

Controlled Substances Disposal

The United States Drug Enforcement Agency's (DEA) Office of Diversion Control (www.deadiversion.usdoj.gov) regulates the disposal of DEA controlled substances. This Office's primary goal is to eliminate the diversion of legitimately manufactured (or used) controlled substances into the illicit drug traffic. DEA controlled substances may only be obtained by those personnel or organizations that complete DEA's registration process. An individual Researcher (i.e., PI) or Department may register with the DEA as a 'Researcher'. This registration grants the PI or Department the authority to purchase and use, for research purposes, DEA controlled substances. Once a PI or Department obtains a DEA controlled substance, they have the responsibility (under DEA regulations 21 CFR 1304) to track the use, security and disposition of these substances. DEA enforcement personnel may ask a PI or Department to account for DEA controlled substances listed in their registration. It is important to maintain all waste disposal records to allow for the accurate accounting of your DEA controlled substances.

PIs or Departments that intend to dispose of DEA controlled substances have three disposal options. Harvard's EH&S Department will assist PI's and Departments with these options:

- 1. **OPTION 1: Denaturing and Disposal Coordinated by Harvard EHS** The DEA has granted approval to destroy DEA regulated Controlled Substances pursuant to the updated 21 CFR 1307. Harvard EH&S conducts these disposal events twice per year in March and October. For assistance, complete the DEA Form 41 (Registrant Record of Controlled Substances Destroyed) listing items intended for disposal and submit the completed form to Harvard EH&S. Please note that the registrant must remain in possession of their controlled substances until they are appropriately destroyed. The registrant must retain the Form 41 for two years after destruction. Only specified EH&S individuals are authorized to complete this process for the university.
- 2. **OPTION 2: Reverse Distribution** This option transfers ownership of the DEA waste substance to a DEA-approved Pharmaceutical Returns Processor for re-use, resale or destruction. This process requires a record of the transfer to be completed that lists the two registrants involved in the transfer, as well as the drug name, dosage form, strength, quantity, and date transferred. For Schedule I and II materials, this transfer also must be accompanied by DEA Form 222. See Section IV of the DEA's Pharmacist's Manual for more details. Copies of any transfer and disposal confirmation paperwork must be maintained by the registrant (e.g., PI or Department) for two years.
- 3. **OPTION 3: Witnessed Burn** This involves the transport of the DEA waste substances to a DEA-approved incinerator. Here, the DEA waste substances must be destroyed in the presence of the PI (or a representative), a federal official (typically U.S. Marshall's office) or a local law enforcement official. This option is unlikely to be needed by the research community.

Contact EHS for assistance:

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