Controlled Substances Program

For Non-Pharmacy Applications

2017

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Attachments

1. 0 PURPOSE

The acquisition, use and disposal of Controlled Substances at Syracuse University (SU) are subject to strict Federal and State Regulations. These regulations set specific requirements and restrictions on registration, acquisition, usage, record keeping, transfer, storage and disposal. The purpose of this document is to provide University policy and procedures in order to meet Federal and State requirements.

2.0 SCOPE

Individuals who manufacture, distribute, dispense, import, export, conduct research or perform chemical analysis with any "Controlled Substances", as defined by the US Drug Enforcement Administration, are subject meeting the requirements set forth in Title 21 Code of Federal Regulation, Part 1300-1399 and Part 80, Subchapter K of the New York State Public Health Law. All members of Syracuse University are subject to the requirements of the regulations referenced herein and are also subject to the requirements of the of the Hazardous Waste Disposal Program.

3.0 DUTIES AND RESPONSIBLITIES

This Section outlines specific duties and responsibilities for Controlled Substance License Holders, Principal Investigators and EHSS.

3.1 Controlled Substance License Holders

1. Are responsible for submitting NYS License and DEA Registration applications and associated fees to all appropriate agencies, as well as, receiving and maintaining copies of all Licenses, Registrations and all related documents for the term of the license/registration and 10 years thereafter.

2. Must maintain an accurate a list of individuals authorized to possess and access Controlled Substances under their purview and submit to EHSS a current list of authorized personnel annually and as requested.

3. Must ensure that authorized users are meeting the requirements of this Program and all applicable State and Federal Laws.

4. Must notify EHSS of any changes, modification, and renewals of a License or Registration.

5. Must notify EHSS when a License or Registration is not to be renewed and submits to EHSS, a final inventory, showing the disposition of all Controlled Substance providing documentation that no controlled substances remain in the possession of any individual covered by the License.

6. Assure that all Controlled Substances are properly used, handled and stored in accordance with the terms and conditions of the License or Registration

3.2 Principal Investigators

1. Must obtain approval from a Syracuse University Controlled Substance License Holder prior to ordering or taking possession of a Controlled Substance.

2. Are responsible for proper security, storage, utilization, record keeping and disposal of all Controlled Substances in their possession.

3. Must maintain all appropriate inventory and use logs for Controlled Substances during possession and for a period of five years thereafter.

4. Must maintain a current list of all laboratory personnel authorized to use a Controlled Substance.

5. Must ensure that all required records for Schedule I drugs are kept separate from those for Schedule II through V Controlled Substances.

6. Must ensure that Controlled Substances are appropriately secured from all unauthorized access and locked unless in usage.

7. Must report verbally and in writing of theft or loss to EHSS and the appropriate License Holder immediately upon discovery.

8. Must provide training to authorized users.

9. Must apply for additional State and Federal approval prior to initiation of any use of Schedule I or Schedule II controlled substances.

10. Must ensure that all use and inventory forms are filled out completely and that all required records are maintained accurately.

11. Must contact EHSS for the disposal of Controlled Substances.

12. Must complete a physical annual inventory as directed by EHO. Copies of usage logs used in the past calendar year will be required to be submitted at that time.

13. Must obtain Institutional approval for each experiment that involves the use of a Controlled Substance of human or animal. Approved protocols must be maintained on file and be made available upon request.

14. Must maintain information on the nature of the research project, and the limitations on Controlled Substance purchase, use and possession.

15. Must post copies of the Department's, Institute's, or Center's NYS License and DEA Registration at each location where Controlled Substances are stored.

3.3 Environmental Health and Safety Services

1. Must maintain copies of Licenses, Certificates of Registration and disposal records.

2. Must review for approval the proposed security controls for storage and access of Controlled Substances.

3. Must coordinate the removal and disposal of Controlled Substances.

4. Must maintain a database of all individuals currently in the possession of Controlled Substances.

4.0 LICENSING AND REGISTRATION

In order to use Controlled Substances for research purposes, approval by the Department of Health of the State of New York, Bureau of Controlled Substances (NYSDOH) and the US Department of Justice, Drug Enforcement Administration (DEA) is required.

At Syracuse University, NYSDOH Licenses and DEA Registrations are held by individuals in several Departments, Institutes, and Centers. Ultimately, the responsibility for ensuring that the License or Registration is properly maintained is that of the individual whose name the license is in. Currently, Licenses and Registrations allow Principal Investigators approved by the Department, Institute or Center to possess controlled substances for research and instructional activities.

4.1 NYSDOH Licensing Requirement Policy

No University personnel or affiliate shall manufacture, obtain, possess, administer or dispense a controlled substance for purpose of scientific research, instruction or chemical analysis without having first obtained a License to do so from the New York State Department of Health. All Licenses are issued for two years from the date of issue and must be renewed by the License Holder. All fees associated with Licensing, amendments and renewals are the responsibility of the License Holder or the Syracuse University Department sponsoring the License.

The Bureau of Controlled Substances of New York State issues two classes of research licenses (Class 4 or Class 7). A typical application for NYSDOH Licensing is located in Attachment B.

4.1.1 Class 4 Researcher License

Research involving Controlled Substances in Schedule II - V (defined in Section 5), may only be conducted after obtaining a Class 4 research License. A University researcher can obtain a separate research license from the NYSDOH, as approved by their Department Chairperson, or be covered under a Departmental License.

4.1.2 Class 7 Research and Instructional License

Research involving Controlled Substances in Schedule I (defined in Section 5.0) may only be conducted after obtaining a Class 7 research License and filing with the NYSDOH three copies of a research protocol describing the research project. At no time, may any individual at Syracuse University possess any Schedule I substance without prior authorization of the Department Chair and EHSS review and approval of the license application.

4.2 DEA Registration Policy

No University personnel or affiliate shall manufacture, obtain, possess, administer or dispense a controlled substance for purpose of scientific research, instruction or chemical analysis without having first obtained a Certificate of Registration from the US Drug Enforcement Agency. All Certificates of Registration are issued for one year from the date of issue and must be renewed by the License Holder. All fees associated with Registration, amendments and renewals are the responsibility of the License Holder or the Syracuse University Department sponsoring the License.

A Certificate of Registration is required by the DEA to conduct research with controlled substances in drug Schedules II through Schedule V. The DEA will only issue Certificates of Registration after a NYSDOH License is obtained. A typical application for registration is available in Attachment C. A University researcher can obtain a separate Certificate of Registration from the DEA, as approved by their Department Chairperson, or be covered under a Departmental License. All fees associated with Registration, amendments and renewals are the responsibility of the Certificate of Registration Holder or the Syracuse University Department sponsoring the Registration.

A special Certificate of Registration from the DEA is required to conduct research using Schedule I substances. At no time, may any individual at Syracuse University possess any Schedule I substance without prior authorization of the Department Chair and EHSS review and approval of the Registration application.

5.0 DEFINITION OF DRUG CATEGORIES

Federal and State Regulations divide controlled Substances into several groups. The schedules are defined below. A list of controlled substances and their associated Schedule are listed in Attachment A of this Program

Schedule I

- The drug or substance has a high potential for abuse.
- The drug or substance has no currently accepted medical use in treatment in the United States.
- There is a lack of accepted safety for use of the drug or substance under medical supervision.
- This schedule has the most stringent requirements and controls.

Schedule II

- The drug, or other substance, has a high potential for abuse.
- The drug or substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.
- Abuse of the drug, or other substance may lead to severe psychological or physical dependence.

Schedule III

- The drug or other substance, has a potential for abuse less than the drugs or other substances listed in Schedule I and II.
- The drug, or other substance has a currently accepted medical use in treatment in the United States.
- Abuse of the drug or other substance may lead to moderate or low physical or high psychological dependence.

Schedule IV

- The drug or other substance, has a low potential for abuse relative to the drugs or other substances listed in Schedule III.
- The drug, or other substance has a currently accepted medical use in treatment in the United States.
- Abuse of the drug or other substance may lead to limited physical or psychological dependence.

Schedule V

- The drug or other substance, has a low potential for abuse relative to the drugs or other substances listed in Schedule IV.
- The drug, or other substance has a currently accepted medical use in treatment in the United States.
- Abuse of the drug or other substance may lead to limited physical or psychological dependence relative to the drugs or other substances, listed in Schedule IV.

6.0 RECORDS

Researchers authorized to possess and use Controlled Substances, shall keep a record of all Controlled Substances received and used by them. Researchers must keep separate records regarding controlled substances received, used, and disposed.

6.1 Receiving Records

A record of all controlled substances received shall include:

- Date of receipt
- Name, address, and registration number of the person from whom the containers were received
- Type (chemical or other name, and physical form) and quantity of drug received

A duplicate invoice or separate itemized list furnished by the vendor and or supplier will be sufficient to meet this record requirement providing it contains all the information required and is maintained in a separate file.

6.2 Records of Use

A record of all controlled substance use shall include:

- Name of the person(s) authorized to control and use such drugs
- Date of use
- Type and quantity of drug
- Signature of the user
- Name of substance and the Lot number assigned by the manufacturer
- Each finished form (such as 10 mg.tablet or 10 mg. concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container. A running total must be kept for each use.
- If controlled substances are compounded or aliquotted, each new container must be labeled and all uses tracked. Note: According to the Animal Welfare Act (AWA), researchers must use pharmaceutical grade medications whenever they are

commercially available. Non-pharmaceutical-grade chemical compounds may only be used in animals after specific review and approval by the IACUC.

- If dispensed to a human, the amount of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, and the written or typewritten name or initials of the individual who dispensed.

6.3 Disposal Records

EHSS will only remove Controlled Substances for which the following information has been provided:

- Name and address and phone number of Department License Holder
- NYS License number
- DEA Registration number
- Trade or generic name of each drug
- Strength as a percent of each drug (ie. 10% Phenobarbital)
- Quantity of each drug (ie. 5 tablets, 10ml each)
- Reason of the surrender
- Source of the drug(s)

Please see Section 9.0 for more details on disposal.

7.0 SECURITY

Controlled Substances shall at all times be properly safeguarded and securely kept at the address of the Licensed Department. Access to Controlled Substance stocks shall be limited to the minimum number of employees actually required to efficiently handle the custody, dispensing, or administration. The License Holder is responsible for the proper safeguarding and handling of controlled substances. The following security controls must be implemented.

- Physical security controls must be appropriate for the schedules and quantity of Controlled Substances on hand. At a minimum, a solid metal cabinet with separate outer and inner, key locked doors is required for Controlled Substances listed in Schedules III, IV and V. A safe is required for Schedule I and II drugs.

- A controlled drug access log must be utilized to record the identities of the staff members approved to access the locked drug storage areas.

- A documented, physical inventory of all Controlled Substances used, handled and stored must be performed biennially (every 2 years).

- Access to Controlled Substances must be restricted to the absolute minimum number of individuals needed and authorized to handle transactions in such items.

- Notification of any loss or theft of Controlled Substances must be made to EHSS immediately upon recognition.

8.0 TRAINING

Principal Investigators are responsible for development and implementation of training for authorized users in the following:

- The nature of Controlled Substance hazards including local and systemic toxicity.
- The specific research procedures that could result in exposure.
- Procedures for properly using, disposal, and securing Controlled Substances, proper use and maintenance of usage log, and incident procedures for lost and/or missing drugs and Inventory.
- The purpose and application of emergency practices and procedures.
- The employee's specific role in prescribed emergency procedures.
- Conditions and situations that could result in personal exposure.

9.0 DISPOSAL

Disposal must be performed in accordance with New York State Department of Health protocol. Controlled Substances may not be disposed of in the trash, Regulated Medical Waste containers or Satellite Accumulation Areas. Controlled Substance that are expired or no longer needed, must be removed by a NYS Approved Reverse Distributor.

EHSS will make the proper notifications and file and maintain the appropriate paperwork related to the disposal of Controlled Substances. Copies of this paper work will be furnished to approved individuals upon request.

At the time of collection, the Principal Investigator must provide Reverse Distributor with the following information:

- Name and address and phone number of Department License Holder
- NYS License number
- DEA Registration number
- Trade or generic name of each drug
- Strength as a percent of each drug

- Quantity of each drug
- Reason for the surrender
- Source of the drug(s)

Due to Federal and State regulation, EHSS may not take possession or transport controlled substances and removal for disposal may only take place at the point of waste generation. The License Holder bears all responsibility for the Controlled Substance until the ultimate destruction of the Controlled Substance has taken place.

ATTACHMENT A
Controlled Substance List

Located at
DEA Briefs & Background, Drug Policy, Drug Scheduling

ATTACHMENT B
NYSDOH License Application

Located at
https://www.health.ny.gov/professionals/narcotic/licensing_and_certification/

ATTACHMENT C
DEA Certificate of Registration Application

Located at
https://www.health.ny.gov/professionals/narcotic/licensing_and_certification/

ATTACHMENT D
Request for the Acquisition of a Controlled Substance

Request for the Acquisition of a Controlled Substance

Please complete, sign, date and submit this from to a Syracuse University Department, Institute or Center Controlled Substance License Holder for approval, prior to ordering or taking possession of a Controlled Substance. Please maintain copies of the approved form in each laboratory Controlled Substances are used.

YES	NO	
☐	☐	I have read and understand the requirements of the Syracuse University Controlled Substance Program.
☐	☐	I will maintain a current list of all laboratory personnel authorized to use Controlled Substances.
☐	☐	I will ensure that Controlled Substances are appropriately secured from all unauthorized access and locked unless in usage.
☐	☐	I will maintain appropriate inventory and use logs for Controlled Substances during possession and for a period of five years thereafter.
☐	☐	I will provide documented training that discusses the procedures for properly using, disposing, and securing Controlled Substances and proper use and maintenance of usage log.
☐	☐	I will refrain from disposing of Controlled Substances in the trash or drain and will contact EHSS for the disposal of Controlled Substances.
☐	☐	I will report verbally and in writing of theft or loss to EHSS and the appropriate License Holder immediately upon discovery.
☐	☐	I have obtained Institutional approval for each experiment that involves the use of a Controlled Substance with a human or animal. Approved protocols are maintained on file and are available upon request.

Certification

I acknowledge responsibility for all Controlled Substances used in my laboratory and I agree to comply with all Federal, and State regulations applicable to Controlled Substances. I certify that all answers to the above questions are accurate and reflect the practices occurring in my laboratory.

Request Submitted By:_____

(Name)

Request Submitted By:_____ Date:_____

(Signature)

Request Approved By:_____

(Name)

Request Approved By:_____ Date:_____

(Signature)