

AUGUSTA UNIVERSITY

DEA RESEARCH APPLICATION PROCESS

- 1.1 Principal Investigators and practitioners engaged in non-clinical research must first apply to the Georgia State Board of Pharmacy for a drug researcher permit (26-4-49G). The DEA application is made concurrently (see section 2 below), unless the practitioner already holds a DEA certificate.
- 1.2 Researcher permit application can be found at <https://gbp.georgia.gov/document/form/pharmacy-facility-application-posted-8918/download> Upon receiving the completed application, a letter of acknowledgement will be sent to the applicant from the Georgia State Board of Pharmacy.
- 1.3 Upon receipt of the acknowledgement letter from the Board, the applicant must contact the Georgia Drugs and Narcotics Agency (GDNA) at <http://gdna.georgia.gov/>, or call GDNA at 404-656-5100, or fax to 404-651-8210, to schedule an inspection of the facilities and the control program at the site.
- 1.4 To issue a permit, the Georgia State Board of Pharmacy must receive a favorable report from the GDNA inspection. Allow a minimum of four weeks for the application to process.
- 1.5 The holder of a drug researcher permit may not engage in the sale, distribution or dispensing of controlled substances.
- 2.1 The DEA Research Application is made to the DEA at the same time as the initial application submission to the state for researcher registration.
- 2.2 Electronic submission of this form is preferred, except for Schedule I (see 2.4 below). Initial researcher application is made using DEA form 225, found at <https://www.deadiversion.usdoj.gov/webforms/jsp/regapps/common/newAppLogin.jsp>

NOTE: Applications for use of Schedule I drugs must be submitted as a hard copy (see 2.3 below). A hard copy form may be downloaded from https://www.deadiversion.usdoj.gov/drugreg/reg_apps/225/225_form.pdf.

Mail the hard copy application to:
U.S. Department of Justice
Drug Enforcement Administration
Central Station
PO Box 28083
Washington, DC 20038-8083

- 2.3 If the DEA chooses to inspect the premises and program, the inspection will usually be coordinated with the GDNA visit. The DEA may choose to rely upon the GDNA inspection results rather than conduct their own inspection.
- 2.4 DEA researcher registration is effective for one year. Initial registration period is for a specific month, and varies from four to fifteen months. Actual registration expiration date appears on the researcher's registration certificate (DEA form 223).
- 2.5 Research involving Schedule I controlled substances requires a separate registration from research involving Schedule II through V.
 - 2.5.1 Researchers intending to use Schedule I compounds must include a Research Protocol (an original plus three copies), as outlined on the application form, in their DEA application.
 - 2.5.2 A researcher needing to use both Schedule I and other scheduled classes would need to apply twice, one application for the Schedule I and a separate application including all other classes requested.
 - 2.5.3 A practitioner license does not include Schedule I controlled substances and the practitioner would have to apply for a separate researcher permit to conduct research with Schedule I.

PROCEDURE – MAINTAINING REGISTRATION

- 3.1 Proposed changes to the registered usage must be approved by the licensing agency prior to making the change.
- 3.2 Registration permits are not transferable.
- 3.3 State registrations become null and void if there is change in the mode/usage, operation, or address of the permit holder.
- 3.4 Location change or substance schedule change to the DEA registration may generally be approved by sending a letter to the special agent in charge; the DEA may re-inspect the premises and registrant's program before approving changes.
- 4.1 Registration is specific to the name and (single) physical location provided by the applicant. If a registrant changes location on the Augusta University campus then, prior to move, the registrant must:
 - 4.2 **Re-apply** to the State of Georgia (researcher) at http://sos.ga.gov/acrobat/examboards/pharmacy/controlled_substances.pdf.

- 4.3 File a change of address with the DEA. Change forms and instruction can be found at <https://www.deadiversion.usdoj.gov/webforms/jsp/regapps/common/updateLogin.jsp>.
- 4.4 The DEA and/or the GDNA may choose to inspect the proposed premises before approving the change.
- 4.5 A researcher using controlled substances at separate locations must maintain separate registrations for each location.
- 5.1 The State Board of Pharmacy renewal application must be submitted with adequate time for renewal.
- 5.2 A researcher permit issued by the Georgia State Board of Pharmacy must be renewed biennially (every two years).
- 5.3 Permits expire on June 30th of every even-numbered year.
- 5.4 Permits are renewed by submitting the renewal form (same as the initial application form) with the application fee.
- 5.5 Any change in the location of the facility, the researcher registrant, or changes in the drugs utilized requires filing a new application.
- 5.6 Renewal registration **MUST NOT LAPSE**.
- 5.7 Each registration must be renewed annually, using DEA form 225A for renewals. Use the application forms found at http://www.deadiversion.usdoj.gov/drugreg/reg_apps/.
- 5.8 A researcher must apply for renewal before the end of the current registration period, not more than 60 days from expiration (for paper applications, apply as soon as possible within the 60 day period, more than 45 days is prudent).
- 5.9 Notification of registration is generally mailed from the DEA to the researcher approximately 60 days before the registration is due for annual renewal. Failure to receive this notice does not alter the registrant's responsibility to apply for renewal.
- 6.1 Maintain records of registration.
- 6.2 Keep the originals of the DEA and state registrations in the registrant's files. Retain for three years past expiration date.

- 6.3 The DEA registration number should not be used as an identification number; the DEA registration number should only be used to provide certification of DEA registration in transactions involving controlled substances. Expect to routinely provide a copy of the DEA registration (DEA form 223) to:
- 6.3.1 Purchasing department that will procure the controlled substances. Refer to RCS 003 Ordering, Procurement.
 - 6.3.2 Reverse distributor used to dispose of controlled substances, following the reverse distributor's instructions. Contact Environmental Health and Safety (706-721-2663) for instructions.

Augusta University is subject to the fee exemption as a fee exemption institution.

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