**UTHealth Controlled Substances FAQs**

**What are the most important aspects of UTHealth’s controlled substance program?**

UTHealth Environmental Health and Safety (EHS) can help answer questions about DEA registrations, storage and handling of controlled substances, how to discard expired or unused controlled substances, and recordkeeping requirements. Give us a call at 713-500-8100. More information can also be found on the EHS Chemical Safety website: [UTHealth Chemical Safety Website](https://www.uth.edu/safety/chemical-safety/index.htm)

**What are controlled substances?**

Controlled substances are any chemical agents or drugs that are regulated by the federal government under the Controlled Substances Act (CSA) and the Code of Federal Regulations (21 CFR, part 1300 to end).

**Is any registration needed for the state of Texas in addition to the DEA registration?**

As of September 1, 2016, researchers will no longer be required to register through the Department of Public Safety. This is great news for researchers as it’s one less expiration date to track and one less fee to pay.

**What are controlled substance schedules?**

The DEA assigns each controlled substance a schedule number (I through V) according to its medicinal value, harmfulness, and potential for abuse or addiction. A higher schedule number indicates the substance has more medicinal value and less potential for abuse or addiction. The letter "N" following the schedule number signifies the substance is non-narcotic (e.g. III N). The DEA code is a 4-digit number assigned to each controlled substance. Please check your DEA registration DEA for the specific substances that are registered under your license.

[DEA Controlled Substances Schedules and Codes](https://www.deadiversion.usdoj.gov/schedules/)

[DEA Orange Book](https://www.deadiversion.usdoj.gov/schedules/orangebook/orangebook.pdf)

The most common controlled substances used in research and respective schedule numbers and DEA codes are listed below.

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| --- | --- | --- |
| Controlled Substance | Schedule | DEA Code |
| Buprenorphine | III | 9064 |
| Diazepam | IV N | 2765 |
| Ketamine | III N | 7285 |
| Pentobarbital (e.g., Nembutal) | II N | 2270 |

**Can other people working in my lab handle/use the controlled substances?**

The licensed researcher is the principal investigator. The PI can establish a list of Authorized Agents who may oversee the ordering, use, and management of the controlled substances, but the PI is ultimately responsible for all that pertains to the controlled substances. To reduce diversion of controlled substances, the list of authorized agents should be kept to the absolute minimum.

**Who can I contact with questions regarding applications and licensing?**

UTHealth Environmental Health and Safety (EHS) can help answer questions (713-500-8100). You can also contact the Houston DEA office at 713-693-3660.

**Are laboratory personnel able to use controlled substances?**

Authorized laboratory personnel should not have key/code access to the controlled substance storage area. Laboratory personnel can work freely on approved experiments without having access to the bulk storage areas.

**Section 4 of the application requests a State License Number. What do I put here?**

Texas no longer requires registration with the Department of Public Service. Leave this section blank.

**Section 6 of the DEA Application mentions fee exemption. Am I eligible for this?**

As an employee of a state university, you qualify for fee exemption. Your supervisor will verify your employment status on the registration (certifying official signature line in section 6).

**When will I need to renew my license?**

Renewals will be required every 3 years. The expiration date will be listed on your license. The DEA started sending electronic renewal reminders in 2017. They will no longer be sent by paper mail. Reinstatement of expired registrations is allowed for one calendar month after the expiration date. Any time past that one month window will require a new application.

**Can I transfer my controlled substances to another PI at the university?**

The DEA must approve the transfer to the authorized PI and both parties must maintain documentation of the transfer.

**I work and store my controlled substances in a shared lab space. Can other PIs share my controlled substance storage cabinet?**

No, every researcher should obtain and use their own safely secured lockbox.

**How do I dispose of my controlled substances?**

Disposal of controlled substances is done through a third party reverse distributor. Schedule I and II require DEA form 222 for disposal, but schedules III-V can be transferred simply with an invoice. Disposal documentation must be held for at least 2 years. Reverse distribution is not free of charge, and the cost ultimately depends on the type and quantity of substance to be disposed. Disposal of controlled substances can be charged as direct cost on grants.

**Can UTHealth EHS dispose of or store my controlled substances?**

No. EHS can only assist with locating a reverse distributor. Call EHS at 713-500-8100 for assistance.

**Will I be subject to compliance inspections?**

Yes. As a courtesy, EHS will survey all controlled substance researchers’ records, use, and storage at least annually. The DEA also has the authority to inspect your facilities at any time.

**The EHS Controlled Substance Researcher Guide mentions a biennial inventory is required. What is this?**

Researchers must inventory all the controlled substances in their possession at the open or close of business as mandated by 21 CFR 1304.11(b)

**Which federal laws state all these requirements?**

The Controlled Substance Act of 1970 and the Code of Federal Regulations (21 CFR, part 1300 to end)

**Resources:**

[**DEA Registration Website**](https://www.deadiversion.usdoj.gov/drugreg/index.html)

[**Federal Regulations**](https://www.deadiversion.usdoj.gov/21cfr/cfr/index.html)

[**UTHealth Controlled Substance Researcher's Guide**](Controlled%20substances%20researcher%20guide%20FY19.doc)