

University of Pittsburgh
**Guidelines for the Ordering and Use of Prescription
Drugs and Devices and Controlled Substances for Non-
Clinical Laboratory Research**

Definitions:

1. Authorized Agent(s) of the Principal Investigator means a maximum of 1-2 designated (i.e., by the principal investigator) members of the principal investigator's research or administrative staff who have completed a DEA Screening Certification and have been authorized, by the University's Office of Human Resources, to have knowledge of the principal investigator's DEA registration number; to order, receive or dispense prescription drugs, prescription devices and controlled substances¹; to access secured controlled substances storage cabinets/safes; and to maintain respective accountability records on behalf of the principal investigator (e.g., in the absence of the principal investigator).
2. Authorized Laboratory Personnel means members of the principal investigator's research staff who have completed a DEA Screening Certification and have been authorized, by the University's Office of Human Resources, to receive, administer, or otherwise use controlled substances in the conduct of the principal investigator's laboratory research. Authorized Laboratory Personnel may include Authorized Agents of the Principal Investigator.
3. Practitioner License means a license issued by the Pennsylvania Department of Health to practice medicine, veterinary medicine, dentistry, nursing, or pharmacy.
4. Certification of Exemption memorandum means a formal (i.e. written) notification indicating the principal investigator's affiliation with the University of Pittsburgh and authorization to possess prescription (i.e., legend) drugs and devices. This memorandum replaces the Registration Exemption previously issued by the Pennsylvania Department of Health.
 - A Certification of Exemption memorandum is required only for principal investigators who do not possess a Practitioner License or an exemption letter from the Pennsylvania Department of Health.
 - The Certification of Exemption memorandum must be signed by the principal investigator's dean or department chair.

¹ Note: Only the Principal Investigator/DEA Registrant shall be permitted to sign a DEA Form 222 for the order of Schedule 1 or 2 controlled substances.

State and Federal Registration Requirements:

1. 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 Federal Drug Enforcement Administration (DEA).² This registration must be surrendered when the use of controlled substances in the investigator's laboratory is terminated.
2. Principal investigators who hold a DEA registration for the clinical use of controlled substances can incorporate, into this same registration, the controlled substances that will be used for laboratory research being conducted under their direction if two provisions are satisfied:
 - DEA regulations require a separate registration for each location where controlled substances are received, secured, and utilized. Accordingly, clinicians who receive or store controlled substances in their clinical practice cannot use the same registration to order controlled substances for their laboratory.
 - The address listed on the clinician's DEA registration must correspond to the laboratory location where controlled drugs are delivered, secured, and utilized.
3. The transfer of controlled substances between principal investigators is discouraged, and can only be performed if both investigators have a currently-active DEA license that covers the particular drug being transferred. Such transfers require proper recordkeeping, including the completion of DEA 222 forms for Schedule 2 controlled substances. Prior to transferring a drug to another investigator, the local DEA office should be contacted at 412-777-1870 to ensure that all required documentation is obtained.

Ordering of Controlled Substances and Prescription Drugs and Devices Through External Vendors³:

1. Controlled substances: To permit internal auditing, orders of controlled substances for laboratory research may only be placed through Butler Schein Animal Health Supply (Butler Schein). Permission must be specifically granted by University Purchasing Services for the use of an alternate external vendor for the ordering of controlled substances (i.e., should the desired controlled substance not be available through Butler Schein).

² http://www.dea diversion.usdoj.gov/drugreg/reg_apps/index.html

³ In accordance with the decision of UPMC administration, subsequent to the issuance of these Policies and Procedures, the UPMC Departments of Pharmacy may no longer be used as a supplier of controlled substances and prescription drugs for laboratory research use.

- Orders for controlled substances shall be submitted separate from orders for other prescription drugs or laboratory equipment and supplies.
- For Schedule III-V controlled substances:
 - If the order total is \$5000 or less, place the order through the University's PRISM system directly to Butler Schein. FAX (800-483-8329) or e-mail (*LindaMiller@butlerschein.com*), to Butler Schein, a copy of 1) the principal investigator's Certification of Exemption memorandum⁴ or currently active Practitioner License and 2) the principal investigator's currently active DEA registration. Specify the corresponding PRISM requisition number on these documents so as to permit their linkage with the controlled substances order.
 - If the order total is over \$5000, submit an electronic requisition⁵ through the University's PRISM system. FAX (412-624-9339) or deliver (3328 Cathedral of Learning), to University Purchasing Services, a copy of 1) the principal investigator's Certification of Exemption memorandum⁴ or the principal investigator's currently active Practitioner License; and 2) the principal investigator's currently active DEA registration. Specify the corresponding PRISM requisition number on these documents so as to permit their linkage with the controlled substances order.
- For Schedule II controlled substances:
 - Deliver (3328 Cathedral of Learning) to University Purchasing Services 1) the original of the first two pages of a completed DEA Form 222⁶; 2) a copy of the principal investigator's Certification of Exemption memorandum⁴ or the principal investigator's currently active Practitioner License; and 3) a copy of the principal investigator's currently active DEA registration. University Purchasing Services will subsequently issue the purchase requisition and mail it and the corresponding required documents to Butler Schein.
- Orders for controlled substances shall be limited to only those drugs specified on the principal investigator's currently active DEA registration.
- Orders for controlled substances shall be limited to the quantity necessary for 1-2 months of laboratory research use.

⁴ A Registration Exemption issued by the Pennsylvania Department of Health can be submitted instead of the Certification of Exemption memorandum.

⁵ <http://www.bc.pitt.edu/prism/>; http://www.bc.pitt.edu/purchasing/documents/-REQUISITIONCHECKLIST-0109_001.pdf

⁶ <https://www.accessbutler.com/WAButler/ProductsandServices/deaform222.pdf>

2. Prescription drugs (excluding controlled substances) and devices: Orders of prescription drugs, excluding controlled substances, or prescription devices for laboratory research may be placed through the external supplier of choice.
- If the preferred external supplier of the prescription drugs or devices is not currently established in the University's PRISM supplier database, submit a completed Supplier Verification Form to University Purchasing Services. With approval of University Purchasing Services, the external supplier will be subsequently added to the PRISM supplier database.
 - If the order total is \$5000 or less, place the order through PRISM directly to the external supplier. FAX or e-mail, to the external supplier, a copy of the principal investigator's Certification of Exemption memorandum⁴ or the principal investigator's currently active Practitioner License. Specify the corresponding PRISM requisition number on this document so as to permit its linkage with the prescription drug/device order.
 - If the order total is over \$5000, submit an electronic requisition through the University's PRISM system. FAX (412-624-9339) or deliver (3328 Cathedral of Learning), to University Purchasing Services, a copy of the principal investigator's Certification of Exemption memorandum⁴ or the principal investigator's currently active Practitioner License. Specify the corresponding PRISM requisition number on this document so as to permit its linkage with the prescription drug/device order.

Storage, Control and Accountability of Prescription Drugs and Devices and Controlled Substances:

1. Prescription drugs and devices and controlled substances shall be stored within a limited access room (i.e., access limited primarily to the responsible principal investigator and his/her research and administrative staff; room locked during non-occupancy).
 - Schedule II-V controlled substances must be stored in a securely locked, substantially constructed cabinet located within the limited access room.
 - Schedule I controlled substances and carfentanil, etorphine hydrochloride and/or diprenorphine must be stored in a safe or steel cabinet (i.e., equivalent to a U.S. Government Class V security container) secured within the limited access room.
 - Access to the key or combination for the controlled substances cabinet and/or safe shall be limited to the principal investigator and the Authorized Agent(s) of the Principal Investigator.

2. Control and accountability of prescription drugs and devices; other than controlled substances:

- The principal investigator shall be ultimately responsible for the control and accountability of prescription drugs and devices stored and used within his/her research laboratory (laboratories); to include ensuring that these drugs and devices are used only for authorized laboratory research purposes.
 - The dispensing of prescription drugs or devices for use in laboratory research shall be under the direct control of the principal investigator or, in his/her absence, an Authorized Agent of the Principal Investigator.
 - The principal investigator shall maintain accurate and up-to-date accountability records of the receipt, dispensing and corresponding laboratory research use of prescription drugs and devices.
 - The principal investigator shall ensure, on a routine basis (i.e., a minimum of quarterly or more frequently based on inventory and use levels), that the inventory of prescription drugs and devices reflected on the accountability records corresponds with the actual inventory on hand, and shall promptly investigate and reconcile any significant discrepancies.
 - Suspected diversion of prescription drugs or devices for other than authorized laboratory research use shall be promptly reported to the University Police Department (412-624-4040).
- Prescription drugs or devices that are expired, damaged, or no longer used shall be promptly removed from active laboratory research use and/or inventory and either returned to the supplier or disposed of in a proper manner. Return or disposal of prescription drugs and devices shall be documented on the respective accountability records.

3. Control and accountability of controlled substances:

- The principal investigator shall require that each member of his/her research or administrative staff who will have access to controlled substances or confidential controlled substance information (e.g., the principal investigator's DEA registration number) must complete a DEA Screening Certification administered by University's Office of Human Resources.
 - The original of the completed DEA Screening Certifications shall be maintained with the respective employees' records by the University's Office of Human Resources. The University Office of Human Resources shall provide copies of the completed DEA Screening Certifications for

Authorized Laboratory Personnel to the responsible principal investigator, who shall maintain these Certifications in such a manner that they are readily available for audit purposes.

- The ability of any individual who responds affirmatively to a DEA screening question to have access to controlled substances or confidential controlled substance information shall be subject to approval of a Waiver Request⁷ by the DEA and any other requirements of the University. In addition, an affirmative response to a DEA screening question may affect an employee's job duties or job status.
- The principal investigator shall be ultimately responsible for the control and accountability of controlled substances stored and used within his/her research laboratory (laboratories); to include ensuring that these substances are used only for authorized laboratory research purposes.
 - The dispensing of controlled substances for use in laboratory research of the principal investigator shall be under the direct control of the principal investigator or, in his/her absence, an Authorized Agent of the Principal Investigator.
 - Controlled substances for use in laboratory research of the principal investigator may only be dispensed to Authorized Laboratory Personnel.
 - The quantity of the controlled substance dispensed to Authorized Laboratory Personnel shall be limited to that which is estimated to be required to complete the experimental procedures scheduled for that day.
 - The principal investigator shall maintain detailed, accurate and up-to-date accountability records of the receipt, dispensing and corresponding laboratory research use of controlled substances. At a minimum, the accountability record for a controlled substance shall be updated on each day that the substance is dispensed for laboratory research use.
 - The principal investigator shall ensure, on a routine basis (i.e., a minimum of quarterly or more frequently based on inventory and use levels), that the inventory of controlled substances reflected on the accountability records corresponds with the actual inventory on hand, and shall promptly investigate and reconcile any significant discrepancies.
 - The principal investigator shall notify, in writing, the local DEA field office within one business day of any report or discovery of theft or significant

⁷ http://www.deadiversion.usdoj.gov/faq/waiver_1301_76.htm

loss of controlled substances and shall complete, and submit to the local DEA field office, a DEA Form 106⁸ regarding such theft or loss. The principal investigator shall also promptly notify the University Police Department (412-624-4040) of the report or discovery of theft or significant loss of controlled substances and shall provide this Office with a copy of all respective DEA reports.

- When determining whether a loss is significant, the principal investigator shall consider, among others, the following factors:
 - the actual quantity of the controlled substance(s) lost in relation to the laboratory activities;
 - the specific controlled substances lost;
 - whether the loss of the controlled substance(s) can be associated with access to the substance(s) by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substance(s);
 - a pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses;
 - whether the specific controlled substance(s) that was (were) lost is a (are) likely candidates for diversion; and, if known,
 - local trends and other indicators of the diversion potential of the missing controlled substance(s).
- Containers of controlled substances that are expired, damaged, or no longer used shall be promptly removed from active laboratory research use and/or inventory.
 - The principal investigator shall contact the local DEA Field Office (412-777-1870) for disposal instructions (e.g., transfer to a Reverse Distributor).
 - The University Environmental Health and Safety Department (412-624-9505) maintains contracts with DEA-registered Reverse Distributors and the principal investigator should contact this office for instructions, if applicable.

⁸ http://www.deadiversion.usdoj.gov/21cfr_reports/theft/

- Transfer (e.g., to Reverse Distributor) or other authorized disposition of the controlled substance shall be promptly (i.e., same day) documented on the corresponding accountability record.

Required Biennial Inventory of Controlled Substances

The principal investigator/DEA registration holder shall ensure that a DEA-required and compliant, biennial (i.e., every 2 years) inventory is performed⁹ of all controlled substances being stored for laboratory research use under his/her direction.

1. Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form by the responsible principal investigator.
 - The inventory record for Schedule I and II controlled substances shall be maintained separate from all other records maintained by the principal investigator.
 - The inventory record for Schedule III-V controlled substances shall be maintained in such a manner that it is readily retrievable from other records of the principal investigator.
2. For controlled substances in finished form the inventory record shall include:
 - the identity (name) of the controlled substance;
 - the strength (e.g., mg/mL; mg/tablet) of each finished form of the controlled substance;
 - the number of commercial containers of each such finished form of the controlled substance; and
 - the number of units or volume of each finished form present in each commercial container (e.g., 3 mL container, 100 tablet container) of the controlled substance.
 - In determining the number of units of each finished form of a controlled substance in a container that has been opened:
 - If a Schedule I or II controlled substance, make an exact count or measure of the contents; or

⁹ The biennial inventory may be taken on any date which is within two years of the previous biennial inventory.

- If a Schedule III-V controlled substance, make an estimated count or measure of the content, unless the container holds more than 1000 tablets or capsules in which case an exact count of the contents must be made.
3. For controlled substances awaiting disposal, held for quality control purposes, or maintained for extemporaneous compounding the inventory shall include:
- the identity (name) of the controlled substance;
 - the total quantity of the controlled substance to the nearest metric unit weight or the total number of units of finished form; and
 - the reason for the controlled substance being maintained by the principal investigator/DEA registrant and whether such narcotic is capable of use in the manufacture of any controlled substance in finished form.

Sanctions for Illicit Activity:

University employees who possess, sell, use or divert controlled substances or prescription drugs or devices in violation of Commonwealth or Federal laws will subject themselves not only to State and/or Federal prosecution for such illicit activity, but shall also immediately become the subject of an independent University action regarding their continued employment.