

DEPAUL UNIVERSITY

Controlled Substances Program

Environmental Health & Safety

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1. INTRODUCTION

1.1 PURPOSE

This program outlines the requirements and responsibilities for the possession and use of controlled substances for authorized research activities at DePaul University. Because select faculty use and/or maintain controlled substances for research activities, the University must comply with federal and state laws and regulations regarding their use, storage and disposal, including relevant U.S. Drug and Enforcement Administration (DEA) requirements at Title 21, Part 1300-1308 of the Code of Federal Regulations (C.F.R.). DePaul is also subject to the Illinois Controlled Substances Act [720 ILCS 570] and the Illinois Department of Professional Regulation (IDPR) requirements related to controlled substances.

The DEA has divided the controlled substances into five schedules (Schedules I-V) based on their usefulness in medicine as a drug and their relative abuse potential and likelihood of causing dependence when abused:

- **Schedule I** - Drugs or other substances that have a high potential for abuse; no currently accepted medical use in the United States and have a lack of accepted safety for use 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 have a currently accepted medical use with severe restrictions; abuse may lead to severe psychological or physical dependence.
- **Schedule III** - Drugs or other substances that have a potential for abuse less than Schedule I or II; currently have an accepted medical use in treatment in the United States; abuse may lead to moderate or low physical and high psychological dependence.
- **Schedule IV** - Drugs or other substances that have a low potential for abuse relative to those listed in Schedule III; currently have an accepted medical use in the United States; abuse may lead to limited physical or psychological dependence those in schedule III.
- **Schedule V** - Drugs or other substances that have a low potential for abuse relative to Schedule IV; currently have an accepted medical use in the United States; abuse may lead to limited physical or psychological dependence relative to those in Schedule IV.

A complete list of the schedules is published annually on an updated basis in the DEA regulations, 21 C.F.R. § 1308.11-1308.15. A link to the current version of the controlled substances schedules is provided in Appendix A.

1.2 SCOPE AND APPLICATION

Individuals who manufacture, distribute, dispense, import, export, conduct research, or perform chemical analysis with a controlled substance are subject to DEA and IDPR regulations. Possession and use of controlled substances at the University is restricted to authorized persons working under the direct supervision of a registrant in accordance with the registration and in compliance with all applicable Federal, State and University requirements. Failure to comply with this policy may be grounds for employee disciplinary action or research termination.

2. ROLES AND RESPONSIBILITIES

Authorized University employees, including Principal Investigators (PIs) or other supervisors of research where controlled substances are used, are responsible for complying with all applicable requirements regarding controlled substances. In order to ensure compliance, it is important that affected faculty, research staff, and students understand their responsibilities related to the acquisition, possession, use, storage, and transfer or disposal of controlled substances.

2.1 UNIVERSITY ADMINISTRATION

The University administration has overall responsibility for instituting policies and programs, establishing systems, and providing resources to help ensure that research activities involving controlled substances are in accordance with all applicable requirements, including DEA regulations. Certain responsibilities have been delegated to the registrant and the individual Departments, Principal Investigators (PIs), and other affected University employees as well as to the Environmental Health and Safety (EHS) Office, Human Resources, and the Public Safety Department.

2.2 REGISTRANT

1. Maintain the DEA registration and Illinois license for controlled substances.
2. Follow all applicable Federal, State and University requirements for authorization, acquisition, security, use, handling, storage, transfer or disposal, reporting and recordkeeping for controlled substances maintained by the laboratory.
3. Maintain a list of the individuals authorized to use or otherwise handle controlled substances, and restricts access only to those authorized individuals.
4. Provide training as necessary for those individuals granted authorization to use or access controlled substances on the requirements of this program and applicable regulations.
5. Work with University EHS and the DEA field office as necessary to ensure the proper disposal/destruction of controlled substances.
6. Maintain an accurate inventory of controlled substances maintained and participate in the biennial inventory process.
7. Notify the DEA field office upon discovery or report of theft or loss of controlled substances.
8. Perform investigation of reported or suspected thefts of controlled substances, working with the Public Safety Department, law enforcement, and other University parties as appropriate.
9. Complete and submit a DEA Form 106 if it is determined that theft or significant loss of a controlled substance has occurred.
10. Maintain records and other documentation required by this program.

2.3 AUTHORIZED INDIVIDUAL

1. Participate in training and authorization prior to handling controlled substances.
2. Comply with Federal, State, and University requirements for controlled substances.
3. Maintain strict control and inventory of controlled substances.
4. Complete all required forms and recordkeeping.

5. Immediately report missing controlled substances to the registrant/PI, the Public Safety Department, and the EHS Office.

2.4 ENVIRONMENTAL HEALTH AND SAFETY (EHS) OFFICE

1. Maintains the written program.
2. Provides guidance to campus units for registering with State and Federal agencies.
3. Provides guidance on storage and disposal of controlled substances.
4. Includes awareness information on the controlled substances management program as necessary during the annual training for science faculty and staff.
5. Coordinates the biennial inventory process.
6. Provides technical guidance and other assistance related to chemical hazards, laboratory safety and waste management, such as periodic laboratory inspections. Works with the registrant(s) as necessary to correct any identified deficiencies related to controlled substances management.
7. Works with the registrant to ensure information on missing or suspected thefts of controlled substances is reported to the Department chair and the Dean.

2.5 HUMAN RESOURCES

1. Conducts inquiries for background screening as part of the authorization process for faculty, staff and students that handle or otherwise have access to controlled substances.
2. Notifies the registrant and the EHS Office of individuals cleared for authorization.

2.6 PUBLIC SAFETY

1. Responds to reported thefts or missing controlled substances and coordinates with the registrant, the EHS Office and local law enforcement as applicable in the investigation.

3. REGISTRATION

Registration with the U.S. DEA and with the State of Illinois is required to possess and use controlled substances for University research activities (see Section 4 for University authorization requirements). There are different registrations under the DEA and the State based on the type(s) of activities involving controlled substances. Only those schedules of controlled substances identified on the registration may be used for the designated purposes listed. The Certificate of Registration must be maintained at the registered location and readily available at all times.

Prior to applying for a new controlled substances registration, the faculty member must notify the EHS Office and ensure that any other applicable project approvals are obtained from the appropriate University committee (e.g., IACUC).

3.1 APPLICATION FOR REGISTRATION

Applicants in the State of Illinois must register with the Illinois Department of Professional Regulation (IDPR). The State Controlled Substances Registration Application for Permanent License Applicants/holders can be obtained on-line and paid for with a credit card. The IDPR 097 (other controlled substances licensees) registration form should be completed and submitted for conducting research on controlled substances schedules I-V, or use of controlled substances schedules I-V as part of instructional activities at universities or colleges. The form can be obtained on-line at: <http://www.idfpr.com/>

The Illinois State Controlled Substances License must be obtained first to apply for a Federal DEA number. [Note: New faculty who already hold a Federal DEA number and a permanent license from another state must apply for an Illinois Controlled Substance License in order to use their current Federal DEA number in Illinois.]

The application for the U.S. DEA registration can be obtained and submitted on-line at: <http://www.deadiversion.usdoj.gov/drugreg> [Note: paper copies and mail submission is also available]. The types of registration under the DEA include:

- Research - For conducting research on narcotic and non-narcotic controlled substances in Schedules II-IV. The DEA form # 225 is submitted for this type of registration, and Form #225A is used to renew this registration.
- Laboratory Chemical Analysis - DEA form # 225 provides authorization to conduct analysis with controlled substances listed in any schedule. Form #225A is used to renew this registration.
- Dispenser of Controlled Substances- For Clinical Research - DEA form # 224 is used by private practitioners (physicians, dentists, veterinarians, nurse practitioners, hospitals, and pharmacies) for clinical and hospital use. Form #224A is used to renew this registration.
- Instructional Activity - DEA form # 224 is used to obtain a new instructional registration for instructional activity only, and covers schedule II-V Controlled Substances. Form #224A is used to renew this registration.

Appendix A of this program includes links to IDPR and DEA forms and other resources.

3.2 REGISTRATION/LICENSE RENEWAL

The registrant is responsible for maintaining a current DEA registration and Illinois license and renewing them as necessary (i.e., typically every 3 years for DEA and annually for the State).

3.3 TERMINATION OF REGISTRATION/LICENSE

To terminate a registration/license, the registrant must notify the IDPR and the nearest DEA office in writing. The registrant should also notify the EHS Office of any registration/license terminations so that the list of University registrants and authorized individuals can be updated accordingly.

4. AUTHORIZATION REQUIREMENTS

Only authorized persons are permitted to utilize or otherwise handle or have access to controlled substances for University research activities. If granted in the registration for substances in Schedules II-V, the registrant may authorize additional personnel (i.e., within same research department and registered physical location) to use the substances for approved activities. The University authorization process requires: employee screening, training, and continued good standing with respect to addressing any compliance deficiencies or other action items identified by the University as part of the controlled substances program.

In addition to the authorization for controlled substances, PIs with animal research protocols utilizing controlled substances must maintain approval by the Institutional Animal Care and Use Committee (IACUC), and research protocols involving recombinant DNA or other covered biological hazards must be approved by the Institutional Biosafety Committee (IBC), in accordance with applicable University requirements.

4.1 EMPLOYEE SCREENING

Employee screening is a critical component in preventing diversion of controlled substances. The DEA recommends that registrants should not employ as an agent or employee who has access to controlled substances:

1. Any person who has been convicted of a felony offense related to controlled substances;
2. Any person who has been denied a DEA registration;
3. Any person who has had a DEA registration revoked; or
4. Any person who has surrendered a DEA registration for cause.

Therefore, DePaul has adopted an employee screening program as part of its authorization process for those individuals who wish to use controlled substances for approved activities under the direction of the registrant. All employees (e.g., technicians, graduate research employees, other staff, etc.) intending to handle or otherwise have access to a controlled substance as part of campus research activities are required to complete a questionnaire and undergo background screening prior to University authorization. Instructions for completed the screening program are included as Appendix B; additional details are provided in the following sections.

4.1.1 Questionnaire

Each individual seeking authorization must complete the Applicant Questionnaire (Appendix C) and submit it to Human Resources.

As outlined at 21 C.F.R. 1301.9, it is the position of the DEA that obtaining certain information is vital to fairly assess the likelihood of an employee committing a drug security breach. The DEA indicates that conviction of crimes and unauthorized use of controlled substances are activities that are proper subjects for inquiry, and assumes that the following questions will become a part of an employer's comprehensive employee screening program:

1. Have you been convicted of a felony within the past five years, any misdemeanor within the past two years, or, are you presently charged with committing a criminal offense?
2. In the past 3 years, have you knowingly used narcotics, amphetamines, or barbiturates other than those prescribed to you by a physician?

These questions have been incorporated into the DePaul screening and authorization process for controlled substances (Appendices B, C, and D). No individual who has been convicted of a felony for any State or Federal law regarding controlled substances will be allowed access to controlled substances.

4.1.2 Inquiries

As part of the screening process, each employee seeking authorization to use or otherwise access controlled substances must complete and submit a waiver to provide consent for Human Resources to initiate a criminal background check and an inquiry with the DEA (refer to Appendix B). The DEA recommends that inquiries concerning employees' criminal records be made as follows:

- **Local inquiries** - Inquiries should be made by name, date and place of birth, and other identifying information, to local courts and law enforcement agencies for records of pending charges and convictions. Local practice may require such inquiries to be made in person, rather than by mail, and a copy of an authorization from the employee may be required by certain law enforcement agencies.
- **DEA inquiries** - Inquiries supplying identifying information should also be furnished to DEA Field Division Offices along with written consent from the concerned individual for a check of DEA files for records of convictions. The Regional check will result in a national check being made by the Field Division Office.

Upon completion of the inquiries, Human Resources will notify the registrant and the EHS Office of those employees who are eligible for authorization. The Eligibility Determination Form (Appendix D) will be completed by Human Resources, signed by EHS and the registrant as applicable, and the form maintained at the registrant's location as identified on the registration/license.

4.2 TRAINING

To help ensure that all faculty and other employees with access to controlled substances understand the relevant requirements for acquisition, storage, use, handling, and disposal, DePaul requires that all authorized persons (registrant, authorized individuals) receive the information and training as appropriate based on their role in the controlled substances program. Participation in training is required in order to obtain and maintain University authorization to use or maintain controlled substances.

Authorized individuals working under the direction of a registrant must receive information and training on the requirements applicable to their job. This training will be coordinated by the registrant. All training records should be forwarded to the EHS Office to allow for entry and tracking with the electronic system.

During the annual training for science faculty and staff, the EHS Office will also provide awareness information on the controlled substances program (during each annual session or periodically as appropriate based on the needs of the program).

4.3 AUTHORIZATION STATUS

A list of authorized persons must be maintained by each registrant. A centralized list of each registrant and all authorized persons under the direction of each registrant will be maintained by the EHS Office.

An authorized person must be in good standing as far as required training and compliance in order to maintain authorization status. In the event of repeated violations and failure to cooperate in addressing compliance deficiencies, an employee may lose University authorization status.

5. PROCUREMENT AND RECEIPT

5.1 PURCHASE OF CONTROLLED SUBSTANCES

Controlled substances must be purchased under a DEA registration number. Schedules III through V can be purchased via purchase order or other standard procurement channels.

The purchase of Schedule II controlled substances requires the submission of DEA Form 222 – U.S. Official Order forms. All requests for official order forms (DEA Form 222) can be made by registrants who are registered in Schedule II. Once the online form is submitted, the requestor will receive the maximum number of order form books allowed for his/her business activity. The top and middle portion of the official order form will be forwarded to the supplier and the remaining portion will be kept by the registrant with other controlled substance records. Once the shipment is received, the order form will be annotated to show the date and amount received. [Note: Records of Schedule II controlled substances must be kept separate from other controlled substances.]

If necessary, the registrant can give power of attorney to another authorized DePaul employee who would be able to act in his/her absence to procure controlled substances. The power of attorney must be retained in the files, with executed DEA Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records.

5.2 RECEIPT OF CONTROLLED SUBSTANCES

The controlled substance is shipped to the registrant and address as indicated on the DEA registration. Once received, the controlled substances must be picked up by the registrant or a designated authorized individual and should be opened to verify the contents so any discrepancies can be rectified with the supplier. If discrepancies cannot be readily addressed, the local DEA field office should be contacted for assistance.

Receipt of controlled substances must be documented, with a record of the chain of custody including each point where the substance changes hands or is used. A usage log (Appendix E) is then maintained by the registrant or authorized individual until the controlled substance is consumed or properly disposed of.

6. USE, STORAGE AND SECURITY REQUIREMENTS

6.1 LABELING

Containers of controlled substances must be labeled with the designated symbol for the schedule category it belongs. Controlled substances must not be transferred from their original containers for inventory purposes. Identifying labels must not be removed from the original containers. If the substance is converted or diluted, the new container must be labeled properly.

The designated symbols for each schedule of controlled substance are as follows:

- Schedule II - CII or C-II
- Schedule III - CIII or C-III
- Schedule IV - CIV or C-IV
- Schedule V - CV or C-V

6.2 STORAGE

The registrant(s) and each authorized individual are required to maintain security for the storage and distribution of controlled substances.

Controlled substances (schedules II-V) must be stored in a securely locked cabinet of substantial construction, located in areas with limited access. Refer to the following section for additional details on security.

6.3 SECURITY

Each registrant is responsible for ensuring that effective controls and procedures are provided to guard against theft and diversion of controlled substances (see 21 C.F.R. 1301.71(a)), including the following requirements and guidance:

- Access to controlled substances must be limited to individuals who have current approval as an authorized person (registrant or other authorized individual).
- Stocks of Schedule II through V controlled substances must be stored in a securely locked, substantially constructed cabinet.
 - Such a cabinet is interpreted as, at minimum, a structure of wood or metal so constructed as to resist easy entry by simple tools of attack, with internally-mounted hinges, and secured by a deadbolt lock. The cabinet should be permanently constructed or attached to a building structure to prevent physical removal.
 - If a safe is used in lieu of a securely locked, substantially constructed cabinet, the safe is to either be secured so as to prevent removal or be at least 750 lbs.
- Controlled substances must never be left unattended.
- Inventories should be kept to a minimum.
- Key locks or combinations should be changed whenever personnel changes.
- Other appropriate security measures must be implemented where necessary to effectively guard against theft or diversion.

The adequacy of security controls is determined based on consideration of a number of factors including the:

1. Location of the premises and the relationship such location bears on security needs;
2. Type of building and office construction;
3. Type and quantity of controlled substances stored on the premises;
4. Type of storage medium (i.e., safe, vault, steel cabinet);
5. Control of public access to the facility;
6. Adequacy of registrant's key control and monitoring system (i.e., alarms and detection systems);
7. Extent of supervision over employees with access, and procedures for handling visitors; and
8. Availability of local police protection.

6.4 INVENTORY

Registrants must maintain complete and accurate inventory records for all controlled substances. These records must be in or near the primary work area, separate from all other records and documents, and available for inspection during regular work hours. A Usage Log form is provided in Appendix E.

In addition to maintaining a current record of controlled substances on hand, each registrant must conduct a new inventory of all controlled substances at least every two years, as described in Section 8.1 of this program.

6.5 BREAKAGE OR SPILLAGE

Breakage of controlled substances is not considered by the DEA to constitute a "loss" of controlled substances. When there is breakage, damage, spillage, or some other form of destruction, any recoverable controlled substances must be disposed of according to DEA requirements. Damaged goods may be disposed of through shipment to a reverse distributor or by a DEA approved process (see Section 7).

If the breakage or spillage is not recoverable, the registrant must document the circumstances of the breakage in the inventory records. Two individuals who witnessed the breakage must sign the inventory records indicating what they witnessed. The submission of a DEA Form 41 is not required for non-recoverable controlled substances.

6.6 REPORTS OF THEFT OR LOSS

The DEA requires a registrant to notify the DEA field office in their area of any theft or significant loss of controlled substances upon its discovery.

At DePaul, any unaccountable loss of a controlled substance or suspicious theft of a controlled substance is to be reported immediately to the registrant, the Public Safety Department and the EHS Office.

The registrant will then:

1. Notify the DEA upon discovery of any thefts or significant losses of controlled substances. Notify the State Administrator within 10 days of the discovery of the theft or loss.
2. Work with Public Safety, other University representatives, and law enforcement as appropriate to investigate each theft or significant loss of controlled substances.

3. Complete a DEA Form 106 online at <https://www.deadiversion.usdoj.gov/webforms/dtlLogin.jsp>, where it is determined that such theft or loss occurred and where the circumstances surrounding the loss are clear (e.g., quantities involved, etc.).

[Note: Only those persons registered with and authorized by DEA to handle controlled substances may utilize and submit DEA Form 106. DEA Form 106 must be filled in online at the DEA Diversion Control Program website (Appendix A).]

Additional guidance for theft or loss includes:

- When details concerning the specific circumstances surrounding the theft or loss are unknown at the time of discovery, the DEA recommends providing initial notice by faxing a short statement to the DEA field office advising of the theft or significant loss.
- If DePaul determines that such loss occurred (e.g., by conducting inventories, internal audits, and/or investigations using internal or law enforcement resources, as appropriate), then the DEA Form 106 should be submitted once the circumstances surrounding the theft or significant loss are clear. The DEA Form 106 must document the circumstances of the theft or significant loss and the quantities of controlled substances involved.
- If an investigation takes more than two months to complete, the DEA recommends that the registrant provide updates regarding the investigation.
- If, after an investigation of the circumstances surrounding the disappearance of the material, it is determined that no theft or significant loss occurred, no DEA Form 106 need be filed. However, the DEA recommends that the registrant advise the DEA that a DEA Form 106 is not needed or will not be filed regarding the incident.
- DEA Form 106 is not intended for minor inventory discrepancies.

6.7 ABANDONED CONTROLLED SUBSTANCES

Under no circumstances are controlled substances to be abandoned by a registrant. [Note: Abandoning substances is equivalent to distributing a controlled substance to an unauthorized person. Any person who is registered with the DEA who violates recordkeeping requirements or abandons controlled substances may be subject to the civil penalties outlined at 21 USC Sec. 842.]

In the event that faculty leave without appropriately disposing or transferring all controlled substances from their laboratory, the department is responsible for the laboratory and will need to contact the EHS Office to arrange for the appropriate disposal. If the faculty was a DEA registrant and it can be determined that the controlled substance(s) were acquired through their registration, the department will need to complete a DEA Form 41 with a cover letter providing all the information required for disposal (see Section 7), in addition to explaining the circumstances as to why the registrant did not complete the Form 41. The department should contact the EHS Office to arrange for disposal. If the substance is also regulated by IEPA, it will be disposed in accordance with applicable IEPA requirements.

7. DISPOSAL PROCEDURES

All controlled substances must be accounted for upon their disposal. To dispose of expired, damaged, or unnecessary controlled substances, the registrant will contact the EHS Office and DEA field office as necessary for assistance in determining the proper disposal of controlled substances in accordance with applicable Federal and State requirements. The registrant will maintain a copy of disposal records for controlled substances for three years after disposal.

The DEA recommends that any registrant seeking to dispose of controlled substances first contact the nearest DEA field office for disposal instructions. The registrant will contact the DEA field office to determine the final disposition of the controlled substance(s), either through a reverse distributor, or in certain cases where approved, by special destruction.

7.1 REVERSE DISTRIBUTOR

Out-of-date, damaged, or otherwise unusable or unwanted controlled substances, including samples, may be transferred to a registrant who is authorized to receive such materials (reverse distributor). DEA Form 222 must be used to transfer Schedule II controlled substances. Schedule III–V compounds may be transferred via invoice. The transfer of Schedules III–V controlled substances must be documented in writing to show the drug name, dosage form, strength, quantity and date transferred, as well as the names, addresses and DEA registration numbers of the parties involved in the transfer of the controlled substances. Records documenting any transfer of controlled substances will be maintained for a period of at least two years.

7.2 SPECIAL DESTRUCTION

For minute quantities or non-Schedule II or III drugs, DePaul may request special destruction of the materials (i.e., incinerate or otherwise destroy). To request special destruction, the registrant will contact the DEA field office and draft a letter that includes:

1. Name, address of the facility wishing to dispose of the controlled substance
2. Name, address and DEA registration number
3. DEA Form 41 - Registrants Inventory of Drugs Surrendered, listing:
 - a. Inventory of drugs to be destroyed;
 - b. Name of drug with strength;
 - c. Quantity of drug;
 - d. Technical name of controlled substance; and
 - e. Signature of DEA notification.

The registrant will submit 3 copies of DEA Form 41 to the DEA. The Special Agent in Charge will authorize and instruct the registrant on the manner to dispose of the controlled substance. Upon receipt of the DEA Form 41 back from the DEA, the registrant or their authorized personnel will be allowed to dispose of the drugs. The disposal must be witnessed by two people, Jenny Graham from the EHS Office, and another faculty or department member.

The date of disposal and the witnesses for destruction (disposal) must be clearly stated on the DEA Form 41. A copy of the completed DEA Form 41 must be returned to the DEA. A copy of DEA Form 41 is available online through the link provided in Appendix A.

8. INVENTORY AND RECORDKEEPING

8.1 BIENNIAL INVENTORY

Each registrant is responsible for participating in the biennial inventory process. The inventory will be coordinated with EHS acting as the inspector. Inventories should be documented using the DePaul Controlled Substance Biennial Inventory Form (Appendix F). Each inventory must contain the following information:

- Date and time of day inventory was conducted;
- Names of controlled substances on hand;
- Quantity of each controlled substance on hand;
 - For commercially bought controlled substances, this must include the: a) finished form (e.g., 10-milligram concentration per milliliter); b) number of dosage units or volume of each commercial container; and c) number of commercial containers of each substance form.
- Signatures of inspector and registrant.

8.2 RECORDKEEPING

The Controlled Substances Act requires complete and accurate records to be kept of all quantities of controlled substances stored, used, and disposed of. Registrants will maintain inventories and records of controlled substances listed in Schedule II separately from all other records. Inventories and records of controlled substances in Schedules III, IV, and V will be maintained separately or in such a form that they are readily retrievable from the ordinary records.

All records related to controlled substances will be maintained for a minimum of three years and must be readily available for inspection by the DEA, IDPR, or the EHS Office or other University auditors.

Each registrant and authorized individual must document all usage and disposal quantities by utilizing the Controlled Substance Usage Log (Appendix E). Log sheets shall be numbered and may be kept in the locked safe or cabinet along with the controlled substances.

The following program records will also be maintained by each registrant at the registered location:

- Controlled substances authorization records (Appendix D).
- Training records (e.g., laboratory- or department-specific).
- Records of receipt of controlled substances such as executed order forms or DEA Forms 222 that indicate the date received, name and address of supplier, the type, strength or concentration, and amount of the controlled substances received. Each record must be signed by the person receiving the controlled substance.
- Inventory records.
- Disposition and disposal records.
- Other DEA forms (e.g., reports of theft or loss, disposal, etc.).

If DePaul wishes to maintain records at a central location other than the registered location, the registrant must send a notification to the DEA as outlined at 21 C.F.R. 1304.04.

APPENDIX A: DEA and IDPR Forms and DEA FORMS

<http://www.deadiversion.usdoj.gov>

Paper form may be obtained by writing to:

Drug Enforcement Administration

Attn: ODR

PO Box 2639

Springfield, VA 22152-2639

APPENDIX B: Employee Screening Program Process Flow

Applicable DePaul Policies:

- Criminal Background Checks

Applicable Regulations:

- 21 CFR 1301.90 (Employee Screening Procedures)
- 21 CFR 1301.93 (Sources of Information for Employee Checks)

In order to comply with regulations and rules for possession and use of controlled substances in laboratory research, DePaul University requires that all faculty, staff, and students who will be authorized to use or otherwise access controlled substances as part of university research activities undergo the following screening program. This Screening Program is intended to prevent theft or diversion of controlled substances and comply with applicable state and Drug Enforcement Agency (DEA) requirements.

Individuals who do not wish to participate in this Screening Program are not eligible to be a part of University research activities in which they will be authorized to use or otherwise access controlled substances.

Related Documents

- (1) Applicant Questionnaire (Appendix C of Controlled Substances Program)
- (2) Background Check Release Form (maintained by HR as part of the Criminal Background Check Policy)
- (3) DEA Cover Letter (Attachment 1 to Appendix B of Controlled Substances Program)
- (4) Eligibility Determination Form (Appendix D of Controlled Substances Program)

Screening Program Process Flow

Step	Responsible Party	Details
Step 1	Registrant	Registrant gives applicant (1) "Applicant Questionnaire" and (2) "Release Form" (available at: http://policies.depaul.edu/policy/policy.aspx?pid=225).
Step 2	Applicant	Applicant completes "Applicant Questionnaire" and "Release Form" and returns both to HR Staffing via email.
Step 3	HR Staffing	HR Staffing (1) initiates regular new employee background check process.
Step 4	HR Staffing	HR Staffing completes DEA Cover Letter and sends (1) DEA Cover Letter; (2) Applicant Questionnaire; and, (3) Release Form to the DEA at the address listed below. <div style="text-align: center;"> US Drug Enforcement Agency Chicago Field Division Office Attention: Diversion Control Kluczynski Federal Building 230 South Dearborn Street, Suite 1200 Chicago, IL 60604 </div> <p><i>If questions or problems, DEA contact information is:</i> Phone: (312) 353-7875 Fax: (312) 353-1235</p>

Step	Responsible Party	Details
Step 5	HR Staffing	<p>Once criminal background check and DEA inquiry are complete, HR Staffing completes and signs the "Initial Determination" section of the "Eligibility Determination Form."</p> <p>An applicant is eligible to participate in the research project if:</p> <ul style="list-style-type: none"> • The applicant answered "No" to both questions on the "Applicant Questionnaire" AND • The applicant's criminal background check did not reveal any felony offenses related to controlled substances AND • The DEA has not flagged the applicant <p>(If applicant is eligible to participate, skip to STEP 8.)</p> <p>Further conversation is required if:</p> <ul style="list-style-type: none"> • The applicant answered "Yes" to either question on the "Applicant Questionnaire" OR • The applicant's criminal background check revealed any felony offenses related to controlled substances OR • The DEA has flagged the applicant <p><i>Note: If the criminal background check reveals information that does not have implications for the individual's participation in a research project involving controlled substances, but may have other implications regarding the individual's employment, the procedure contained in the "Criminal Background Check" policy will be followed.</i></p>
Step 6	HR Staffing	If further conversation is required, HR Staffing will provide all applicable information to Environmental Health & Safety (EHS).
Step 7	Registrant EHS	EHS will facilitate a conversation with the Registrant to make a final determination as to whether the applicant is or is not authorized to participate. Once a final determination has been made, EHS and Registrant will complete and sign the "Final Determination" section of the "Eligibility Determination Form" and return to HR Staffing.
Step 8	HR Staffing	HR Staffing scans Eligibility Determination Form and emails to Registrant and EHS.
Step 9	HR Staffing Registrant EHS	Record Keeping: HR Staffing will keep all documents from the Screening Program in the employee's personnel file as required by DePaul policy. The Registrant and EHS will keep a copy of the Final Determination Form as required by registration.

APPENDIX C: Applicant Questionnaire

Please complete the questions and sign below. Please return (1) this form and (2) the Criminal Background Check Release Form (available at <http://policies.depaul.edu/policy/policy.aspx?pid=225>) to HR Staffing via email.

Name:	Date:
Department:	Registrant/PI:
Laboratory location:	

1. Within the past five (5) years, have you been convicted of a felony, or within the past two (2) years, of any misdemeanor, or are you presently formally charged with committing a criminal offence? (Do not include traffic violations, juvenile offences or military convictions, except by general court-martial.)

Yes No

If yes, please provide additional details (e.g., nature of conviction, offense location, date, sentence).

2. In the past three (3) years, have you ever knowingly used any narcotics, amphetamines, or barbiturates, other than those prescribed to you by a physician?

Yes No

If yes, please provide details.

By signing below, I certify that the above answers are true. I understand that providing false information or omitting information may jeopardize my ability to work on the above mentioned research project. I understand that any information I provide will not necessarily preclude my ability to work on the above mentioned research project, but will be considered as part of the overall decision as to whether I may participate.

Signature

APPENDIX D: Eligibility Determination Form

Name:	Date:
Department:	Registrant/PI:
Laboratory location:	

To be completed by HR Staffing:

Initial Determination

- Applicant is eligible to participate in the research project detailed above.
- Further conversation is required regarding whether applicant is eligible to participate in the research project detailed above.**

***If further conversation is required, HR Staffing will contact the Registrant and Environmental, Health & Safety (EHS) and provide them with the applicable information so that the Registrant and EHS may have further conversations as necessary.*

Signature (HR Staffing)

To be completed by Environmental, Health & Safety and Registrant (if applicable):

Final Determination *(if applicable)*

- Applicant is eligible to participate in the research project detailed above.
- Applicant is not eligible to participate in the research project detailed above.

Signature (Environmental Health & Safety)

Signature (Registrant)

APPENDIX E: Eligibility Determination Form

Principal Investigator:		DEA #:		Department/ Location:	
Controlled substance name (list schedule):		Date Received:		Expiration Date:	
Manufacturer/ Supplier:		Lot/ID #:		Finished Form:	
Units per container:		Number of containers:		Total Units:	

Note: If acquired from or distributed to another DEA registrant, list below or attach documentation indicating the registrant name, address, DEA #, date and the number of units acquired or distributed.

Date	ID #(optional)	Person Administering	Previous Balance	Amount Administered	New Balance

*To dispose of expired, damaged, or unnecessary controlled substances, contact the Environmental Health & Safety Office. Final disposition of controlled substances must be in accordance with applicable Federal and State requirements.

