatment in the United States,

and abuse may lead to limited physical dependence or psychological dependence relative to substances in schedule IV.

Drug Enforcement Administration (DEA): Serves as the single federal agency to coordinate the Federal Government's drug control activities. Holds the responsibility to prevent diversion and abuse of controlled substances and ensuring an adequate and uninterrupted supply is available to meet the country's legitimate medical, scientific, and research needs.

Georgia Board of Pharmacy: Responsible for the regulation of pharmacists and pharmacies in Georgia.

6. Procedure

A. Registration

1) DEA and Georgia Board of Pharmacy Registration (PI Level)

Each controlled substance user must hold an individual DEA and Georgia Board of Pharmacy registration corresponding to their research location(s). Institutional registrations are not permitted for research use.

2) Initial Registration Process

The PI must:

- Submit an E-mail request for approval to work with controlled substances to ehs@kennesaw.edu. With the request, provide:
 - Laboratory room numbers
 - Security plan description
 - List of authorized users
 - Expected controlled substances and quantities
 - Description of research protocols
 - IACUC, IBC, and IRB registration approval numbers, as applicable
- Receive EHS approval before Georgia Board of Pharmacy or DEA license application submission.
- Schedule a pre-registration inspection by EHS by reaching out to ehs@kennesaw.edu.
 - The pre-registration inspection can take place while permits are in the process of being reviewed and approved.
- Obtain a Georgia Board of Pharmacy Research Permit
 - The application, titled "Pharmacy Facility Application", is available at:
- Once the Georgia Board of Pharmacy license is received, complete DEA Form 225 *via* the DEA Diversion Control website.
- No controlled substances may be ordered until the PI's DEA registration arrives and all pre-registration inspection action items have been appropriately addressed.

3) Modification or Renewal

PIs must:

- Renew Georgia Board of Pharmacy Permit every 2 years (expiry is on June 30th of even years)
- Renew DEA registrations **annually** (DEA Form 225a)
- Update the EHS on:
 - Location changes
 - Any location change requires pre-approval and inspection
 - Personnel updates
 - New substances being added
 - Schedule modifications

4) Termination of Registration

PIs leaving the institution or discontinuing controlled substance use must:

- Notify the EHS in writing
- Conduct a final inventory
- Transfer or dispose of all controlled substances
- Submit record archives to EHS

B. Procurement

5) 3.4.1 Schedule I and II Substances

Require:

- EHS approval prior to submission (E-mail ehs@kennesaw.edu to request approval)
- DEA Form 222 (paper or CSOS electronic equivalent)
- Secure delivery to the registered PI or designee
- Documentation of receipt on the perpetual inventory log

6) Schedule III–V Substances

May be ordered via:

- Standard institutional purchasing systems
- Vendor ordering portals

Must include:

- PI DEA number
- Shipping only to the registered address
- Immediate logging into perpetual inventory upon receipt

C. Security and Storage

7) Physical Security Requirements

Schedule I–II

- Stored in a substantially constructed safe or steel cabinet
- The safe or cabinet must be:
 - Lockable
 - At least 750 lbs or bolted to the building structure
 - Located in a restricted-access laboratory
- Requires two-factor security:
 - Locked and controlled lab/room

- Locked safe/cabinet
- The laboratory and safe/cabinet locks must be keyed differently

Schedule III–V

- Stored in **locked steel cabinets or lockboxes**
- Located inside a locked room
- Schedule III-V substances can be stored with Schedule I-II substances.

D. Access Control

- Only **Authorized Users** listed on the PI's registration may access controlled substances.
- A current access list must be maintained by the PI and EHS.
- Visitors, students, or interns may **not** access controlled substances.
- Keys/combinations must:
 - Be unique
 - Never be shared
 - Change whenever personnel leave

E. Inventory and Recordkeeping

This is a core element of DEA compliance. Failure to maintain accurate inventories is a federal violation.

8) Initial Inventory Requirement

When issued a DEA registration, a registrant must take an initial inventory, including the following:

- All controlled substances in all forms (powders, solutions, dilutions)
- Exact quantities on hand
- Date and time
- Name, strength, and form
- The number of dosage units or volume of each finished form in the commercial container
- The number of commercial containers of each finished form
- The total count of the substance
- DEA schedule
- Name and signature of person conducting the inventory

If there are no stocks of controlled substances on hand, make a record showing a zero inventory. When a drug not previously listed as a controlled substance is scheduled, the drug must be inventoried as of the effective date of scheduling, if possessed by the registrant. Copies must be submitted to the EHS.

9) Biennial Inventory Requirements

Every PI must perform a **biennial inventory** at least every two years, including all of the information in the initial inventory record. Copies must be submitted to the EHS.

10) Perpetual Inventory Logs

PIs must maintain **ongoing, real-time** records of:

- Receipt
- Usage (with protocol reference)

- Transfers
- Administration (e.g., to animals)
- Disposal

Logs must include:

- Date and time
- Amount withdrawn or added
- Remaining balance
- Authorized user's initials or name
- Purpose of use
- Witness signature for Schedule I–II transactions

11) Inventory for damaged, defective, impure, or other substances

For damaged, defective, or impure substances awaiting disposal, substances held for quality control purposes, or substances maintained for extemporaneous compounding, the inventories must include (in addition to the initial inventory requirements):

- Name of the substance
- Total quantity of the substance to the nearest metric unit weight or the total number of units of finished form
- The reason for the substance being maintained
- Whether the substance is capable of use in the manufacture of any controlled substance in finished form

12) Record Retention

All controlled substance records must be securely stored and retained for **at least two years**, including:

- Purchase records, including receipts and/or invoices
- Form 222s, whether executed or not
- Power of Attorney authorization to sign order forms, if applicable
- Certificates of Analysis (COAs)
- Usage logs, including dispensing, distribution, and destruction records
- Inventory records, including inventories of drugs surrendered for disposal (DEA form 41)
- Records of theft or significant loss (DEA Form 106)
- Transfer forms
- Access authorization lists

The EHS maintains a central archive.

F. Transfer and Use

13) Transfer Between PIs

Transfers are permitted only between DEA-registered PIs. All transfers must:

- Be approved by the EHS
- Use DEA Form 222 (Schedule I–II)
- Include transfer logs for Schedules III–V
- Update perpetual inventories for both parties

Unauthorized sharing is a DEA violation.

14) Use in Research

All dilution, preparation, and administration records must:

- Be documented
- Include the date, time, and user name
- Include initial and final weights
- Include concentration calculations
- Be signed by the preparer and, if Schedule I–II, a witness

G. Waste and Disposal (Reverse Distribution)

15) Acceptable Disposal Methods

Controlled substances must be disposed of by:

- A DEA-registered reverse distributor, or
- A EHS-supervised destruction event

Household disposal or drain disposal is prohibited.

16) Disposal Procedure

- PI contacts EHS to initiate disposal.
- EHS determines whether reverse distribution or witnessed destruction is required.
- PI completes:
 - **DEA Form 41** (for destruction)
 - Inventory entries showing destruction
- A witnessed destruction requires:
 - PI
 - EHS
 - One additional authorized witness
- Maintain all documentation for 2+ years.
- Examples of acceptable destruction
 - Chemical digestion
 - DEA-approved neutralization kits
 - Incineration via reverse distributor

H. Theft and Loss Reporting

17) Reporting Requirements

A PI must **immediately** notify:

- EHS
- DEA Atlanta Field Office for any:
 - Significant loss
 - Suspected theft
 - Discrepancy in inventory

This must occur **within 24 hours** of discovery.

18) Required Documentation

- DEA Form 106 (Report of Theft or Loss)
- Internal incident report

- Inventory reconciliation
 - Corrective action plan
- The EHS coordinates with Campus Police for investigations.

7. Mandatory Training and Audits

All PIs and Authorized Users must complete:

- **Initial Controlled Substances Training** upon joining the program
- **Annual refresher training**
- **Topic coverage:**
 - Regulatory requirements
 - Security and storage expectations
 - Inventory and recordkeeping
 - DEA reporting
 - Waste and disposal
 - Rights and responsibilities

Completion is required to maintain authorized user status.

8. Inspection and Audits

EHS will conduct:

- **Annual compliance audits** of each registered location
- **Unannounced spot checks** based on risk profile

Audit components:

- Inventory accuracy
- Storage and security compliance
- Authorized user list verification
- Record completeness
- Expiration management
- Evidence of diversion

Non-compliance may result in corrective actions, retraining, or suspension of privileges.

9. Appendices

References:

[Diversion Control Division | Schedule I Controlled Substances Research Information](#)
[Researchers Manual: An Informational Outline of the Controlled Substances Act](#)