Guidelines for the Use of Controlled Substances for Research

The Ohio State University College of Pharmacy

All Ohio State University faculty and staff who use controlled substances in research are required to comply with the University Policy on Individual Investigator Use of Controlled Substances in Research. The Policy allows colleges to establish additional college-specific procedures and guidelines for the use of controlled substances by faculty and research staff in their academic units. These guidelines describe the procedures for the ordering, storage, recordkeeping, use, inventory and disposition of controlled substances for research purposes in the College of Pharmacy. . The Associate Dean for Research in the College of Pharmacy holds the DEA license for the research labs of the college. Any faculty member desiring a separate DEA license must notify the Associate Dean for Research prior to application for the license.

TRAINING REQUIREMENTS

All principal investigators and laboratory personnel (trainees and staff) authorized to order, use or administer controlled substances must attend an in-person training session on the proper use of controlled substances in research, prior to ordering or using any controlled substance. Training will be delivered by the Associate Dean for Research and/or the Research Administrative Manager. At the completion of the training session, attendees must pass a test (score of 80% or better) to demonstrate understanding of the guidelines. Any questions which are not answered correctly will be reviewed with the Research Administrative Manager in a face-to-face meeting. An authorized user list will be maintained centrally, and in each investigator's lab (Appendix A). The Research Administrative Manager should be notified immediately upon termination of employment/graduation of any authorized user.

ORDERS

All orders for Schedule II drugs must be initiated through the office of the Associate Dean for Research. DEA order forms will be initiated from the Associate Dean for Research, and the records will be maintained in the office of the Associate Dean for Research. Orders for Schedule III – V and other regulated drugs (e.g., ephedrine, ergotamine, phenylpropananolamine, pseudoephedrine) must be submitted for approval to the College of Pharmacy's Research Administrative Manager. Copies of all packing slips for Schedule II – V and regulated drugs must be submitted to the Research Administrative Manager upon receipt.

STORAGE

Storage of all controlled substances must be secure, and each PI is responsible for complete accountability for all controlled substances stored or used in their laboratory. This means that controlled substances must be stored in a locked steel cabinet or other substantial cabinet. Controlled substances should not be stored in a glass-fronted cabinet, or be visible from the outside of the cabinet.

The principal investigator is responsible for effective controls for proper storage. This includes limiting the number of keys and the number of employees with access to the keys. The keys must be kept in

secure locations. If a combination lock is used, the combination must be changed after employee turnover.

Each principal investigator should maintain a list of authorized users (agents) of controlled substances within the research group. This list must correspond with the list of users (agents) who have completed the training requirements outlined above.

RECORDKEEPING

Each investigator should maintain a laboratory drug log (see Appendix form B). Each bottle should be numbered and tracked on a separate form (see Appendix form C) which also lists the name of the controlled substance, dosage form, strength/concentration. The residual amount should be tracked as well. At the time of administration/use, record the following:

- Animal species (including ID information) administered the drug, or cell culture or other in vitro system use.
- Animal ID number
- Date of administration/use
- Identification of personnel using/administering the drug
- Amount used and amount remaining

A copy of the packing slip with handwritten date of receipt and initials of receiving person should be on file for each controlled substance order received (See Appendix D). Records must be maintained for three years after the last usage/completion of the controlled substance.

INSPECTION

The Associate Dean for Research and/or the Research Administrative Manager will inspect each lab at least twice yearly to assure appropriate controls, storage, and recordkeeping. Any deviations from the approved procedures will result in notification of the Principal Investigator. Any deficiencies must be addressed within five business days.

INVENTORY

A **mandatory** inventory will be conducted every two years, consistent with DEA requirements. The date and time of the inventory will be announced one week in advance.

DISPOSAL

For injectable drugs, once the bottle is empty, the bottle should be "rinsed" with water prior to disposal in the appropriate container (e.g. glass waste container). A similar approach should be used for bottles containing solid controlled drug/chemical formulations. Expired drugs may be returned to the Associate Dean for Research or Research Administrative Manager. Any expired or unwanted controlled drugs will be disposed of annually consistent with DEA regulations.

ACCOUNTABILITY

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Each principal investigator and their designated agents utilizing controlled substances will be accountable for following the guidelines for use of controlled substances. Each investigator is responsible for maintaining appropriate controls (e.g., ordering, storing, recordkeeping), and compliance with inspection and/or inventory requests. Consequences for failing to meet the expected standards may include retraining, re-examination, or loss of privileges to have and/or use controlled substances. Any deficiencies will be reported by the Research Administrative Manager to the graduate studies committee (for graduate students), division chair (for faculty and staff), and an annual performance report will be provided to the Office of the Dean. These issues may be considered in annual performance reviews.

TRANSFERS AND CLOSEOUTS

Controlled substances may not be transferred between laboratories or investigators. If a lab is closed out, or if a controlled substance is no longer needed, it should be returned to the office of the Associate Dean for Research. These will be disposed of annually, consistent with DEA regulations.

IMPORTS AND EXPORTS

No controlled substances may be imported from another country. No controlled substances may be exported.

SYNTHESIS OF CONTROLLED SUBSTANCES

The synthesis, derivation, or isolation of controlled substances is not permitted under the College of Pharmacy's DEA license. Any non-scheduled substances items which are reclassified as controlled substances will be subject to the same procedures as controlled substances, effective on the date of reclassification.

RESOURCES:

Lists of controlled substances: http://www.deadiversion.usdoj.gov/schedules/index.html

The Ohio State University Policy on Individual Investigator Use of Controlled Substances in Research: http://orc.osu.edu/files/2011/01/Individual-Investigator-Use-of-Controlled-Substances-in-Research-Final-SMC-Approved-Policy-9-28-112.pdf

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