Standard Operating Procedure for the Disposal of Controlled Substances Used in Research

Purpose

This document establishes procedures for the disposal of unwanted or expired DEA controlled substances used in research, teaching, or testing activities.

Scope

This standard operating procedure applies to all research, teaching, or testing activities at Mississippi State University. Clinical activities, such as the Longest Student Health Center Pharmacy and the College of Veterinary Medicine Pharmacy, are excluded.

Procedure

Prior to disposal of expired, unwanted, or damaged controlled substances, the registrant should complete the Controlled Substances Disposal Form found at this link https://www.orc.msstate.edu/controlled-substances. After completing this form, please contact ORC&S at iacuc@orc.msstate.edu to receive instructions on the next steps in the disposal process. The Office of Research Compliance & Security is not permitted to take possession of, handle, or destroy controlled substances.

Disposal Process:

- 1. DEA Registrant will contact ORC&S and provide the completed Controlled Substances Disposal Form 41 by email at iacuc@orc.msstate.edu.
- Controlled substances that are expired, unwanted, or damaged (i.e., unused vials, expired dilutions, or broken/damaged containers with recoverable contents) must be transferred to a reverse distributor for destruction.
 - a. If you are using a reverse distributor, DEA Form 222 must be completed and on file for the drugs that are transferred to the reverse distributor. The reverse distributor will be responsible for completing the DEA Form 41 for the destruction of the drug(s).
 - b. For a lab self-disposal: DEA Form 41 must be completed and kept on file.
 - i. Non-Retrievable Contents: (research guide)
- 3. Clearly label the substances for disposal (e.g., "to be disposed", "do not use", or "expired").
- 4. Segregate the substances labeled for disposal from remainder of inventory within the secure storage location (i.e., safe, lock box).
- 5. Each DEA registrant must complete the Registrant Record of Controlled Substances Destroyed DEA Form 41.
- 6. The ORC&S Staff will send a copy of the completed DEA Form 41 and a copy of the disposal confirmation record to the US Department of Justice, Drug Enforcement Administration, Diversion Control Division as well as the registrant.
- 7. Copies of the Controlled Substances Disposal Form and DEA Form 41 will be maintained by the registrant and the Office of Research Compliance & Security for two years in accordance with <u>21 U.S.C. 827.</u>

Significant Loss or Theft:

In the event of needing to report a significant loss or theft of a controlled substance, the DEA Form 106 can be completed using the <u>online TLR Report</u> through DEA. You will be asked to provide background information relating to this significant loss or theft incident, such as the date and place, the type (night break-in, armed robbery, etc.), and the estimated value of the controlled substances, etc. You will also be asked to include the National Drug Code (NDC) and quantity of the controlled substance being reported as a theft or significant loss. This must be reported in total milligrams (mg), or Kilograms (KG). If the NDC drug is liquid or powder, you will need to enter the total milliliters/milligrams (ml/mg); if tablet, enter the total count of tablets. After submitting, the DEA registrant should save a copy of this completed form with their records for at least 2 years.