

AUGUSTA UNIVERSITY

USE OF DEA CONTROLLED SUBSTANCES IN RESEARCH

Augusta University policies and guidelines require that all Principal Investigators who work with DEA controlled substances in research have current registration with the Georgia Board of Pharmacy and the DEA, maintain such licenses and comply with all State and Federal regulations regarding the acquisition, storage, use, record keeping, and disposal of those substances. Below are the key points.

Contact the Chemical Safety Office

Notify the Chemical Safety Office (CSO) at 706-721-2663 to request assistance and support at the following stages:

- To prepare and submit required applications to State and Federal DEA
- When facility inspection by the State Drugs and Narcotics Agency is scheduled
- When license(s) is/are approved and provide numbers and expiration date(s) to the CSO
- Whenever an inspector visits your lab, whether scheduled or unscheduled, for an audit.

Preparing State Application

Download application at:

<https://gbp.georgia.gov/document/form/pharmacy-facility-application-posted-8918/download>

Complete pages 3, 6, 7, 17, 18 and 19 and mail with a \$100 check to:

Georgia Board of Pharmacy
2 Peachtree Street, N.W., 36th Floor
Atlanta, GA 30303

Preparing Federal DEA Application

Complete form 225 online at:

<https://www.deadiversion.usdoj.gov/webforms/jsp/regapps/common/newAppLogin.jsp>.

Federal DEA Application Fee Exemption

Augusta University researchers are subject to fee exemption being a State institution.

Certifying Official: Barbara Manley-Smith, Director, Research Facilities

BASMITH@augusta.edu
706-721-9678

Ordering/Receiving DEA Controlled Substances

Use DEA form 222 to order controlled substances. Note on the form receipt of the substances and the date it was received. Update chemical inventory in the database by entering controlled substance, quantity and date it was received.

Authorized Use of Controlled Substances

The registered licensee is legally responsible for managing the controlled substances in accordance with federal and state regulations, including record keeping and security provisions. Lab workers may engage in approved activities under the direction of the DEA permit/license holder. The license holder is required to screen those employees prior to authorization.

Storage of Controlled Substances

Environmental storage conditions of controlled substances should meet manufacturer's recommendations and must be in a locked box in an unmovable fixture that is also secured with access controlled by the PI. The intent is to provide effective controls to guard against theft or diversion of the controlled substances. This is critical and security must be evident during the facility inspection for approval to be granted.

License Renewal

- State registration expires June 30th every **EVEN YEAR** and **MUST** be renewed prior to expiration.
- Federal DEA is renewable annually from issue date.

Disposal/Destruction of Controlled Substance

The CSO conducts monthly disposal/destruction of expired and/or unwanted DEA controlled substances on the last Wednesday of each month. Any DEA licensee who wishes to dispose of any controlled substance is required to complete a DEA form 41 and submit the completed form to the CSO prior to the event. The form and instructions are found at:

http://www.deadiversion.usdoj.gov/21cfr_reports/surrend/41_form.pdf.

The CSO will notify the Augusta University Police Dept. and request their presence at each event. On the scheduled date, a PI or a representative will transport the substances for destruction to the EHS Waste Building, CS 1006. A Duly Sworn Augusta University Police Officer will inspect the substances submitted for destruction and confirm that they match what is recorded on the DEA form 41. Once confirmation is made, a CSO staff member will destroy the substances by emptying and dissolving the contents of each controlled substance container into a beaker with organic solvent and bulk the solution in a drum of organic chemical waste that are typically disposed of by incineration. The entire process is witnessed by the Police Officer. Each DEA form 41 will be signed by the CSO representative and the Police Officer as a witness. The PI retains the original and a copy is maintained in the Chemical Safety Office.