

The University of Kansas (KU)
Institutional Animal Care and Use Committee

Policy on Controlled Substances

1.0 Scope and Application

The ACU procures all pharmaceutical grade drugs for animal use and maintains a DEA research (II-V) research registration for this purpose. This policy is established to ensure appropriate procedures for procurement, distribution, use, recordkeeping, and disposal of controlled substances used in teaching or research animals at the University of Kansas and is applicable to all personnel using controlled substances for the aforementioned purposes. Failure to comply with the method outlined below may result in suspension of privileges to use controlled substances.

2.0 Summary of Method

- All individuals who transport, administer, or otherwise have access to controlled substances used or intended for use in teaching or research animals must undergo a criminal conviction check and receive authorization from University Human Resources. The check must be completed prior to access or handling of controlled substances. Contact University Human Resources at 864-4946 for information regarding the criminal conviction check.
- Investigators must order pharmaceutical grade drugs for animal use from the ACU. The ACU maintains a DEA research (II-V) registration for this purpose. Drug orders must be correlated to a specific AUS, and ACU veterinary personnel verify correlation prior to processing and/or dispensing. Orders for pharmaceutical grade drugs must be submitted through use of the online Drug, Supplies, and Equipment Order Form available at www.animalcare.ku.edu. The ACU does not maintain stock inventory. Orders should be placed in advance of need to allow for variable delivery depending on vendor availability and shipping arrangements.
- Prior to processing an order for controlled substances, the ACU Clinical Veterinarian or designee must verify personnel authorization to access controlled substances and review the associated Animal Use Statement to determine if use of the substance is described. The ACU Clinical Veterinarian or designee must also review the ACU Controlled Substance Master Inventory to determine if all prior dispersals to the individual and/or laboratory have been accounted for. The ACU will not order or dispense additional controlled substances until the status of previously dispensed drugs has been determined. An order for controlled substances will only be processed when all of the above requirements have been satisfied.
- Each controlled substance vial procured under the ACU DEA registration is assigned a unique identifying code that includes drug name abbreviation, a consecutive vial inventory number, and an aliquot designation, if applicable.

- Upon receipt, controlled substances are logged on the ACU Controlled Substance Master Inventory, listing:
 - Drug name
 - Unique identifying code
 - Amount received
 - Date received
 - Person receiving

- Controlled substances are only dispensed to authorized personnel and are tracked by entering the following information on the ACU Controlled Substance Master Inventory:
 - Dispense date
 - Dispensed by
 - Dispensed to
 - Drug expiration date

- Principal Investigators must ensure controlled substances are stored in an area of limited access and are securely locked in a substantially constructed cabinet. Controlled substances must be secured behind two locks. Laboratory doors can be considered one lock, if doors of unattended labs are kept locked.

- A Controlled Substance Inventory Sign-Out Form (CSISOF) must be completed for every controlled substance dispensed by the ACU and includes the following information:
 - Dispense date
 - Dispensed to
 - Unique identifying code
 - AUS #
 - Location where drug will be securely stored
 - Signature of responsible individual

A copy of the CSISOF is provided to the individual accepting responsibility for controlled substance use and a copy is maintained for ACU records.

- A Controlled Substance Incremental Use Log (CSIUL) is issued with every controlled substance dispensed by the ACU and includes the following information:
 - Drug name
 - Unique identifying code
 - Date issued
 - Principal investigator
 - AUS #
 - Dispensed to
 - Location where drug will be securely stored
 - Volume received
 - Expiration date

- Principal Investigators are responsible for ensuring accurate and proper maintenance of controlled substance records by personnel in their laboratory. Each time the controlled substance is used, the date, species (animal identification), volume removed from vial, balance remaining in vial, and initials of the authorized user must be recorded on the CSIUL.
- When the vial of controlled substance is depleted OR expired, the authorized user must return the vial and the corresponding CSIUL to the ACU.
- The ACU Clinical Veterinarian or designee is responsible for reconciling returned CSIUL forms and the ACU Controlled Substance Master Inventory.
- Audits and inspection of controlled substance procurement, dispersal, use, storage, and recordkeeping may be conducted unannounced by ACU, IACUC, and DEA.
- Audits and inspections of laboratory controlled drug storage and CSIUL forms are conducted semiannually by ACU veterinary personnel.
- At least every two years, the ACU must complete an inventory of all stocks of controlled substances on hand as required by 21 CFR Section 1304.11.

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