Standard Operating Procedure for the Audit of Controlled Substances

Purpose

This document establishes procedures for auditing the use of controlled substances (CS) used in research, teaching, or testing activities.

Scope

This standard operating procedure applies to all research, teaching, or testing activities at Mississippi State University and will outline the procedures that will be followed by the ORC&S Staff to audit inventory and records of controlled substances held by DEA registrants. This audit will occur annually to coincide with the Fall semi-annual IACUC facility inspection.

Procedures:

- 1. ORC&S Staff will contact each DEA registrant and notify them of the visit and schedule a time.
- 2. During the semi-annual inspections of the IACUC, the ORC&S Staff will visit each investigator's laboratory where the controlled substances are stored.
- 3. The following is a list of items that will be reviewed:
 - a. **DEA License Registration.** Each investigator's DEA License will be checked for validity.
 - b. **Storage of Controlled Substance.** Is the CS stored in a secured location (locked cabinet or safe) where unauthorized use will not occur?
 - c. **Valid Dates.** Make sure the CS has not expired. If expired, have they been disposed of properly with the use of a reverse distributor? Expired controlled substances are not allowed to be used. If expired and not yet disposed of, please explain how and when this will take place, and confirm with ORC&S once this process is completed.
 - d. **Usage/Disbursements Records.** For each CS the Record of Use Log will be checked for proper labelling, date substance was used, activity it was used for, amount removed, amount remaining, and authorized signature and initials.
 - e. **Disposal Records.** Disposal records will be checked to verify that each CS that is no longer in use by the lab has been disposed of correctly.
 - f. Transfer Records. Documentation of the DEA Form 222 to show records of any transferred drugs.
 - g. **Personnel**. Lists of all Authorized Users, Authorized Agents, and/or Powers of Attorney under your DEA Registration.
 - h. **Order Forms / Invoices**. Any documentation that provides detailed information regarding ordering of controlled substances (ex: type, amount, seller, etc.)
- 4. Any inconsistencies or abnormalities found as a result of this audit must be rectified by the DEA Registrant immediately.
- 5. A report of the inspection will be created by the ORC&S Staff conducting the audit and shared with the DEA Registrant. As suggested by *The Guide* (pg. 34), the report will be included in the IACUC semi-annual inspection report submitted to the Institutional Official, and OLAW (if applicable).