University of Pittsburgh

Guidelines for the Ordering, Security, and Disposal of 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 substances; 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.

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). 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.

    - 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, unless the address of the practice is at the same site as the laboratory where drugs are used. For this purpose, the biomedical science complex in Oakland (Biomedical Science Towers, Scaife Hall, Presbyterian Hospital, and Montefiore Hospital) is considered to be one site. Note that Children's Hospital, the McGowan Institute, and other buildings that are not physically connected to the Oakland biomedical complex, are considered to be separate sites.

        - The address listed on the clinician's DEA registration must correspond to the laboratory location where controlled drugs are delivered, secured, and utilized.

2. 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 through External Vendors:

To permit internal auditing, orders of controlled substances for laboratory research may only be placed through Covetrus North America (Covetrus). 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 Covetrus).

Detailed guidance for ordering controlled substances is available on the Panther Express website:

https://cfo.pitt.edu/pexpress/documents/DEAChecklist.pdf

Storage, Control and Accountability of Controlled Substances:

1. 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 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 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 Request 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.

    - The quantity of the controlled substance dispensed to laboratory personnel shall be limited to that which is estimated to be required to complete the experimental procedures scheduled for that day (or over a weekend period). Note that all individuals who handle or administer controlled substances must have completed a DEA Screening Certification.

- 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 loss of controlled substances and shall complete, and submit to the local DEA field office, a DEA Form 106 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. If expired, the containers should be marked as "Expired, DO NOT USE."

- Expired or unwanted containers of controlled substances with residual material must be disposed of via a reverse distributor. The Environmental Health and Safety Department arranges quarterly visits of a DEA-licensed reverse distributor to Campus, allowing for the disposal of controlled substances at no cost to the investigator.

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 performed 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

       - 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.