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Controlled Substances Used in Research Fact Sheet

This fact sheet is for general safety awareness. Individual SOPs for all experiments and processes involving controlled substances must be developed by each laboratory.

Introduction

Controlled Substances (CS) are drugs or chemicals regulated by the Drug Enforcement Administration (DEA) due to their potential for abuse. All Registrants and Authorized Users of controlled substances must be appropriately registered with the Maryland Office of Controlled Substances Administration (OCSA) and federally with the DEA.

This information encompasses the acquisition, utilization, production, storage, disposal, and lawful disposition of Controlled Substances as it pertains to researchers at the University of Maryland. The researcher as the Registrant may delegate authority to staff or students as Authorized Persons. Authorized Persons are under the responsibility of the Registrant and subject to the same regulations.

This guidance does not apply to licensed medical practitioners who dispense controlled substances as part of their professional duties or dispensation of controlled substances within the context of human subjects' research.

Classification (Schedules I-V)

Substances are categorized into five schedules based on their medical utility and abuse potential:

Schedule I: High potential for abuse with no currently accepted medical use in the U.S. (e.g., heroin, MDMA). These require a separate registration specifically for Schedule I substances.

Schedules II-V: These have accepted medical uses but varying levels of potential for abuse and dependence. Schedule II drugs (e.g., fentanyl, morphine) have the highest abuse potential among those with medical use

Applicable Regulations

The DEA and the OCSA govern the use of controlled substances for research and teaching purposes. The 1970 Drug Enforcement Act 21 CFR 1300-1399 provides the right for the DEA to issue citations, revoke registrations, and refer cases to the Attorney General for prosecution if warranted.

Researcher Roles and Responsibilities:Registration

At the University of Maryland, each investigator who wishes to use controlled substances for research purposes must apply for BOTH a state and federal license.

Contact contrsubs@umd.edu to obtain verification of the fee-exempt status for both the Maryland OCSA Registration/Renewals and the Federal DEA Registration/Renewals. Do not send applications or other content with personal identification information. Questions specifically about the application process or your application status should be directly addressed to the appropriate entity.

For more information on the steps to obtain licenses, please visit the DEA Licensing for UMD Researchers, which was published by the Division of Research.

Record Keeping

All Registrants are required to maintain comprehensive and accurate records of all controlled substances, as per 21 CFR 1304.11a. This includes records of usage, receipts, disposal, ordering, and a complete inventory. The DEA requires records to be retained for a **minimum of two years** and made accessible for inspections. Inventory must be performed and documented at a minimum upon receipt of materials and every 2 years. Additional record retention requirements may apply to your laboratory from the university and other regulatory agencies.

A current log detailing the substance's usage, location, time, and purpose must be consistently maintained, according to 21 CFR 1304.03. These records should cover both stock and working solutions. Each container (even in a multi-pack) must be given a unique identifier to track its specific usage from receipt to disposal, and dilutions or mixtures must be included in the inventory. It is recommended by ESSR that bound notebooks are utilized to prevent the loss of records, as loose-leaf paper and binders may result in misplaced documentation. All records must be written in indelible ink. Dilutions and preparations must be labeled appropriately, and stored in the same manner as the original CS material.

Security

The Registrant is responsible for the proper use and physical security of their controlled substance inventory. Controlled substances must be secured in a vault, safe, or secured enclosure under double locks. The regulations provide minimum standards and each storage location will be reviewed by the DEA for effective controls and operating procedures.

Use of Materials

Controlled substances must be handled only by the Registrant and Authorized Users. They may not be transferred to another researcher, even if that researcher has a license of their own. Material must be kept secure during use and stored appropriately after use. Personal protective equipment (PPE), determined by risk assessment, may be required for handling the material. Contact ESSR for guidance on PPE.

When CS will be used in research with animals, each container should be labeled with an expiration date. Any dilutions or mixtures need to be labeled with their contents and expiration

date and are subject to the same documentation and security requirements as undiluted material.

Diversion theft or loss of controlled substances

Diversion of CS could refer to theft, falsifying records, substitution/tampering, improper waste disposal, unauthorized access, or unauthorized distribution. This includes an intentional theft (stolen on purpose) or an unintentional removal of materials, such as a vial left in a labcoat pocket. The loss of materials must be documented when controlled material is rendered unusable, such as the result of a spill or contamination.

Any personnel with reasonable suspicion of or knowledge of irregularities, theft diversion, or loss of controlled substances must report information to the Registrant, University of Maryland Police Department (UMPD, 301-405-3333) and ESSR. Federal regulations require that Registrants notify their Field Division Office of the DEA, in writing, of the theft or significant loss of any controlled substance within **one business day** of discovery. A report of diversion may trigger an audit by the DEA and/or a police investigation.

Disposal of controlled substances

Appropriate disposal of controlled substances that are expired, unwanted, or damaged (i.e., unused vials, expired dilutions, or broken/damaged containers with recoverable contents) must be performed and documented. Expired material must be labeled appropriately to prevent use.

Controlled substances must be rendered non-recoverable for theft-prevention and worker safety. It must never be discarded in the regular trash or down a drain. Coordinate with Environmental Affairs or reach out directly to a reverse distributor to schedule disposal. The intended method of disposal should be included in the registration documentation, and the registration may need to be updated if the method of disposal will change. Disposal methods may include direct pick up by a reverse distributor, on-site destruction with an approved chemical process, or other means. Disposal must be documented and witnessed, with records **retained for a minimum of 2 years.**

Orphaned controlled substances

Occasionally controlled substances are found in a laboratory that is not included in a PI's DEA license. This can include materials that were not on the DEA list when purchased, but have since been classified as a controlled substance. In this case, please contact the Office of Research Safety. Research Safety staff will provide the Orphaned Controlled Substance Removal Application and assist in coordinating with UMPD and Reverse Distribution.

Additional Resources

In June of 2022, the DEA released a Researcher's Manual: An Informational Outline of the Controlled Substances Act , which offers some clarification of situations that may not occur in clinical practice.