Responsibilities of Controlled Substance Registrants and Authorized Personnel

Controlled Substance Registrant:

Each researcher authorized to use controlled substances is responsible for understanding and complying with all regulations of the DEA regarding registration, purchase, use, and proper disposal of controlled substances used in their research. The PI retains all liabilities for loss, theft or misuse of any controlled substance acquired through their registration. For complete information see US DOJ DEA.

In brief, the registrant will:

- Ensure compliance with all federal laws
- Ensure safe, secure storage of controlled substances, §1301.71
- Ensure that all employees with access to controlled substances are appropriately screened
- Ensure that all required records for inventory, dispensing, and disposal of controlled substances are
- maintained
- Report significant losses or theft of controlled substances to the DEA
- Assure legal and proper disposal of controlled substances
- Ensure that appropriate procedures are followed when performing a drug transfer

Controlled Substance Authorized Personnel:

These individuals must perform research activities under the supervision of the registered PI or their authorized agent. Authorized personnel must complete the daily use forms accurately and ensure secure storage of unused chemicals and partially used vials at the end of the day.

In brief, Authorized Personnel:

- Ensure safe, secure storage of controlled substances
- Complete DEA employee screening security questions
- Maintain all required records to track the use and disposal of controlled substances
- Promptly report any theft or significant losses of controlled substances

DEA Required Inventories: Initial, Biennial and daily logs

One of the most common discrepancies DEA registrants should be aware of involves the Initial and Biennial Inventories (Title 21 Code of Federal regulations, part 1304). A majority of DEA registrants either maintain incomplete inventories or maintain no inventories at all. Even if you are not actively working with controlled drugs in your research, these inventories must be completed as to the quantity of controlled substances on hand.

Initial:

Each DEA registrant is required to take an Initial Inventory of all controlled substances on hand on the date they first engage in controlled substances activity. * The DEA requires that the inventory include:

a. The inventory date.
b. The time the inventory is taken (i.e., opening or close of business).
c. The drug name.
d. The drug strength (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter)
e. The drug form (e.g., tablet, capsule, etc.).
f. The number of units/volume (e.g., 100-tablet bottle or 3-milliliter vial).
g. The total number of commercial containers of each such finished form (e.g. four 100-tablet bottles or six 3-milliliter vials). Please label each bottle/vial with a unique identifier # to keep track of each bottle used.

*If the substance is listed in Schedule I or II, make an exact count or measure of the contents. If the substance is listed in Schedule III, IV or V, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case you must make an exact count of the contents.

DEA recommends that the inventory record include:

a. The name, address and DEA registration number of the registrant.
b. The signature of the person or persons responsible for taking the inventory.

Include in your inventory controlled substances that have been supplied to you as samples and controlled substances that have expired and are awaiting destruction. Controlled substances listed in Schedule II must be recorded separately from those controlled substances listed in Schedules III, IV, and V. DEA does not provide a specific form for inventories; however, AAHA press have log books designed for keeping inventories of controlled drugs. Dr. Kapsalis (ekapsali@med.miami.edu) can provide you a sample for you to get started.

Logs of controlled drug use:

After the Initial Inventory is conducted, each DEA registrant is responsible for his/her daily logging of controlled drugs. For Daily logs of controlled drug use, you need to keep separate logs for aliquoting a controlled substance similar to what you would do to track ketamine/xylazine mixtures that the UM IACUC reviews at inspections. Once a controlled substance is used to make a dilution, it is important to track the usage, disposition and disposal of the new dilution which contains a controlled substance. A separate controlled substance aliquot log should be generated and maintained by the investigator to record activities associated with the diluted aliquot.

Biennial inventory:

After the Initial Inventory is conducted, each DEA registrant is required to conduct a Biennial inventory. The Biennial Inventory should include the same information as the Initial Inventory and must be continued every two years as long as the DEA registration is active. Typical inventory checks include: 1) hands-on counting inventory and not a database check; 2) must be completed in a single business day, i.e., before the start of the work day or at the end of the work day; 3) at least two authorized personnel (licensed researcher and authorized agent or authorized lab personnel); and 4) use of some kind of inventory form; 21 CFR 1304.11(b). AAHA log books is one format that is often used.

Although these inventories are required by DEA and at the time at a DEA audit, you are not required to send a copy to DEA. You are only required to keep these inventories on file and available for inspection **for at least two years** from date of inventory after the final disposition of the controlled substance. You should still conduct daily, weekly and/or monthly inventories (according to the how much controlled drugs are used) to assure accurate and consistent records for your controlled substances.

If you follow these simple guidelines, you will be following federal requirements, thus, keeping your registration in good standing!

Disposal

Damaged, expired, unwanted, unusable, or non-returnable controlled substances must be accounted for, stored, and disposed of in accordance with applicable state and federal regulations. Disposal of a controlled substance must render it non-retrievable. You can dispose of your controlled drugs via EHS.

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