

The University of Memphis

Controlled Substance Licensing and Registration Instructions

State of Tennessee Licensure

Researchers planning to conduct research involving acquisition, creation, or use of a controlled substance under the auspices of the University of Memphis shall first obtain a State of Tennessee license. To initiate the licensing process, download and complete the state research license application form from https://tn.gov/assets/entities/health/attachments/Researcher_Application.01-2017.pdf. Completion of this form will require a concise description of the planned research use of the controlled substance, a plan for secure storage, and payment of a fee.

Upon obtaining the state license, registration with DEA is required.

Exemptions:

A licensed physician, dentist, or veterinarian lawfully administering, dispensing, or prescribing a legend drug or controlled substance in the course of the individual's professional practice to an ultimate user for a recognized medical purpose is exempt from this requirement. In addition, a manufacturer or distributor whose research protocol has been approved by the federal food and drug administration under the agency's auspices, or otherwise subject to jurisdiction of the federal food and drug administration and if lawful under that jurisdiction is exempt.

US DEA Registration

US DEA registration requires inclusion of the licensee's state license number and identification of the controlled substances used. For work with Schedule I substances, applicants must attach three copies of a more detailed Schedule I Controlled Substance Protocol.

Registration instructions and links to the registration application, DEA Form 225, are available at <http://www.deadiversion.usdoj.gov/drugreg/process.htm>. Persons already registered with DEA as a medical practitioner are not required to obtain an additional DEA registration for research involving any drug in Schedules II-V if this clinical registration is being actively used to prescribe drugs to patients.

For any research involving Schedule I drugs, a researcher's registration (DEA Form 225) is required for all researchers, including medical practitioners who are already registered with DEA.

Upon receipt of a registration application, the DEA may schedule a telephone interview or an on-site inspection.

New registrants must complete their initial inventory of controlled substances immediately upon receipt of their DEA registration, on the first day of business after registration. In most cases, this initial inventory will show zero quantities.

DEA registration must be renewed annually, except for the practitioner's (clinical) registration which must be renewed every three years.