

Clemson University

Institutional Animal Care and Use Committee (IACUC)

Policy Number: 2.10

Policy Title: Controlled Substances in Animal research

Section 1: Purpose

The following policy describes the licensing requirements for the use of controlled substances in animal research.

Section 2: Scope

This policy applies to all active and approved Animal Use Protocols (AUPs).

Section 3: Policy

Controlled Substances (CS) are drugs for which there is a potential for abuse/addiction. CS are divided into Schedules I-V depending on their medical use in the United States and relative potential for abuse and dependence. See the [Clemson University Occupational and Environmental Safety](#) page for more details.

A CS license is always required to obtain or use CS. The individual responsible for holding this license varies by situation:

- A Non-Practitioner's license, held by the principal investigator (PI), is required when the use of CS is anticipated for planned research procedures such as surgery, euthanasia as an endpoint, anticipated sedation, or pain management, and/or is the direct focus of the study.
- A Practitioner's License, held by the University's Attending Veterinarian (AV), may only be used for animal care such as cases of emergency euthanasia or unexpected pain relief scenarios.

All PIs who use controlled substances in their research must obtain individual research licenses. All CS PIs plan to use as part of research procedures (even if applied by technicians) must be listed in the AUP and will require a license. These include CS used for:

- Surgical procedures (anesthetics)
- Pain relief post procedure (analgesics)
- Planned Euthanasia
- Sedation

PIs should contact the Clemson University Occupational and Environmental Safety (OES) office to begin the licensing process. OES will help PIs register with SC DHEC and then with the DEA, prior to conducting any research using controlled substances. Additional information is on the [Clemson University Occupational and Environmental Safety](#) page.

PIs may **not** distribute CS to another investigator or student who does not have applicable licenses/permits for possessing that substance. Clemson University's AV may **not** provide CS to investigators.

Veterinarians in the CU animal care and use program will provide veterinary care involving CS under their own practitioner's license in instances of pain relief for humane care (apart from expected use) or emergency euthanasia. Veterinarians who must intervene under the authority of the animal care and use program will administer CS under their practitioner's license and using CS from their own supply.

Procedures involving CS may not begin until a controlled substances license is obtained, and CS are ordered and received under that license.

If a CS license expires or is revoked for any reason, the PI is considered noncompliant. Associated animal welfare concerns will be handled on a case-by-case basis.

The IACUC will verify associated records for AUPs during semi-annual inspections and may conduct unannounced audits or records. This is to provide PIs the opportunity to address concerns internally.

SC DHEC and the DEA may (and will) independently inspect all registrants for storage and records in what are likely to be unannounced visits to the facility. Unsuccessful visits could result in loss of license or criminal penalties.

References:

[Drug Enforcement Administration Researchers' Manual: An Informational Outline of the Controlled Substances Act](#)

[Clemson University Occupational and Environmental Safety Controlled Substances Information](#)
[SC DHEC New Registrations Information, Researcher Applicants](#)

Controlled Substances in Animal Research Flow Chart

