AuditCon

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ACUA

Protecting Your Animals and Employees Involved with Controlled Substances in Animal Research

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8:55 – 9:45

Valla Wilson, CIA , CRMA, CHIAP ™

- Serves as the Practice Director, Business Risk Assurance and Advisory Services for the Eminere Group, LLC, providing Internal Audit, Compliance, Revenue Cycle, Enterprise Risk Management, Quality Assurance, and other Consulting services primarily in the higher education and healthcare industries.
- Has over 30 years of Internal Audit/Compliance experience including having served as Chief Audit Executive, Chief Compliance Officer, Chief Privacy Officer and Research Integrity Officer roles at Academic Medical Centers and Health Systems.
- Held other operational and consulting leadership roles with public accounting, higher education, healthcare, fortune 500 and government organizations.
- Was previously an Experienced Manager for Anderson, LLP, providing Internal Audit Co-Sourcing/Outsourcing and Risk Consulting services.

Session Objectives

- Explain the use of controlled substances in animal research
- Describe controlled substances and animal research regulatory requirements including licensing, registration, inventory, record keeping, distribution and controlled substances dispensing
- Identify procurement, receiving, transfer and inventory management practices and controls
- Discuss responsibilities for controlled substance storage and physical security access
- Identify controlled substances wastage and disposal practices

Polling questions:

1. How many are from academic medical centers and or have a health system?
2. How many are new to higher education or research?
3. How many have performed audits in animal research?
4. How many of you have performed an internal audit in animal research area including controlled substances management program for preventing theft of controlled substances?
5. How many performed reviews of controlled substances or drug diversion programs?
6. Do you have it on your audit plan?

Animal Research Overview

- Research is defined as the systematic investigation into and study of materials and sources in order to establish facts and reach conclusions.
- Animal research is the use of non-human animals in scientific experiments and studies to understand biological processes, examine disease progression, and test the safety and effectiveness of new medical treatments before human clinical trials.
- Animal research is governed by strict laws like the Animal Welfare Act (AWA), requiring institutional approval and ethical review boards (such as IACUC).
- The use of controlled substances in university animal research is strictly regulated by the Drug Enforcement Administration (DEA) under the Controlled Substances Act (CSA) and state or local laws.
- Every university must maintain an authorized registration and strict internal oversight to prevent diversion, abuse, or improper administration.
- **Recent changes by NIH and NCI, use of new approach methodologies (NAMs)**

Breaking News…

- *In September 2026, the U.S. federal government enacted some of the most sweeping policy changes regarding animal testing. Led by a joint push from the Department of Health and Human Services (HHS), the FDA, and the NIH, these initiatives focus heavily on codifying, funding, and modernizing the transition away from animal models.*
- *Beginning October 5, 2026, applicants submitting NCI grant application utilizing animal models for their specific study must provide justification as to why available alternatives are inferior and include a validation plan demonstrating how any findings derived from animals will ultimately be validated in a human model system (e.g., human organoids, patient biopsies, or patient-derived xenografts)directly within the public-facing project abstract.*

Use of Controlled Substances in Animals

Controlled Substances are chemicals, pharmaceutical agents, etc., that have been identified by the United States Department of Justice/Drug Enforcement Administration (DEA) as having the potential for abuse. These substances have been categorized by the federal government into five "schedules", or categories based on their medicinal use and potential for abuse.

Primary Reasons for Use

- **Anesthesia:** Drugs like ketamine or sodium pentobarbital are used to keep animals completely unconscious and pain-free during surgeries or invasive imaging procedures.
- **Pain Relief (Analgesia):** Narcotic analgesics like buprenorphine or butorphanol are administered to manage post-operative or procedural pain, ensuring animal welfare standards are met.
- **Euthanasia:** High doses of certain controlled substances (such as sodium pentobarbital solutions) are utilized for the humane and painless euthanasia of research animals at the end of a study.
- **Behavioral or Neurological Studies:** Specific controlled substances may be tested directly on animals as part of pharmacological research to study addiction, neurological responses, or how a drug interacts with living biological systems.

Five Schedule Categories - Schedule 1 – Schedule V

Five Controlled Substances Schedule Categories

- **Schedule I**
  - No accepted medical use, high abuse potential; may not be used in research without a separate DEA Schedule I registration (e.g., heroin, LSD, marijuana).
- **Schedule II**
  - High abuse potential with severe dependence risk; DEA Form 222/CSOS required to order (e.g., fentanyl, morphine, pentobarbital, methadone).
- **Schedule III**
  - Moderate to low physical dependence potential; common in anesthesia and euthanasia protocols (e.g., ketamine, buprenorphine, Telazol).
- **Schedule IV**
  - Low abuse potential relative to Schedule III; widely used sedatives in animal research (e.g., diazepam, midazolam, butorphanol, phenobarbital).
- **Schedule V**
  - Lowest abuse potential; limited-quantity narcotic preparations (e.g., codeine-containing cough preparations, pregabalin).

Key Oversight/Requirements

- **Drug Enforcement Agency (DEA)**
  - The Controlled Substances Act (CSA)
- **United States Department of Agriculture (USDA)**
  - Animal Welfare Act (AWA)
- **Office of Laboratory Animal Welfare (OLAW) under NIH**
  - Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals
- **Institutional Animal Care and Use Committee (IACUC)**
  - Responsibilities include reviewing and approving animal research protocols, animal facility inspections, reviews and investigations of animal care incidents and complaints
- **Code of Federal Regulations (CFR) include**
  - **9 CFR Chapter 1-III Animal Welfare**
  - **21 CFR Part 314**
  - **21 CFR Parts 510 - 511 New Animal Drugs, New Animal Drugs for Investigational Use**
  - **21 CFR Part 1301 Registration of Manufacturers, Distributors and Dispensers of Controlled Substances**
  - **21 CFR Part 1304 Records and Reports of Registrants**
  - **21 CFR 1306 Prescriptions/Administration**
  - **21 CFR 1308 Schedules of Controlled Substances**

Institutional Risks

Strategic	• Research growth is central to university strategic plans; a DEA action or loss of research funding can halt programs.
Compliance/Legal	• Heavily regulated; fines/penalties and loss of research funding; lawsuits for employee diversion and drug overdoses.
Reputational	• Diversion incidents and animal welfare violations erode public trust, donor support and faculty recruitment.
Physical Security/Safety	• Decentralized labs with limited storage security, shared keys and after-hours access create theft, tampering and personnel exposure risks.
Operational	• Decentralized ownership, staff turnover, inconsistent training and manual logs across departments, labs and PIs.
Financial	• Fines, legal defense costs, remediation, drug loss and suspended or reduced grant funding.
System Security	• Manual paper/spreadsheet inventories, unrestricted access to ordering and e-records, and inadequate security access increases risk of undetected changes and stolen controlled substances.

Drug Diversion Risks in Animal Research

Reasons why risks may be higher for University drug diversion in the animal research space

- Lack of complete oversight and accountability, other than the IACUC
- Decentralized environment and limited animal research staff
- Lack of employee awareness of multiple regulatory agency requirements, policies and procedures and conflicting priorities increasing compliance risks
- Multiple students, post-docs, technicians have access to research labs
- Mandatory background checks may not be adequate and could allow unauthorized individuals to access to high-schedule drugs
- Recordkeeping deficiencies, lack of real time logging of administered doses
- Inadequate reconciliation processes for inventory and drug usage
- Movement of animals and controlled substances may be stored in an unregistered room
- Physical storage of controlled substances may not be in required structure or secure
- Lack of a second authorized witness signature for drug waste or inappropriate disposal
- Non-compliance with requirements for drug waste

Licensing and Registration

Federal DEA Registration - Researchers must register with the Drug Enforcement Administration (DEA) using DEA Form 224 (and renew every 3 years via Form 224a) for each specific project location (specific room number).

- The PI must log and directly supervise lab techs or co-investigators acting as authorized agents to administer drugs under their license

State Controlled Substance License - Most states require an equivalent state-level controlled substance authority (such as a state Department of Health or Pharmacy Board permit) prior to federal registration approval.

Institutional Oversight - Protocols must be reviewed and approved by the Institutional Animal Care and Use Committee (IACUC) before acquiring or administering any scheduled drug to research subjects.

Inventory and Recordkeeping

Initial & Biennial Inventory - A complete, physical count of all stocks must be taken on the first day of operations (initial) and repeated at least every two years (biennial).

Usage Logs - Researchers must maintain a continuous, real-time usage log. Each entry must document the date, animal protocol number, species, amount used, amount wasted, and the initials of the authorized user.

Disposal Tracking - Expired or unused drugs cannot simply be thrown away. They must be disposed of via a DEA-registered reverse distributor or an approved chemical destruction method, accompanied by DEA Form 41.

Separation of Files - Schedule I and II drug records must be physically or digitally separated from Schedule III, IV, and V records.

Retention Period - All records including acquisition invoices, receipts, inventories, usage logs, and disposal documents must be kept and made readily retrieval for inspections for a **minimum of 2 years**.

Distribution and Dispensing



Closed Distribution System - Transferring or sharing controlled substances between independent research labs or unregistered personnel is strictly prohibited.

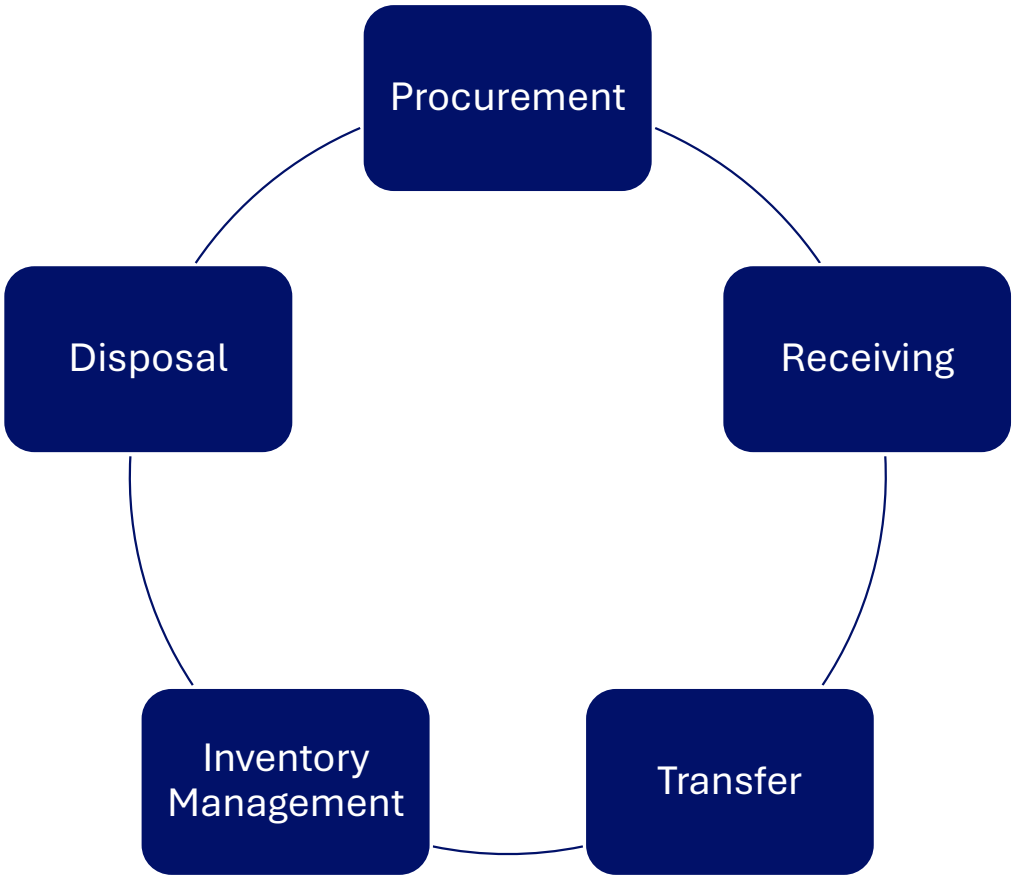


Real-Time Dispensing Logs - Every container must have an individual log tracking receipt date, initial volume/count, each dispensing event (date, amount used, animal ID/protocol number, running balance), and the initials of the authorized user.



Wasting and Disposal - Partial doses or expired medications designated as waste require documentation of the waste method (such as an approved chemical inactivator) and co-initialization by a witness or appropriate DEA Form 41 submission.

Controls Substances Management



Procurement Practices/Controls

IACUC-Approved Protocols - Orders can only be placed for drugs, dosages, and quantities that explicitly match an active, approved animal research protocol.

Veterinary Consultation - Purchase requests for specialized veterinary pharmaceuticals (e.g., carfentanil, buprenorphine) must often be vetted by the attending veterinarian to confirm appropriate clinical use.

Authorized Ordering Only - Only the primary investigator (registrant) or individuals formally granted Power of Attorney (POA) may legally sign procurement documents.

Form 222 & CSOS - Ordering Schedule I and II drugs requires the electronic Controlled Substance Ordering System (CSOS) or physical DEA Form 222.

Vendor Verification - Drugs must be sourced exclusively from manufacturers or distributors holding active DEA registrations and state board of pharmacy licenses.

Let's not forget about segregation of duties!

Receiving Practices/Controls

Blind Check-In - The receiving researcher should independently count and verify the shipment contents against the packing slip before looking at the original purchase order.

Immediate Delivery Bypass - Courier deliveries must bypass general university or corporate loading docks and be brought directly to the registrant's designated, secure laboratory space.

Tamper Inspection - Containers must be inspected immediately for broken seals, altered expiration dates, or fluid leakage common in liquid veterinary vials.

Log-In Requirements - The receiver must immediately document the date received, exact quantity/volume, manufacturer lot number, vial serial numbers, and provide their signature.

Transfer Practices/Controls

Multi-Site Registration Constraints - Medications cannot be transported between separate campus buildings or field research sites unless those specific addresses are listed on the DEA registration.

Form 222 for Schedule II Transfers - Moving a Schedule II drug from a central institutional repository to an individual investigator's lab requires a formal DEA Form 222 transaction.

The 5% Distribution Rule - An animal research lab cannot transfer more than 5% of its total annual dosage units to another registered researcher without being legally classified as a distributor.

Chain-of-Custody Escorts - Hand-carrying controlled substances between authorized surgery rooms and holding rooms requires a logged, dual-signature chain of custody.

Inventory Management Practices/Controls

Vial-Specific Logging - Every single bottle or vial must have its own dedicated log sheet tracking usage in milliliters or milligrams, rather than logging transactions by the box or case.

Dilution and Cocktail Tracking - When creating "cocktails" (e.g., mixing ketamine and xylazine), researchers must create a secondary log tracking the dilution date, total volume, and calculation math.

Physical Segregation - Schedule I and II drugs must be stored in a securely anchored, GSA-approved safe or steel cabinet, completely separate from Schedule III-V stocks.

IACUC Post-Approval Monitoring - Compliance officers must conduct unannounced physical audits, comparing the volumes remaining in active vials against the animal numbers recorded in surgical logs.

Hospital vs University Drug Diversion Programs

		University Labs	Hospital
1	**Registration Types and Operational Boundaries**	Register as "Researchers." This registration is highly restrictive. A researcher's license is bound to a specific Principal Investigator (PI) and a specific room number. If an animal researcher wants to move a vial to an unregistered lab room down the hall, it is legally considered an unauthorized distribution.	Register as "Institutional Practitioners." A single hospital registration typically covers the entire physical building, allowing the central pharmacy to distribute drugs to various floors, wards, and satellite clinics under a unified umbrella.
2	**Physical Security Requirements**	Must store stocks in a securely locked, substantially constructed cabinet or safe. Because labs rarely have automated electronic cabinets, the DEA strictly mandates physical barriers (e.g., steel boxes bolted directly to a concrete wall or floor) to prevent a student or technician from carrying the entire safe away.	Utilize heavy-duty, commercial-grade walk-in vaults or sophisticated electronic automated dispensing cabinets (like Pyxis or Omnicell). The DEA permits these decentralized electronic lockboxes because they track individual employee biometric access in real time.

Hospital vs University Drug Diversion Programs

		University Labs	Hospital
3	**Recordkeeping and Inventory Tracking**	Track drugs based on a manufacturing and chemical usage model. Manual paper or digital Vial Usage Logs consist of detailed tracking of exact milligram or milliliter balance of container.	Track drugs based on a dispensing model mapped to patients. The records consist of automated pharmacy logs, electronic medical records (EMRs) detailing patient and administered medications.
4	**Personnel Screening (Insider Threat)**	A specific DEA Screening Statement with signature is required for every student, post-doc, or technician declaring they have never had a DEA registration denied/ revoked, and have no felony drug convictions,	Rely on standard HR background checks, professional medical board licensing, excluded parties review and automated system alerts to screen employees who handle narcotics.
5	**Co-Regulation Layers**	Co-regulated by the USDA and the university's Institutional Animal Care and Use Committee (IACUC).	Co-regulated by the Department of Health and Human Services (HHS) and clinical accreditation bodies (like The Joint Commission) focusing on human patient safety.

Past University Cases of Cited Violations

- ***University of Wisconsin–Madison*** **- Fined multiple times by the USDA, including $77K in 2023 and 74K in 2020 in civil penalty settlements for various animal welfare violations.**
- ***University of Southern California (USC)*****- 2024 penalty for $114K federal following a severe inspection failure.**
- ***Oregon Health and Science University (OHSU) -*** **2022 Settlement - agreed to a $37,900 penalty issued by the USDA's Investigative and Enforcement Services (IES).**
- ***University of Oklahoma (OU) Health Sciences Center*** **- fined by USDA for $19K following a series of eleven severe protocol failures.**

Key Takeaways

- It is critical to have effective internal controls for controlled substances similar to the centralized diversion model for patient care.
- For the management of controlled substances cycle, from procurement to disposal, key controls you would expect for other supplies and goods should be considered (e.g., segregation of duties, dual controls, system security, etc.)
- A formal research, controlled substances monitoring program is necessary for ensuring compliance with regulations, policies, and procedures.
- Mandatory training of Principle Investigators and research teams should be tailored to the lifecycle of controlled substances in animal research programs and tracked for accountability.

Q & A



Contact Information

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