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Owner Dave Webster
 Policy Area SMH Pharmacy Policy
 Applicability University of Rochester - Strong Memorial Hospital

Controlled Substances in Research Labs

Research conducted at the University of Rochester Medical Center that requires the use of controlled substances (CS) must meet all of the rules and regulations of Article 33 of NYS Public Health Law and Part 80 of Controlled Substance Regulations. This policy applies to any research lab (e.g. animal research, in-vitro research) engaged in controlled substance activities.

Section A – CS used within the Strong Memorial Hospital/URMC Facility and ordered through the URMC Department of Pharmacy

Part I – Verification for use of Controlled Substances

All Principal Investigators will need to be identified on the ordering form (URMC 312 Requisition Form or other approved electronic form) for any medication ordered for research purposes. The indication of the PI and validation of the University Committee on Animal Resources Number (UCAR #) will be the verification used to authorize ordering, storing, and use of controlled substances.

Part II – Ordering of Controlled Substances (CS)

1. Principal Investigator (PI) or designee must complete a requisition for ordering controlled substances. The PI must indicate their name in print as well as sign the order form to authorize use of the product in research. Orders without the PI name and signature will not be accepted.
2. Protocol number (UCAR #) will be verified with records of approved protocols. Any request that does not have an authorized UCAR# will not be accepted. Orders for protocols which have expired will not be accepted. The order must also contain an approved ledger account number to be verified with the UCAR database. Each requisition will only have one account ledger.

3. After receipt of order and delivery, an email will be sent to the PI indicating the medications delivered. The email address from the approved protocol form will be used for the PI. Any unauthorized requisition should be immediately communicated to the pharmacy vault and Associate Director of Pharmacy.

Part III – Delivery of CS Order

1. Orders will be delivered to the appropriate lab following an accepted order. Arrangements can be made for pick up from the main inpatient pharmacy if needed.
2. Orders will be ready within two business days from the receipt of the order. For any special order situation (medications which are not currently stocked), this will add additional lead time depending on the product and ordering process required.
3. Individuals accepting delivery or picking up the order must have their URMIC issued picture identification with them and be approved as either the PI or associate for the specific protocol.

Part IV – Storage of CS

1. All storage of CS must be compliant with state and federal regulations governing the proper storage and inventory control of controlled substances.
 - a. All items must be stored in an independently double locking cabinet or automated machine such as PYXIS. For double locking cabinets, the keys must be kept in a secured location and accounted for at all times. The keys are the responsibility of the PI to ensure only authorized lab employees have access to CS cabinets.
 - b. Cabinets must be bolted to a wall or permanent structure so that they are not easily removed from the area.
 - c. Inventory control must maintain a perpetual inventory reflective of the disposition of any controlled substance being stored in the area. The balance must be verified (counted) at "change of shift" – for non-patient care areas, effectively the opening or closing of daily activities in the lab. This information can be maintained on the CDAR.
 - d. Only Controlled Substances shall be stored within the cabinet.

Note: See Pharmacy Policy and Procedure 10.A – Controlled Substance Handling, for further details on storage and disposal.

Part V – Auditing and Inspecting

1. All areas that store controlled substances will be inspected at least once monthly by pharmacy staff. The inspection will include verification that controlled substances are being stored appropriately and securely in accordance with state and federal requirements. Current inventory balance will be verified with CDAR. Any expired medications will be removed from the area and documented as such. Inspections may be unannounced and completion will be documented on a monthly inspection form.
2. Any violations of proper storage or inventory of controlled substances will be brought to the immediate attention of the PI associated with the protocol.

3. Multiple violations under the same protocol may result in termination of services to supply controlled substances to the area at the discretion of the Supervising Pharmacist for Strong Memorial Hospital.
4. In accordance with state law, CS that cannot be accounted for or any suspected diversion must be immediately reported to the Associate Director of Pharmacy who will determine the need to report to the NYS Department of Health Bureau of Narcotics Investigation and/or DEA. In addition, this report will also be communicated to the Chair of UCAR and Associate Director of Animal Research.

Section B – Animal Research Labs ordering Controlled Substances outside of URMCH Pharmacy

The URMCH Department of Pharmacy can provide CS for labs on site at Strong Memorial Hospital. For locations outside of the hospital, they will need to be registered to order CS directly, where a DEA Registrant (typically the PI) is responsible for the safe storage, documentation records, and appropriate use of the substances.

1. All storage requirements indicated in part IV above apply to the area where CS are being stored
2. The area will be inspected on a routine basis (monthly) by the DEA Registrant (typically the PI) or designee, with documentation of compliance to CS storage and usage regulations. Discrepancies in CS inventory should be reported to the appropriate division leader and any significant loss or suspected diversion must be reported to the NYS Department of Health Bureau of Narcotics Investigation in addition.

Approval Signatures

Step Description	Approver	Date
Pharmacy Administrator	Dave Webster	11/30/2023
Policy Owner	Dave Webster	11/30/2023

Older Version Approval Signatures

Pharmacy Administrator	Dave Webster	8/2/2021
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Applicability

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