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Controlled Substances

Definition:

A controlled substance is generally a drug or chemical whose manufacture, possession, or use is regulated by federal and/or state government.

Controlled substances may be used only for duly authorized, legitimate medical or scientific research purposes, to the extent permitted by a registrant's license and registration, and in conformity with state and federal statutes and regulations.

Registration and Licensing Requirements:

The purchase of Controlled Substances requires a license with the New York State Department of Health (NYSDOH) and registration with the Drug Enforcement Administration (DEA). Contact Environment, Health and Safety (EHS) for assistance in the application process at <u>askEHS</u>.

Vendor Selection:

Controlled substances can only be purchased from vendors that have signed the attestation for selling controlled substances approved by Cornell University Procurement Services. These vendors include:

- Krackeler Scientific for Sigma-Aldrich products
- MWI
- Midwest Vet
- Coventrus (Schein)
- VWR

Roles and Responsibilities:

End User/Unit:

- All principal investigators with a need to purchase, possess, and use controlled substances (Schedule I-V) for laboratory research must register, and maintain active registration, with the <u>Federal Drug Enforcement Administration</u> (DEA). This registration must be surrendered when the use of controlled substances in the investigator's laboratory is terminated. An investigator cannot provide controlled substances to another individual UNLESS they are collaborating on the same study and are co-listed on the same protocol that governs the work the controlled substances are used for.
- 2. It is also the responsibility of the end user to obtain a NYSDOH license. Usage of another license or registration number for purchases is prohibited.
- 3. Complete a DEA form 222 for purchases of Schedule I and II controlled substances and attach to the I Want document or purchase request submitted to the BSC.
- 4. Orders for controlled substances shall be limited to only those drugs specified on the principal investigator's currently active DEA registration.

BSC:

1. Each controlled substance purchase must be covered by a valid NYSDOH license, DEA registration, and purchase order for the authorized controlled substance schedule.

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- a. If the approved vendor does not have a current copy of the DEA registration and NYSDOH license, then a copy must accompany the requisition, or the vendor will not process the purchase order.
- 2. Confirm that DEA form 222 is attached to requisitions for Schedule I and II controlled substances.
- 3. Use commodity code 97000000 on the requisition for controlled substances.
- Notes:
 - The approved vendor will ship the controlled substance to the address listed on the DEA registration.
 - Notifications of controlled substances purchased will be sent to the licensee/registrant associated with the registration number used.
 - Neither Cornell University EHS nor Procurement Services hold a university license or registration for purchasing or utilizing controlled substances.

Procurement Services:

- 1. Review vendor selection and documentation
- 2. Issue the purchase order

Payment Methods

A purchase order is required for the purchase of controlled substances. Use of a procurement card, disbursement voucher, cash, check, personal payment, or money order is prohibited. Licensee/Registrant will not be able to purchase controlled substances utilizing a Purchasing Card (P-card), cash, check, or money order. Contact Procurement Services for questions about the procurement of controlled substances and EHS regarding the usage of controlled substances in research.

Resources:

For more information regarding the use or purchase of controlled substances in research, consult:

- EHS Controlled Substances website: <u>https://sp.ehs.cornell.edu/lab-research-safety/bios/controlled-substances/Pages/default.aspx</u>
- Regulatory Agencies:
 - NYS Department of Health (NYSDOH): www.health.ny.gov/professionals/narcotic/licensing_and_certification
 - o Drug Enforcement Agency (DEA): <u>www.deadiversion.usdoj.gov/drugreg/index.html</u>