

Wayne State University Controlled Substances Program

Office of Environmental Health & Safety

I. To Whom Does This Program Apply?

This Controlled Substance Program (CSP) applies to all Wayne State University faculty and research staff who hold individual Drug Enforcement Administration (DEA) Research Registrations, now referred to as “federal research registration”, as well as State of Michigan Controlled Substance licenses, now referred to as “state license”, specifically for the use of controlled substances (CS) in research. The CSP *does not* apply to Wayne State University faculty and research staff members who hold individual federal research registrations and state licenses for the use of CS in clinical treatment associated with human subject research.

II. Overview

Controlled substances are drugs regulated by the federal Drug Enforcement Administration (DEA) and the State of Michigan because of their potential for abuse. Controlled substances may be used in Institutional Animal Care and Use Committee (IACUC) approved protocols by University faculty and professional staff members who are licensed by the State of Michigan and hold a federal research registration. This program also applies to in vitro (lab bench-related) work as well.

To legally obtain and use CS in IACUC approved animal or in vitro research in the State of Michigan, investigators must either: 1) hold a current individual federal research registration *or* 2) conduct the research as an “agent” (as defined herein and in Appendix 3) of a University faculty researcher who holds a current federal research registration and state license.

The purpose of this document is to describe the processes and responsibilities required for WSU employees who wish to conduct research involving CS. It describes the responsibilities of Wayne State University faculty and research staff members who use CS with respect to compliance with the DEA and State of Michigan regulations regarding usage, handling, storage, recordkeeping and disposal and/or transfer of CS. Appendix 2 and Appendix 5 refer to the state and federal rules and regulations that apply to the use of CS under their program. Forms and suggested procedures for compliance are also provided.

III. Controlled Substance Definitions

Controlled substances are drugs or other chemicals that have the potential to be abused. The Drug Enforcement Administration (DEA) divides CS into five schedules based on their potential to be habit forming, and usefulness in medicine as a drug. For a more comprehensive listing, refer to the DEA Office of Diversion Control website (www.deadiversion.usdoj.gov):

- Schedule I**drugs, or other substances that have a high potential for abuse, no currently accepted medical use in the United States, and are accepted as unsafe even under medical supervision.
- Schedule II**drugs or other substances that have a high potential for abuse, currently have an accepted medical use in treatment in the United States, or a currently accepted medical use with severe restrictions.
- Schedule III**drugs or other substances that have a potential for abuse that is less than Schedule I or II CS, with currently accepted medical use in treatment in the United States. Schedule III drugs may lead to moderate or low physical dependence and high psychological dependence.
- Schedule IV**drugs or other substances that have a low potential for abuse relative to those listed in Schedule III. These drugs have a currently accepted medical use in the United States, and abuse of them may lead to limited physical or psychological dependence relative to those in Schedule III.
- Schedule V**drugs or other substances that have a low potential for abuse relative to Schedule IV. These drugs have a currently accepted medical use in the United States, and abuse of them may lead to limited physical or psychological dependence relative to those in Schedule IV.

IV. Monitoring and Inspection

The Office of Environmental Health and Safety (OEHS) is responsible for monitoring the recordkeeping, inventory, security, and disposal of CS used in research by Wayne State University faculty and research staff members. Reviews will be conducted annually to assure university compliance with DEA and State of Michigan regulations and this program. If deficiencies are identified during an audit, subsequent audits may be performed more frequently than once per year to assist with adherence to regulatory compliance.

V. Wayne State University Registration Requirements

Wayne State University faculty and research staff members holding current individual federal research registration as well as state licenses must notify the OEHS of their registration and license. The OEHS shall serve as the primary point of contact for Wayne State University faculty and research staff members who hold or intend to hold an individual federal research registration or a state license. Wayne State University faculty and research staff members who intend to register with the DEA for a federal research registration and to obtain a state license must notify OEHS prior to registering. The DEA requires that faculty and staff obtain a state license before the agency will issue a federal research registration.

VI. Controlled Substances Licensing and Registration

A. Federal Drug Enforcement Administration

All persons conducting research involving CS must be registered with the DEA. The type of registration required varies according to the nature of the activity involving CS. Separate

registrations may be required for individual activities involving CS covered by this program as described below.

1. Research: The DEA Form 225 (download from www.deadiversion.usdoj.gov) is submitted for research registration, with the following information required:
 - Investigator - Name, address, institution, and a qualifications statement including *curriculum vitae* with bibliography.
 - Project - Title, statement of purpose, controlled substance name and the amount needed, location of research, security statement, and a technical description of the substance use.
 - Authority - Institutional approval and grant number if applicable.
2. Laboratory Chemical Analysis: DEA Form 225 (download from www.deadiversion.usdoj.gov) provides authorization to conduct analysis with CS listed in any schedule.

B. The State Board of Pharmacy

In addition to the DEA paperwork, researchers must obtain a state license by completing, and submitting to the Michigan Department of Community Health, Board of Pharmacy “Application for Controlled Substance Research License” (http://www.michigan.gov/documents/mdch_csresearchapp_147627_7.pdf). This form is required for every person who manufactures, distributes, prescribes, dispenses or conducts research with CS.

Obtaining a Controlled Substance Research License and Registration

How do I get a Controlled Substance License/Registration?

Obtaining a license to use CS is a relatively easy process, but it does take some time. You will need to get both a state license and a federal research registration.

A. Obtain a State License

A state license is required before the DEA will approve the federal registration. After you have submitted your application for the license, you may apply for the federal research registration. You do not have to wait until you receive the state license number to submit the federal application. To obtain a state license you must complete an application form and submit to a criminal background check.

1. The State License application.

- a. Fill out the “Application For Controlled Substance Research License” found here: http://www.michigan.gov/documents/mdch_csresearchapp_147627_7.pdf
- b. You will need the following supplemental information:
 - i. Credentials to conduct the proposed research, i.e. qualifications, including curriculum vitae (CV)
 - ii. List of other staff/persons involved
 - iii. Research Project:
 - a) Title of project
 - b) Statement of the purpose
 - c) Name of CS involved, amount (with justification) of each CS needed and its source.
 - d) Research protocol (detailed description of procedures), including number and species of research subjects, dosage to be administered, route and method of administration, and duration of project.
 - e) Location where research will be conducted.
 - f) Statement of security provisions for storing and dispensing the CS(s) in order to prevent diversion.

Note: In Michigan, the “Application for Controlled Substance Research License”, must be submitted to conduct research with Schedule I CS.

2. Criminal background check

Fingerprinting and a criminal background check are also required. The Wayne State University Police Department has been approved by the State of Michigan to process fingerprints for all WSU faculty applying for a state license. At the WSU Police Department, applicants will fill out a form, and their fingerprints will be electronically scanned. This process will take approximately 30 minutes to complete. This information will then be electronically transmitted to the Michigan State Police for the required background check. To schedule fingerprint scans, please contact Lt. Robert Barron by email (ac4978@wayne.edu) and copy Capt. Emery Burk (ac3793@wayne.edu) and Richard Harrison (ak5143@wayne.edu). The WSU Police Department is located at: 6050 Cass Avenue, Detroit, Michigan. Free parking is available in front of the WSU Police Headquarters.

B. Obtain a Federal Research Registration

The federal research registration process may be initiated once the state license application has been submitted. Final approval from the DEA will not be granted until a state license has been granted, but starting the DEA application process while the State of Michigan application is pending will shorten the overall process.

Drug Enforcement Administration Controlled Substance Registration Application. Complete Form 225 for a new applicant.

See: http://www.deaddiversion.usdoj.gov/drugreg/reg_apps/index.html. The \$244 application fee is waived for WSU employees. Department chairs may serve as certifying officials.

Additional information and specific instructions may be found at:
<http://www.oehs.wayne.edu/controlled-substances/how-to-obtain-cs-license.pdf>.

See Appendix 4 for frequently asked questions.

VII. Authorized Agent Use

Authorized agents who use CS under an investigator's Research Registration must be documented on the *Wayne State University Controlled Substances Authorized Agent List* (Form A), which is copied and forwarded to the Office of Environmental Health & Safety. Keep ONLY a copy of Form A with the controlled substance inventory.

The registrant /licensee is responsible for managing the CS in accordance with the requirements of the regulations (21 CFR 1300 to 1321) including inventory, record keeping and security provisions. Authorized agents of the registrant/licensee may engage in approved activities under the direction of the registrant/licensee. Lab employees can be considered authorized agents of the person with an active state license and federal research registration if they are acting in the usual course of their business or employment and with proper screening and authorization by the registrant/licensee. The registrant/licensee must screen all authorized agents. Form A (Appendix 1), as described in the next section, satisfies the screening requirements for authorized agents.

State law and federal regulations provide limitations on who can be an authorized agent (MI R 338.3145, Rule 45. (1) and 21 CFR 1301.90).

VIII. Employee Questionnaire

The DEA requires all individuals who plan to work with CS to fill out a questionnaire containing the two questions below (21 CFR, 1301.90):

- 1) Within the past five years, have you been convicted of a felony, or, within the past two years, any misdemeanor, or, are you presently charged with committing a criminal offense?
- 2) In the past three years, have you knowingly used narcotics, amphetamines, or barbiturates other than those prescribed to you by a physician?

The questionnaire (Form A) may be printed, completed and mailed to:

Annette Tremonti
WSU Office of Environmental Health & Safety
5425 Woodward, Suite 300
(313) 993-4079
ad8831@wayne.edu

The questionnaire is also available on line at:

http://www.oehs.wayne.edu/controlled-substances/WSU_Controlled_Substances_Program.php.

Completed questionnaires will be kept on file with the Office of Environmental Health and Safety as long as the individual is working with CS.

IX. Recordkeeping Requirements: An Overview

Individuals holding federal research registrations and state licenses are responsible for maintaining appropriate records and inventories of all CS used. Faculty and research staff members who obtain and use CS as Agents under federal research registrations are also responsible for maintaining appropriate records and inventories of CS used in their research at the university. The term "Agent" refers to an authorized person who acts on behalf of, or at the direction of, a licensed researcher.

Controlled substance records must conform to the record keeping requirements of federal law and the procedures described below. Controlled substance records include all purchasing records, use and destruction records, controlled substance ordering forms (DEA Form 222), and inventory records. Faculty and research staff members who purchase CS from outside pharmacy vendors/suppliers and use their own federal research registration are responsible for maintaining the DEA Form 222s and individual purchase invoices associated with such purchases. All licensed and required faculty and research staff members are responsible for maintaining the CS records.

All CS records must be readily available upon request by Federal or University inspectors and stored separately from the ordinary business records of the registrant. Schedules I and II CS records must also be maintained separately from records for Schedule III, IV, and V CS.

Federal law requires that all controlled substance records shall be maintained for a minimum of two years from the date they were created. In the event that the records are copied for an inspection, they must be kept for an additional two years from the date of copying (21 CFR 1304.04, 1304.11, 1304.21 and 1304.22). These records include, but are not limited to purchasing, inventory, and disposal records. Wayne State University requires registered/licensed

investigators to retain controlled substance records for five years following the date of such inventory or other CS records.

X. Purchasing Controlled Substances: Procedures and Record Keeping

Wayne State University faculty and research staff must use the controlled substance account code 721H5 when purchasing CS through the WayneBuy system. The request is automatically routed to the Director of the OEHS who will confirm the authorization to purchase CS and to Purchasing who will confirm that the purchaser holds a current federal research registration, state license, and that the delivery address is correct. A purchase order will then be generated and sent to the vendor with a scanned copy of the original DEA order Form 222 (for Schedule I and II only). Purchasing will also provide OEHS with the purchase order number. If the purchase is not approved, OEHS will work with the purchaser to resolve the issue.

A. Schedule I or II

Any person registered to conduct research with CS in Schedule I or II must send, in triplicate, DEA Form 222 with a hard copy of the purchase order to the supplier. OEHS does not have copies of this form. The form is available on the DEA's website. See Appendix 5.

B. Schedule I CS that is not commercially available

Requests to obtain Schedule I CS that are not commercially available must be made to the National Institute on Drug Abuse. The link is: <http://www.drugabuse.gov/>.

C. Schedule III-V

DEA Form 222 is not required to purchase Schedule III-V CS.

D. Maintaining Purchase Records

Wayne State University faculty and research staff members are responsible for obtaining and maintaining the following information for all CS purchased from pharmacies or distributors:

- The name of the controlled substance purchased
- The size and strength of the controlled substance purchased, i.e. bottle size and concentration
- The amount purchased (which should match the amount received), i.e. quantity received
- The name, address, and DEA number of the company from which the controlled substance was purchased
- A copy of the invoice, i.e. payment order
- A copy of the purchase order
- A copy of the shipping document, i.e. Fed Ex air bill, UPS bill, etc.
- A copy of the packing slip, i.e. itemized list of contents

The purchasing record (purchase order, invoice, shipping document, or packing slip) must be annotated with the handwritten date of receipt.

There are additional recordkeeping requirements for investigators purchasing Schedule II CS. Investigators purchasing Schedule II CS from pharmacies or distributors are required to

retain a copy of the invoice and individual DEA Form 222 for each purchase. Investigators purchasing Schedule II CS from non-university sources must also complete a Record of DEA Form 222. Use to maintain accountability for all DEA Form 222s used. The entries for the date and the quantity received that are on the form should then match the date and quantity received entries on the Controlled Substances Record (Form 1, http://www.oehs.wayne.edu/controlled-substances/cs_form_general_inventory_log.doc) for each drug purchased.

XI. Storage and Security

Security depends greatly on the type, quantity, and form of CS being used in a research project. Schedule I, II, III, IV, and V CS must be stored in a locked steel cabinet or a locked substantially constructed cabinet. For examples, see SelectLocks.com at the following link: <http://www.selectlocks.com/Locking-Cabinets>.

Controlled substances should not be located near a glass panel where they can be visible from the outside. Researchers must provide effective controls to guard against theft. This includes limiting the number of keys and the number of employees who will have access to the keys. Keys for locked cabinets must be kept in secure locations when not in use. Developing a key accountability standard operating procedure (SOP) is recommended. If combination locks are used, combinations must be changed whenever there is turnover of any employee who has knowledge of the combination and access to the CS. In addition to key/combination access control, only authorized personnel are allowed in a university laboratory where CS are used or stored. Laboratory employees and students are considered authorized agents of the individual with an active federal research registration if acting under the authority of a DEA registrant. Non-laboratory visitors entering areas where CS are used or stored should always be asked to provide identification and the purpose of their visit. When maintenance work is done in the controlled substance storage area, the research staff must maintain adequate observation.

XII. Inventory Records

Maintaining an accurate inventory for CS is one of the most important aspects of the DEA enforcement programs and the university's compliance program. In following best research practices and to avoid OEHS and DEA audit red flags, investigator controlled substance inventories should not exceed the amount necessary for research. Keeping an up-to-date inventory will assist in identifying potential loss, theft, and/or the diversion of CS. Faculty and research staff members must maintain an up-to-date inventory of the CS in their laboratories.

All faculty and research staff members are required to maintain a Wayne State University Controlled Substance Record (Form 1, http://www.oehs.wayne.edu/controlled-substances/cs_form_general_inventory_log.doc) for each controlled substance used in their laboratories. The form meets DEA requirements for controlled substance inventory, administration, and use documentation. Complete DEA inventory requirements can be found at the following site: http://www.deadiversion.usdoj.gov/21cfr/cfr/1304/1304_11.htm .

XIII. Controlled Substance Disposal: Permitted Methods and Record Keeping

To minimize waste, faculty and research staff members with research registrations/licenses should only purchase and store quantities of CS that they reasonably intend to use. Damaged, expired, unwanted, unusable, or non-returnable CS must be accounted for, retained, and disposed of in accordance with applicable state and federal regulations (21 CFR 1304.11).

There are two disposal options for expired or unwanted CS. The Office of Environmental Health and Safety should be contacted to help determine the correct disposal method.

A. Contact the Supplier

Some suppliers will take back unused pharmaceuticals for credit. If possible, this is the best means of controlled substance disposal. The CS should be unused and in resalable form.

B. Reverse Distribution

This option involves transfer of ownership of the controlled substance to a DEA-approved Pharmaceutical Returns Processor for re-use, re-sale or destruction at a hazardous waste incinerator. Reverse distribution requires completion of DEA Form 222 and DEA Form 41 (http://www.deadiversion.usdoj.gov/21cfr_reports/surrend/index.html) for Schedule I and II. Reverse distribution requires completion of DEA Form 222 for Schedule III-V. Those interested in reverse distribution of CS should first contact OEHS.

A Registrant's Inventory of Drugs Surrendered form (DEA Form 41, http://www.deadiversion.usdoj.gov/21cfr_reports/surrend/index.html) must be completed prior to disposing of any DEA controlled substance. Two copies of the form must be sent to the local DEA branch by OEHS and one copy must be retained by the investigator for at least five years.

Investigators must maintain disposal records with the following information:

- The investigator's DEA number, name, and address
- If a reverse distributor is used, the reverse distributor's DEA number, name, and address
- The number of units (in finished forms and/or commercial containers) disposed of, and the manner of disposal

The disposal record must be dated to reflect when the products were sent for destruction and left the inventory.

XIV. Separation of Investigators from the Institution

Controlled substances purchased by investigators conducting research are the property of Wayne State University. Faculty and research staff members holding individual federal research registrations and investigators holding CS as agents who plan to leave the university (e.g. accept a position at another university, company, or retire) must contact the Office of Environmental Health and Safety prior to their departure to arrange appropriate transfer or disposal of the CS.

XV. Spills

Breakage, spills, or other witnessed controlled substance losses do not need to be reported. This type of loss, however, must be documented by the registrant and witness on the inventory record. Controlled substances that can be recovered after a spill, but cannot be used because of contamination (e.g., tablets), must be placed in the disposal/destruction waste stream as described in “**Disposal Options**” above. If the spilled controlled substance is not recoverable (e.g., liquids), the registrant must document the circumstances in their inventory records and the witnesses must sign.

XVI. Theft of or Missing Controlled Substances Reporting

Investigators must maintain complete accountability of all CS stored or used in their laboratory. Keeping good records is essential for the detection of shortages or missing CS. Theft or misuse of a controlled substance is a criminal act that must be reported by phone to the following agencies:

- DEA Detroit Division(313) 226-7537 / Fax: (313) 225-2163
- Wayne State University Police DepartmentEmergency Number: (313) 577-2222
- OEHS Number:(313) 577-1200 / Fax: (313) 993-4079

In addition to reporting theft or misuse of CS by phone, a Report of Theft or Loss of Controlled Substances form (DEA Form 106) must be completed and submitted to the DEA office located at DETROIT DIVISION, 211 W. Fort Street, Suite 610, Detroit, MI 48226. Investigators must retain one copy of any DEA Form 106 submitted to the DEA for at least five years.

On-line reporting to the DEA is also necessary if small quantities of CS are unaccounted for on a recurring basis. The on-line reporting process can be accessed at http://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html. Investigators should print and retain one copy of any on-line DEA Form 106 submitted in their controlled substance inventory records.

XVII. Responsibilities

A. Office of Environmental Health and Safety

- Provide guidance to campus units for registering with state and federal agencies
- Provide advice on storage of CS
- Dispose of CS
- Annual audits

B. Registered Controlled Substance User

- Ensure compliance of the physical facilities with Federal, State, and University regulations and policies governing the proper use of CS
- Ensure compliance of laboratory personnel with Federal and State and University regulations and policies governing the proper use of CS
- Provide and employ proper storage for CS
- Maintain accurate CS records

- Report theft or loss of CS
- Ensure proper disposal of CS

XVIII. Corrective Measures

Failure of investigators and agents to follow the requirements of this Controlled Substances Program may result in personal, civil, and criminal liability under state and federal law and disciplinary action under applicable faculty and staff policies, including loss or limitation of an investigator's privilege to conduct animal research.

Appendix 1

Form A
**Questionnaire for Employees Who Will Have Access To
Substances Regulated by the US Drug Enforcement Agency**

The Drug Enforcement Agency requires that any person who will have access to controlled substances as a result of employment at Wayne State University answer the following questions. Any false information or omission of information may jeopardize your position with respect to employment. Information revealed in this questionnaire will not necessarily preclude your employment, but will be considered as an overall evaluation of your qualifications. The responses to this questionnaire will be held in the strictest confidence.

- 1) Within the past five years, have you been convicted of a felony, or, within the past two years, any misdemeanor, or, are you presently charged with committing a criminal offense? If yes, furnish the details of conviction, offense, location, date and sentence. Do not include traffic violations, juvenile offenses or military convictions, except by general court martial.

Yes NO

If you answered "yes", please provide details here:

- 2) In the past three years, have you knowingly used narcotics, amphetamines, or barbiturates other than those prescribed to you by a physician?

Yes NO

Name: _____

Banner ID: _____

Department: _____

Principal Investigator: _____

By typing or signing my name below, I certify that I am the above named person and that the information I have provided is complete and accurate.

Signature (type or sign): _____

Today's Date: _____

Return form by campus mail, fax or email to:

Annette Tremonti
WSU Office of Environmental Health & Safety
5425 Woodward, Suite 300
313.993.4079
ad88@wayne.edu

Or complete online at:

http://www.oehs.wayne.edu/controlled-substances/WSU_Controlled_Substances_Program.php

Appendix 2

Controlled Substance Regulations and Agencies

State of Michigan

- Michigan Regulations and Administrative Rules – Controlled Substances
 - Michigan Act 368 of 1978 Public Health Code: Article 7
Controlled Substances
 - Michigan Board of Pharmacy – Administrative Rules:
Controlled Substances

 - State License Michigan Department of Community Health (MDCH)
 - MDCH Bureau of Health Professions – Licensing for Health Care Professionals
 - State of Michigan Board of Pharmacy – Controlled Substance Licensing Information

For questions regarding controlled substance licensing contact: MDCH Bureau of Health Professions –
Investigation Division: PO Box 30545, Lansing MI 48909
Phone: (517) 373-1737
Email: bhpinfo@michigan.gov

Federal Government

- Federal Regulations
 - Title 21 United States Code – Controlled Substance Act
 - Title 21 Code of Federal Regulations, Part 1300-1399
 - federal research registration Drug Enforcement Agency (DEA)
 - DEA Office of Diversion Control – Controlled Substance Registration
 - DEA Support
 - Registration Categories and Fees
 - Questions and Answer

For questions regarding federal research registration contact:

Detroit DEA Field Office
431 Howard Street, Detroit, MI 48226
Phone: (313) 234-4000
Fax: (313) 234-4149
URL: www.deadiversion.usdoj.gov

Appendix 3

Definitions

Drug Enforcement Administration	the Drug Enforcement Administration in the Department of Justice.
Controlled Substance	a drug or other substance, or immediate precursor, included in Schedule I, II, III, IV, or V of part B of this subchapter. The term does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1986.
Authorized Agent	an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser; except that such term does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman, when acting in the usual and lawful course of the carrier's or warehouseman's business.
Practitioner	a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.
Readily Retrievable	certain records are kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.
Chemical Mixture	a combination of two or more chemical substances, at least one of which is not a list I chemical or a list II chemical, except that such term does not include any combination of a list I chemical or a list II chemical with another chemical that is present solely as an impurity.
Net Disposal	for a stated period, the quantity of a basic class of controlled substance distributed by the registrant to another person, plus the quantity of that basic class used by the registrant in the production of (or converted by the registrant into) another basic class of controlled substance or a non-controlled substance, plus the quantity of that basic class otherwise

disposed of by the registrant, less the quantity of that basic class returned to the registrant by any purchaser, and less the quantity of that basic class distributed by the registrant to another registered manufacturer of that basic class for purposes other than use in the production of, or conversion into, another basic class of controlled substance or a non-controlled substance or in the manufacture of dosage forms of that basic class.

Reverse Distributor

a registrant who receives controlled substances acquired from another DEA registrant for the purpose of-

- returning unwanted, unusable, or outdated controlled substances to the manufacturer or the manufacturer's agent; or
- where necessary, processing such substances or arranging for processing such substances for disposal.

Registrant

include entities such as controlled substance and listed chemical manufacturers, importers, exporters, distributors, and pharmacies, hospitals, physicians, nurse practitioners, and physician's assistants and researchers who have a controlled substance license and registration.

Appendix 4

Frequently Asked Questions

U.S. Department of Justice Drug Enforcement Administration
Office of Diversion Control

Web Link: <http://www.deadiversion.usdoj.gov/drugreg/faq.htm>

Question: What is the processing time for a new or renewal application?

Answer: New Applications (DEA Form 224) are processed within 4 to 6 weeks. Renewal Applications (DEA Form 224a) are processed within approximately 4 weeks.

Question: Has my application been processed?

Answer: You may call 1-800-882-9539 for the status of your application or you may call the DEA Field Office nearest you.

Question: Can you fax a new or renewal application/certificate?

Answer: Applications may be faxed under special circumstances, however, applications cannot be returned for processing via fax. Completed applications must be mailed with the appropriate fee and an original signature. Certificates are never faxed, however, we can send the requester a form letter that shows the Drug Enforcement Administration (DEA) number is current.

Question: Can you verify a DEA number?

Answer: NO. It is DEA Program that the credentialing of a physician may be accomplished by requesting a copy of the physician's current DEA registration certificate, which indicates the issue and expiration dates. This would satisfy the requirements for verification of a DEA registration. In addition, the DEA provides a list of active DEA registrants to the National Technical Information Service (NTIS), a component of the United States Department of Commerce. This list of active DEA registrants may be obtained from NTIS as a single purchase, or on a monthly or quarterly basis by calling 1-800-363-2068 or on the web at www.ntis.gov/product/dea.htm.

Question: How does a Schedule I researcher apply for a DEA registration?

Answer: A Schedule I research applicant should submit a DEA Form 225 with the required registration fee and must include the following information:

Investigator:

- Name, address, DEA registration number (if any)
- Institutional or company affiliation
- Qualifications, including curriculum vitae (CV) with a list of publications
- Research Project:
 - Title of project
 - Statement of the purpose
 - Name of controlled substances (CS) involved, amount (with justification) of each needed and source.

- Research protocol (detailed description of procedures), including number and species of research subjects, dosage to be administered, route and method of administration, and duration of project.
- Location where research will be conducted.
- Statement of security provisions for storing and dispensing the CS(s) in order to prevent diversion.
- If investigator plans to manufacture or import the CS(s), statement of quantity to be manufactured or imported and sources of chemicals to be used or substance to be imported.
- Authority (if applicable):
 - Institutional approval
 - Approval of a Human Research Committee for human studies.
 - Indication of an approved active Notice of Claimed Investigational Exemption for a New Drug (IND) (number).
 - Indication of an approved funded grant (number), if any.

The applicant should mail the items to this address:

U.S. Department of Justice
Drug Enforcement Administration
Attn: Registration Section ODR
P.O. Box 2639
Springfield, VA 22152-2639

Appendix 5

For DEA Regulations Governing Controlled Substances see:

Title 21, Code of Federal Regulations, Section 1310.18 for additional instructions

-1304.04 Maintenance of Records & Inventories

http://www.deadiversion.usdoj.gov/21cfr/cfr/1304/1304_04.htm

-1304.11 Inventory Requirements

http://www.deadiversion.usdoj.gov/21cfr/cfr/1304/1304_11.htm

-1304.21 General Requirements for Continuing Records

http://www.deadiversion.usdoj.gov/21cfr/cfr/1304/1304_21.htm

-1304.22 Records for Manufacturers, Distributors, Dispensers, Researchers, Importers & Exporters

http://www.deadiversion.usdoj.gov/21cfr/cfr/1304/1304_22.htm

-1305.12 Procedures for executing DEA Form 222

http://www.deadiversion.usdoj.gov/21cfr/cfr/1305/1305_12.htm

-1305.13 Procedure for filling DEA Forms 222

http://www.deadiversion.usdoj.gov/21cfr/cfr/1305/1305_13.htm

-1307.21 Procedures for disposing of Controlled Substances

http://www.deadiversion.usdoj.gov/21cfr/cfr/1307/1307_21.htm

See also: www.deadiversion.usdoj.gov