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1.0 EXECUTIVE SUMMARY

A number of substances regulated by the United States Drug Enforcement Administration (DEA) and other agencies are used for research and instructional purposes at Florida International University (FIU). These substances are known as "controlled substances," and their possession and use are governed by regulations that require established procedures to ensure safety and prevent abuse. This Controlled Substance Safety Manual describes responsibilities and procedures for research and instructional activities by those individuals who are authorized to work with controlled substances under the auspices of FIU.

The key elements of FIU’s Controlled Substance Program consistent with the DEA regulations are:

- Proper DEA registration and permitting procedures
- An internal registration and approval process
- Administrative and operational controls on the ordering, receipt, disposition, storage and disposal of these substances
- Provisions for inventory control, audits and inspections
- Provisions for record keeping responsibilities

The major responsibilities assigned to individuals and various departments are described in section 4. It is important to note that:

- The regulations and procedures described in this manual relate to use of controlled substances (CS) in research and instructional activities and may not be applicable to patient care applications.
- Research or instructional use of CS at FIU may only be done under the Environmental Health & Safety (EH&S) authorization and Drug Enforcement Administration (DEA) Registration Certificate. Personal Registration Certificates, though available through DEA, may not be used to order, receive, use, or dispose of controlled materials at FIU.
- FIU personnel who participate in illicit activities in the use of CS are subject to federal and state prosecution, as well as university action such as suspension or termination of employment.
- This Controlled Substance Safety Manual details procedures for ordering, receiving, storage, security, use, disposal and record keeping of controlled substances, which shall be adhered to by all individuals and concerned departments.
- The registrants (primary/alternate CS officers) are responsible for maintaining inventory of order, receipt, use, storage, loss and disposal of CS and for compliance with federal, state regulations pertaining to their use of CS.
• Background questionnaire and check help ensure that individuals who have access to CS are law-abiding and reliable. They also provide a method for satisfying state and federal entities that FIU has an effective screening process.
• The CS should be used at the specified location. For transferring to another location or to a different institution you will need prior approval from DEA, EH&S and the institution.
• Questions concerning CS may be directed to the Controlled Substance Safety Officer at the FIU EH&S office extension 70489/72621.
2.0  Overview and Purpose

Federal and state regulations require procedures that ensure safe and authorized use of CS at any place of business, research or manufacturing. This Controlled Substance Safety Manual sets forth the FIU’s guidelines to ensure that the university’s research and instructional activities involving the receipt, use, manufacture, disposition and disposal of CS are carried out in accordance with these federal and state regulations.
3.0 DEFINITIONS AND ACRONYMS

1. Definitions

Alternate Controlled Substance Officer – An individual responsible to perform duties of the Primary Controlled Substances Officer in his/her absence (see Primary Controlled Substance Officer).

Background Check – Checking of criminal conviction records of an individual in any jurisdiction from state and federal records. Each registrant completes Security Screening Form (Appendix 2) and submits to the local law enforcement to authorize them to conduct background check.

Controlled Substances (CS) - Controlled substances and certain other chemicals, both narcotic and non-narcotic substance, which come under the jurisdiction of federal and state laws regulating their manufacture, sale, distribution, use and disposal.

Controlled Substance Code Number - A number assigned to CS by the DEA for the purpose of administration and regulation of the materials.

Control Substance Committee (CSC) - A Standing Committee at Florida International University that oversees all aspects of use and management of CS for research and instructional purposes within the University. The CSC provides guidance and oversight in order to ensure that the possession, use and disposition of CS by University personnel comply with pertinent federal and state laws and regulations and with the specific conditions of permits issued by the Drug Enforcement Administration (DEA) to authorized personnel.

Control Substance Safety Officer (CSSO) – A staff member of the Office of Risk Management & Environmental Health & Safety, knowledgeable with Drug Enforcement Agency’s regulations, who is responsible for the day-to-day oversight of the activities involving CS at the University and who is authorized by the University to take necessary action in the event that the CS guidelines of the University, federal or state laws and regulations are not being followed.

Controlled Substance Tracking Number - A number, assigned by EH&S, to each separate purchase of controlled substances by a researcher or instructor. This number is used to identify the CS for record keeping and inventory purposes. This number is a combination of the CS code number, purchase requisition number and the bottle number, if more than one bottle is purchased at a time. The numbers are separated by a hyphen (-). Example: 2270-XXXXX XX- 1, 2270-XXXXX XX- 2, for a pentobarbital (code 2270), purchase requisition number XXXXXX and bottle 1 and 2, respectively.

Form 41 – Form details inventory of controlled substances surrendered to the DEA for destruction/disposition of outdated CS.

Form 106 – Form for reporting lost or stolen CS to the DEA.

Form 222 - A form issued by the DEA that must be filled out in order to purchase or transfer Schedule I and II CS. The dispenser or vendor sends a copy of the form to the DEA.
Form 223 – This form is a Controlled Substance Registration Certificate issued by the DEA in the name of registrants. A copy of this certificate must be submitted to the suppliers (or must be in their file) along with purchase order requisition for CS of all schedules.

Form 224 - An application form issued by the DEA, which must be completed and submitted to DEA by all new applicants for registration as a teaching instructor or other purposes (retail pharmacy, hospital/clinic, practitioner or mid-level practitioner) identified on the form for schedule II to V CS.

Form 224a - An application form issued by the DEA, which must be completed and submitted to DEA by applicants to renew their DEA registration as a teaching instructor or for other purposes identified on the form for schedule II to V CS.

Form 225 – An application form issued by the DEA, which must be completed and submitted to DEA by all new applicants for registration as a researcher or for other purposes (manufacturer, distributor, analytical lab, importer or exporter) identified on the form for schedule I to V CS.

Form 225a – An application form, issued by the DEA, which must be completed and submitted to DEA by applicants to renew their DEA registration as a researcher and teaching instructor or for other purposes identified on the form for schedule I to V CS.

Primary Controlled Substance Officer – An individual designated responsible for receipt, storage, dispensing and recordkeeping of CS in the department when the registration for the CS is in the name of a department.

Registrant – Any person who is registered pursuant to either section 303 or section 1008 of the Act (21 U.S.C. 823 or 958).

Registration Certificate – A document issued in individual users' names (or in a department’s name for departmental registration) by the DEA, permitting manufacture, research, medical and other uses and handling of CS (Form 223).

Schedule - Any of five groups or classes of CS, divided as such by their relative potential for abuse, status of accepted medical use and the degree of physical or psychological dependence that may be caused by abuse of the material.

Screening – Screening for registrant requires completion of Questionnaire Form (Appendix 1), Security Screening Information Form (Appendix 2) and Controlled Substance Request for Authorization Form (Appendix 3). Screening for other authorized personnel requires completion of Questionnaire form.

Special Agents In Charge – Person from DEA responsible to enforce federal laws on the proper use and disposition of CS and drugs, conduct enforcement hearings, take custody of, and make disposition of seized substances.

2. Acronyms

CS – Controlled Substances

CSC – Controlled Substance Committee
3.0 Definitions and Acronyms

CSSO - Controlled Substance Safety Officer

CSDR - Controlled Substance Disposition Recordkeeping

DEA - The United States Drug Enforcement Administration which is the arm of the United States Department of Justice with oversight and responsibility for the enforcement of the CS laws and regulations of the United States

DHR - The Division of Human Resources of Florida International University

EH&S - Environmental Health & Safety Department of Florida International University
4.0 RESPONSIBILITIES, AUTHORITY AND REGULATORY COMPLIANCE

The FIU's program for regulation and administration of CS distinguishes between patient-care applications (e.g., Student Health Services or University Pharmacy and use by faculty and staff involved in research or instructional activities. The use of CS in patient-care applications is not within the scope of this control program. Pharmacists and physicians supporting Employee or Student Health Services will operate under their own DEA Registration Numbers and will maintain their own records of purchase, disposal and other regulated practices at Florida International University.

1. The Controlled Substance Committee (CSC) provides guidance and oversight over all aspects of use and management of CS for research and instructional purposes within the University. The CSC develops University policies and procedures and guidelines to ensure that all possession, use and disposition of CS by the University personnel at Florida International University comply with pertinent federal and state regulations and with the specific conditions of permits (registrations) issued to the University researchers.

These regulations include the following:

1) Code of Federal Regulations: Title 21, Chapter II (Parts 1300 to end) - These regulations implement the Controlled Substances Act of 1970, the Diversion Control Amendments of 1984, 1985, 1986 and subsequent amendments.
2) Florida State and local law enforcement agencies for law enforcement and regulatory purposes.

All records regarding the use of CS are subject to review by representatives of the University (EH&S and Public Safety), and investigators from the U.S. Drug Enforcement Agency (DEA).

2. The FIU EH&S is responsible for:

- Coordinating the University's DEA Controlled Substance Program.
- Developing, revising and distributing compliance procedures
- Coordinating communication between the University and the DEA.
- Coordinating receipt and renewal of DEA Controlled Substance Registration Certificates.
- Issuing purchase and use approvals.
4.0 RESPONSIBILITIES

- Auditing the records and procedures of individuals and departments who have possession of CS under DEA Registration Certificates Issued to University’s researchers and/or departments.

- Providing a list of the current authorized users of controlled substances to DHR enabling DHR to implement exit procedures for users of CS before they leave FIU.

3. Department chairs ensure that Controlled Substance Officers (primary and alternate), principal investigators, faculty members and any other individual employed by the department who will have access to CS are familiar with the provisions of this Manual which is written to ensure that the possession, use and disposal of CS is done in accordance with federal and state laws.

4. Controlled Substance Officers (primary and alternate) are responsible for:
   - Compliance with federal, state regulations pertaining to their use of CS.
   - Preparation of application packages for obtaining and renewing DEA Controlled Substance Registration Certificates.
   - Selection and training of auxiliary staff that will receive and use dispensed small quantity of the CS from the registrant and maintain records concerning the use of CS. Providing the names of auxiliary staff to EH&S and updating their authorization with EH&S.
   - Maintaining inventory of order, receipt, use, storage, loss and disposal of CS.
   - Maintaining strict control over inventory and security for the CS.
   - Contacting EH&S with questions concerning use of the CS or regarding missing portions of the CS.

5. The Department of Public Safety is responsible for investigation and enforcement actions pertaining to illegal use or possession of CS.

6. Purchasing Department is responsible for proper processing of requisition for CS purchases and will coordinate such purchases with the Controlled Substance Safety Officer.

7. DHR is responsible for the implementation of separation procedures which require the permit holder to obtain clearance from EH&S and submit to DHR prior to releasing their final leave payout.

8. The Facility Management Department is responsible for assisting departments, researchers and faculty members in implementing physical security controls to prevent theft and diversion of CS such as by installing safes, locks and alarm systems, bolting safes to the ground, changing key or card access numbers, etc.
5.0 Controlled Substance Schedules and Drug Codes

Federal regulations divide CS into five classifications or "schedules" based on:

- Whether they have an accepted medical use.
- Their relative potential for abuse.
- The degree of dependence that may be caused by abuse of the controlled substance.

Substances within each schedule are also divided into **narcotic** and **non-narcotic** categories.

The following characteristics apply to the schedules indicated:

**Schedule I**
(a) The drug or other substance has a high potential for abuse.
(b) The drug or other substance has no currently accepted medical use in treatment in the United States.
(c) Accepted safety for use of the drug or other substance under medical supervision has not been established.

**Schedule II**
(a) The drug or other substance has a high potential for abuse.
(b) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted use with severe restrictions.
(c) Abuse of the drug or other substance may lead to severe psychological or physical dependence.

**Schedule III**
(a) The drug or other substance has a lower potential for abuse than the drugs or other substances in Schedules I and II.
(b) The drug or other substance has a currently accepted medical use in treatment in the United States.
(c) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

**Schedule IV**
(a) The drug or other substance has a low potential for abuse relative to the drugs or other substances in Schedule III.
(b) The drug or other substance has a currently accepted medical use in treatment in the United States.
(c) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule III.
Schedule V
(a) The drug or other substance has a low potential for abuse relative to the drugs or other substances in Schedule IV.
(b) The drug or other substance has a currently accepted medical use in treatment in the United States.
(c) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule IV.

Each controlled substance in the five schedules has been assigned a Code Number. This number identifies the CS / drug for administrative and other purposes, and should be referenced on requisitions, purchase orders and correspondence with DEA official.
### 6.0 REGISTRATION

Under the Controlled Substance Act of 1970 prior to procuring any controlled substance each user must obtain a registration number by submitting an application to the Drug Enforcement Agency on the prescribed form. Form DEA-225 is required and shall be completed by all individuals who will be using CS of any schedule I to V for research and, for instructional activities, if a schedule I substance. Form DEA-224 must be completed for schedule II to V substances used for teaching (no research). This is shown in Table below:

<table>
<thead>
<tr>
<th>Registration Class</th>
<th>Schedule</th>
<th>DEA Form</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analytical Lab</td>
<td>I to V</td>
<td>New 225</td>
<td>Check box Analytical Lab in Section 2. Check all boxes (Schedule I, Schedule II Narcotic, Schedule II Non-Narcotic, Schedule III Narcotic, Schedule III Non-Narcotic, Schedule IV and Schedule V) in Section 3. In Section III check box for official order forms for Schedule I and II CS. There is no need to list drug codes.</td>
</tr>
<tr>
<td></td>
<td>(1 to 5)</td>
<td>Renewal 225a</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Renewal 225a</td>
<td></td>
</tr>
<tr>
<td>Researcher</td>
<td>I (1)</td>
<td>New 225</td>
<td>For registration class “Researcher” check box Researcher w/Sched I in Section 2 (Business Activity). Check box Schedule I in Section 3 (Drug Schedules). For Schedule II-V CS a separate registration is required from Schedule I. In Section III check box for official order forms for Schedule I CS. Check the applicable drug codes in schedule I.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Renewal 225a</td>
<td></td>
</tr>
<tr>
<td>Researcher</td>
<td>II to V</td>
<td>New 225</td>
<td>For registration class “Researcher” for Schedules II to V CS a separate registration is required from Schedule I. Check box Researcher w/Sched II- V in Section 2. In Section III check all applicable boxes (Schedule II Narcotic, Schedule II Non-Narcotic, Schedule III Narcotic, Schedule III Non-Narcotic, Schedule IV and Schedule V). In Section III check box for official order forms for Schedule II CS. Check the applicable drug codes in different schedules.</td>
</tr>
<tr>
<td></td>
<td>(2 to 5)</td>
<td>Renewal 225a</td>
<td></td>
</tr>
<tr>
<td>Teaching Institution</td>
<td>I (1)</td>
<td>New 225</td>
<td>There is no Schedule I registration for Teaching Institution. For institutes like Forensic Sciences check the box Analytical Lab in Section 2. See Analytical Lab registration.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Renewal 225a</td>
<td></td>
</tr>
<tr>
<td>Teaching Institution</td>
<td>II to V</td>
<td>224</td>
<td>Check box Teaching Institution in Section 2. In Section III check all applicable boxes (Schedule II Narcotic, Schedule II Non-Narcotic, Schedule III Narcotic, Schedule III Non-Narcotic, Schedule IV and Schedule V). In Section III check box for official order forms for Schedule II CS. Check the applicable drug codes in different schedules.</td>
</tr>
<tr>
<td></td>
<td>(2 to 5)</td>
<td>Renewal 225a</td>
<td></td>
</tr>
</tbody>
</table>

Along with the completed forms (DEA-225 or DEA-224, as applicable) the following must be completed and submitted to EH&S when applying for registration:
• Questionnaire form (Appendix 1)
• Security Screening Information form (Appendix 2)
• Controlled Substances Request for Authorization (Appendix 3)
• Research Title and Protocol. See 21 CFR 1301.18 for research protocols.
• Control Substance Fact Sheet ((Appendix 5)

6.1 Procedure for the Registrant

The registrant is responsible for managing the CS in accordance with requirements of the regulations including inventory, record keeping and security provisions. As part of the screening process, a questionnaire, which includes the following questions (21 CFR, 1301.90) must be completed by each employee (non-practitioner) who wishes to obtain registration to handle DEA CS:

• 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? (Do not include any traffic violations, juvenile offenses or military convictions, except by general court-martial.)
• In the past 3 years, have you knowingly used narcotics, amphetamines, or barbiturates other than those prescribed to you by a physician?

Any individual who answers yes to either of the questions must provide details (conviction, offense, location, date and sentence). The CSSO and DHR shall evaluate this information and determine whether the application will be forwarded to DEA for review and consideration. In addition, the employee must also complete the Security Screening Information form, which authorizes the local law enforcement and regulatory agencies to conduct background check. Questionnaire and Security screening required is required for all registrants. This is also required for primary and alternate controlled substance officers who will have access to controlled substances for a department permit. The CSSO reviews the documents. If the documents are satisfactory, CSSO completes the section “CERTIFICATION FOR FEE EXEMPTION” of the form DEA-225 or DEA-224, as applicable, and submits to the DEA for registration after obtaining signature from the Director of E H & S. The CSSO also submits required copies of the protocol along with the application form.

Research assistants and co-principal investigators of the registrant may engage in approved activities under the direction of the registrant. They also complete the questionnaire and may be granted authorization if the answers to all the questions are “no”. The copy of the “Questionnaire” of each employee to be authorized to work with controlled substances should be forwarded to the CSSO, and their names should appear in the Controlled Substances Request for Authorization Form (Appendix 3) or on Authorization Update Form (Appendix 4). The registrant will also file these forms for his/her records.
7.0 RENEWAL OF REGISTRATION

DEA grants registration for specified schedule of CS for a specific period. This registration period is one year for application submitted on Form-225 and three years for controlled substances for which Form 224 is required. The registration must be renewed by submitting (or filing on-line) Form 225a or 224a, as applicable, in order to be able to work with CS after the previous registration expiration period. Approximately 60 days prior to expiration, registrants receive at the address registered with the DEA notice from the DEA informing them to renew their registration. In case of relocation the registrants must notify the DEA regarding change of address with a copy to the University CSSO. The CSSO will update DHR with new location of the registrant.
8.0 ACQUISITION AND USE PROCEDURES

These procedures describe how CS are to be ordered, received and handled by individuals who are engaged in instructional or research activities at or through FIU. Individual subsections are devoted to the use authorization, ordering, receiving, storage and security, disposal and record keeping procedures. Biennial inventory and precursor control requirements are addressed in separate sections.

8.1 Use Authorization Procedures

CS may be used only by those registrants (permit holders) who are authorized to use them and only in the laboratory or location that is identified in the protocol (if research) or the place where the instructional activities are to take place. The registrants may be individuals or departments. The FIU Controlled Substance committee in its meeting on June 06, 2006 (agenda item # 06-06-06-01) agreed that all new permits should be in the names of departments rather than individual users. Federal law requires that the authorized user report any changes of professional or business address to the DEA. 21 U.S.C. Section 827(g). Persons who desire to use controlled substances at FIU must first complete a Controlled Substance Request for Authorization form and forward it to the CSSO for review along with a completed form DEA-225 or DEA-224, as applicable, questionnaire form, Security Screening Information form and a copy of the use protocol or if applicable, research protocol approved by the Institutional Animal Care and Use Committee (IACUC). The CSSO through Director EH&S forwards the application for registration to the DEA. The registration certificate provides authorization to use controlled substances within specified categories for certain types of research or instruction. For example, a researcher may obtain an authorization to use Schedule II CS for experimentation on pre-natal effects of CS exposure in rats.

Authorization to use CS to registrants is granted by the DEA. The research assistants or co-principal investigators of the registrants may be authorized by EH&S only after the registration by the registrant is received from the DEA. They shall not have access to the safe storing CS. The small dispensed quantity of CS given to them for teaching/research will be accounted by them and the registrant. However, the responsibility for inventory, use and security of the CS lies solely with the registrant. The authorization accorded by EH&S to the registrants or their co-principal investigators to use CS is valid only as long as the registrant’s permit issued by DEA is valid. This authorization will remain valid subject to the following conditions:

(a) There are no changes in procedures or the types of CS used. To document this, a Controlled Substances Use Authorization Update must be filed annually with EH&S. Also, the UPDATE form (Appendix 4) must be submitted to EH&S whenever a change in personnel who have access to the CS occurs.
(b) The user scores adequately on the annual EH&S audit of controlled substance records and use procedures.

Once the initial USE AUTHORIZATION APPLICATION is approved by EH&S, a USE AUTHORIZATION CERTIFICATE will be mailed back to the applicant. This document does not need to be posted, but must be kept on file.

All employees or associates or students listed on the CS Use Authorization Application read and sign the Controlled Substance Fact Sheet. The Principal Investigator and registrant must also sign the Fact Sheet. Signed Fact Sheets must be sent to the CSSO. The registrant must keep all copies in their records to be available for inspection.

8.1.1 Adding Controlled Substances to Permit
Complete the applicable DEA registration form (DEA-224 or DEA-225) and submit to EH&S along with the following for forwarding to DEA:

- A letter to DEA requesting permit for additional CS required
- A copy of the current permit
- Research protocol

8.1.2 Adding Controlled Substances to Analytical Lab Permit
Since the analytical labs may be analyzing a number of CS and it is not practical to list all of them, Analytical Lab permit holders are not required to list the codes for all CS (see DEA Form 225 Drug Schedules page 2 of 4, Appendix 18). Analytical Lab permit holders are not required to amend their permit so long as their permit shows the Schedule in which the controlled substance they want to use falls.

8.2 Ordering Procedures
Prior to placing order for purchasing any controlled substance a “Letter of Exemption for Purchase of CS” must be obtained from the Florida Bureau of Health (See Appendix 6 for the sample letter).

CS are ordered from a vendor or agency licensed to sell/dispense them.

All purchases of CS whether through Panther Soft system or Pro-Card must be approved by the CSSO. It is violation of the FIU’s procedures to procure CS without approval from CSSO.

(a) To order CS:

1. Complete and submit Purchase Requisition to EH&S for forwarding to the Purchasing Department. Give complete details (name, schedule, code, and quantity) of the controlled substance, delivery location, address, phone and fax number of the vendor. The delivery address of the registrant must match with
2. that given on the registration certificate. Make sure to check the box for purchase of DEA CS.
3. Submit Form DEA-222 for Schedule I and II CS only.
4. Submit a copy of Form DEA-223 (controlled substance registration certificate).
5. Submit documents that show name, code and quantity of the controlled substance the registrant is authorized to procure.

The vendors require the following for different schedules:

- Schedule I: Mail order with a copy of the DEA registration and completed Form 222.
- Schedule II: Mail order with a copy of the DEA registration and completed Form 222.
- Schedule III: Mail or Fax order with a copy of the DEA registration.
- Schedule IV: Mail or Fax order with a copy of the DEA registration.
- Schedule V: Mail or Fax order with a copy of the DEA registration.

Note: Form 222 is not required for purchase of Schedule III to V CS.

6. After the Purchase Requisition is approved by the CSSO, a signed copy will be sent to registrant. The original will be sent to the Purchasing Department, along with copies of a filled-out DEA Form 222, and the DEA Registration Certificate under which the CS will be purchased and used.

(Note: Purchasing Departments are not to process Purchase Requisition until approved Purchase Requisition has been received from the CSSO, along with the DEA form and Registration Certificate copy.

(b) Purchase Requisition may only be signed by individuals who are registrants or Primary (or alternate) CS officers, and are currently on the authorized list maintained by EH&S. Drug companies periodically request this list of authorized purchase order signatories and fill orders only after verifying signatures. This will be coordinated with the Purchasing.

8.3 PROCUREMENT

All procurement of CS must be coordinated with the CSSO. All materials must be delivered directly to the registrant. Contact the CSSO for additional information concerning this process.

8.3.1 Procurement Process for Schedule I and II Controlled Substances

All orders for Schedule I and II CS must include a DEA Form 222 to be given to the CSSO. The registrant should request these forms at the time of initial registration, also additional forms can be ordered from the DEA as necessary. Complete Form 222 without error (void any forms with corrections and keep on file) and be sure all
8.0 ACQUISITION AND USE PROCEDURES

information is accurate. Following completion of the DEA form, complete the purchase requisition. An object code for CS must be entered on requisition. Also check the applicable box CS. This checking of box will alert Purchasing Department to request EH&S approval for the order. The CSSO will verify the quantity authorized and ordered, assign a tracking number, approve the purchase, and mail/deliver the requisition to the Purchasing Department with a copy to the authorized user. The CSSO will also retain a copy of the documents on file.

The controlled substance will be shipped directly to the registrant (primary controlled substance officer). Upon receipt, the registrant will open the outer packaging to verify the contents of the order and ensure that no damage to the contents has occurred. The registrant will complete the Controlled Substance Order/Receipt Record (Appendix 7) and send to the CSSO to notify that the controlled substance has been delivered. The CSSO must also be notified of receipt of any CS directly to the laboratory without a purchase order. To ensure that the CSSO is notified of the receipt of controlled substance the registrant will send semi-annually photocopy of the order/receipt record to the CSSO. This will be checked during annual inspections.

8.3.2 Procurement Process for Schedule III-V Controlled Substances
DEA Form 222 is not required for Schedule III-V CS. Follow the procedure for purchase of controlled substances.
NOTE: CS are not transferable between researchers/laboratories.

8.4 Receiving Procedures for Controlled Substances
(a) CS are to be delivered only to the registrants (CSO). They may NOT be received by individual researchers. When the registrant orders a controlled substance he/she shall request the purchasing department to instruct the vendor to deliver the substance at his/her departmental address ONLY and not at the Scientific Receiving or Central Receiving. To ensure that the controlled substance is not left unattended in purchaser’s department the following will be done:

The registrant will train his/her office staff to receive the CS (described to them as special research material) and to store in a locked cabinet prior to handing over to the registrant. He/she will also inform his/her office that a package containing special research material is expected within the next few days, and that they should be careful to see that the package receives the due care and is not left unattended. If the registrant is not available to take charge of the package on the day the package is received, the individual receiving the package should call EH&S at extension X 72621 or X 70489 for taking custody of the material. The CSSO may also visit the registrant’s department and educate the office staff normally receiving the materials. The lab managers will also be educated. The lab managers meet every month. This is one of the forums to educate the staff receiving/delivering (e.g., Scientific Receiving, if the shipping company delivers to them) CS.
8.0 ACQUISITION AND USE PROCEDURES

(b) When a controlled substance is received, it is to be immediately stored in the safe vault. The authorized user should then notify the CSSO of the Controlled Substance's arrival.

(c) Maintain separate records of Schedule I and II CS (Appendix 7).

(d) File all original invoices of all CS, Schedule I and II separate from Schedule III-V.
(e) Enter in copy 3 (purchaser’s copy) of the Form 222 the number of commercial or bulk containers furnished on each item and the date on which the containers were received by the purchaser.

8.5 STORAGE AND SECURITY PROCEDURES

(a) CS are to be stored according to requirements for stability and sterility printed on the label (e.g., packaging integrity and refrigeration).

(b) The CS must be kept ONLY in a fixed and stationary, secure and substantially constructed locked cabinet, vault or other containment furniture. Access to the CS cabinet is to be limited to individuals who are registrants (or controlled substance officers) whose names are listed on the Controlled Substance Authorization form and approved Controlled Substance Use Authorization Update.

(c) A permanently locked room accessible only to the authorized users may serve as a vault if the locked safe is placed in this room.

(d) If practical, these containment structures should be located in a room or office that is not accessible to the general public or students who are not involved in approved laboratory and research activities.

(e) Key locks or safe combinations should be changed whenever personnel changes occur, or on a prearranged schedule determined by the department chair.

(f) Flip-off tops and other types of seals affixed to controlled substance containers are not to be removed prior to use, to assure the integrity of the container.

(g) ANY unaccountable loss of controlled substance, or loss apparently due to theft or misuse is to be reported to the Public Safety and CSSO immediately upon discovery.

(h) CSSO may conduct an inspection of proposed controlled substance storage locations or containment furniture prior to issuing a Use Authorization Certificate to an applicant. The storage site is also subject to periodic inspection by CSSO.
(i) Section 1301.72 of 21 CFR describes physical security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs; storage areas, as under: Schedules I and II: Raw materials, bulk materials awaiting further processing, and finished products, which are CS, listed in Schedule I or II, shall be stored in one of the following secure storage areas:

(1) Where small quantities permit, a safe or steel cabinet;

   (i) Which safe or steel cabinet shall have the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques;

   (ii) Which safe or steel cabinet, if it weighs less than 750 pounds, is bolted or cemented to the floor or wall in such a way that it cannot be readily removed; and

   (iii) Which safe or steel cabinet, if necessary, depending upon the quantities and type of CS stored, is equipped with an alarm system which, upon attempted unauthorized entry, shall transmit a signal directly to a central protection company or a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Administrator may approve.

(2) A vault constructed before, or under construction on, September 1, 1971, which is of substantial construction with a steel door, combination or key lock, and an alarm system; or

(3) A vault constructed after September 1, 1971:

   (i) The walls, floors, and ceilings of which vault are constructed of at least 8 inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with \( \frac{1}{2} \)-inch steel rods tied 6 inches on center, or the structural equivalent to such reinforced walls, floors, and ceilings;

   (ii) The door and frame unit of which vault shall conform to the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques;

   (iii) Which vault, if operations require it to remain open for frequent access, is equipped with a "day-gate" which is self-closing and self-locking, or the equivalent, for use during the hours of operation in which the vault door is open;
(iv) The walls or perimeter of which vault are equipped with an alarm, which upon unauthorized entry shall transmit a signal directly to a central station protection company, or a Local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Administrator may approve, and, if necessary, holdup buttons at strategic points of entry to the perimeter area of the vault;

(v) The door of which vault is equipped with contact switches; and

(vi) Which vault has one of the following: Complete electrical lacing of the walls, floor and ceilings; sensitive ultrasonic equipment within the vault; a sensitive sound accumulator system; or such other device designed to detect illegal entry as may be approved by the Administration.

Schedules III, IV and V. Raw materials, bulk materials awaiting further processing, and finished products which are controlled substances listed in Schedules III, IV and V shall be stored in the following secure storage areas:

(1) A safe or steel cabinet as described in paragraph (i) for Schedules I and II of this section;

(2) A vault as described for the aforementioned vault (as in constructed after 1971 section) equipped with an alarm system as described in (v) of this section;

(3) A building used for storage of Schedules III through V controlled substances with perimeter security which limits access during working hours and provides security after working hours and meets the following specifications:

(i) Has an electronic alarm system as described in (i) (3) section,

(ii) Is equipped with self-closing, self-locking doors constructed of substantial material commensurate with the type of building construction, provided, however, a door which is kept closed and locked at all times when not in use and when in use is kept under direct observation of a responsible employee or agent of the registrant is permitted in lieu of a self-closing, self-locking door. Doors may be sliding or hinged. Regarding hinged doors, where hinges are mounted on the outside, such hinges shall be sealed, welded or otherwise constructed to inhibit removal. Locking devices for such doors shall be either of the multiple-position combination or key-lock type and:

(a) In the case of key locks, key control shall be required to limit access to a limited number of employees, or;

(b) In the case of combination locks, the combination shall be limited to a minimum number of employees and can be changed upon termination of
employment of an employee having knowledge of the combination; (4) A cage, located within a building on the premises, meeting the following specifications:

(i) Having walls constructed of not less than No. 10 gauge steel fabric mounted on steel posts, which posts are:

(a) At least one inch in diameter;

(b) Set in concrete or installed with lag bolts that are pinned or brazed; and

(c) Which are placed no more than ten feet apart with horizontal one and one-half inch reinforcements every sixty inches;

(ii) Having a mesh construction with openings of not more than two and one-half inches across the square,

(iii) Having a ceiling constructed of the same material, or in the alternative, a cage shall be erected which reaches and is securely attached to the structural ceiling of the building. A lighter gauge mesh may be used for the ceilings of large enclosed areas if walls are at least 14 feet in height,

(iv) Is equipped with a door constructed of No. 10 gauge steel fabric on a metal door frame in a metal door flange, and in all other respects conforms to all the requirements of 21 CFR 1301.72(b)(3)(ii), and

(v) Is equipped with an alarm system which upon unauthorized entry shall transmit a signal directly to a central station protection agency or a local or state police agency, each having a legal duty to respond, or to a 24-hour control station operated by the registrant, or to such other source of protection as the Administrator may approve;

(5) An enclosure of masonry or other material, approved in writing by the Administrator as providing security comparable to a cage;

(6) A building or enclosure within a building which has been inspected and approved by DEA, and continues to provide adequate security against the diversion of Schedule III through V controlled substances, of which fact written acknowledgment has been made by the Special Agent in Charge of DEA for the area in which such building or enclosure is situated;

(7) Such other secure storage areas as may be approved by the Administrator after considering the factors listed in Sec. 1301.71(b), (1) through (14);
(8) (i) Schedule III through V CS may be stored with Schedules I and II CS under security measures provided by 21 CFR 1301.72(a):

(ii) Non-CS, and other materials may be stored with Schedule III through V CS in any of the secure storage areas required by 21 CFR 1301.72(b), provided that permission for such storage of non-controlled items is obtained in advance, in writing, from the Special Agent in Charge of DEA for the area in which such storage area is situated. Any such permission tendered must be upon the Special Agent in Charge's written determination that such non-segregated storage does not diminish security effectiveness for Schedules III through V CS.

(c) **Multiple storage areas.** Where several types or classes of CS are handled separately by the registrant or applicant for different purposes (e.g., returned goods, or goods in process), the CS may be stored separately, provided that each storage area complies with the requirements set forth in this section.

(d) Accessibility to storage areas. The controlled substance storage areas shall be accessible only to an absolute minimum number of specifically authorized employees. When it is necessary for employee maintenance personnel, non-employee maintenance personnel, business guests, or visitors to be present in or pass through controlled substance storage areas, the registrant shall provide for adequate observation of the area by an employee specifically authorized in writing. Given below are Access Control Procedures:

1. CS will be stored in safes inside a storage area.
2. The safe will have a key, which can be accessed only by the registrant (Controlled Substances Officer) who shall be accountable for the inventory of the CS.
3. The safe shall be bolted or screwed so that anybody entering the controlled area shall not be able to remove the safe.
4. The registrant shall provide to the Controlled Substance Safety Officer details of the location of the safes for storage of their controlled substances. If the registrant intends to share the safe with other registrants (as in the case of departmental registration, he or she (Primary Controlled Substances Officer) will be the person primarily responsible for coordinating access to the shared safe. This person whose name is registered with DEA as the primary contact person may designate another person (Alternate CS Officer) with access in his/her absence. The primary registrant must provide to the CSSO the names of all registrants who are sharing the common safe. Each registrant shall be responsible for the inventory of his/her controlled substances.
8.6 Disposition of Controlled Substances

(a) CS are not to be loaned or shared with any other researcher or laboratory. They are only to be used by the persons listed on the Controlled Substance Use Authorization Application Form and Controlled Substance Use Authorization Application Update Form for the specific use indicated on the form.

(b) Any loss of CS or discrepancy in record keeping is to be reported to CSSO immediately upon their discovery. If theft or misuse is suspected, the Public Safety must also be notified immediately.

(c) Based on the details and amount involved in reported losses, the CSSO may need to file a DEA Form 106 (loss Form) or submit an incident report. The University (through Public Safety and EH&S) also reserves the right to impound CS and records pertinent to an investigation into inventory or record keeping discrepancies.

(d) All expired substances or those left over at the end of the research or instructional activity for which they were required, are to be accounted for.

(e) Procedure for disposing of CS is provided by federal regulation, 21 CFR Section 1307.21 as follows:

(a) Any person in possession of any controlled substance and desiring or requiring to dispose of such substance may request assistance from the Special Agent in Charge of the Administration in the area in which the person is located for authority and instructions to dispose of such substance. The request should be made as follows:

(1) If the person is a registrant, he/she shall list the controlled substance or substances, which he/she desires to dispose of on DEA Form 41, and submit three copies of that form to the Special Agent in Charge in his/her area; or

(2) If the person is not a registrant, he/she shall submit to the Special Agent in Charge a letter stating:
   (i) The name and address of the person;
   (ii) The name and quantity of each controlled substance to be disposed of;
   (iii) How the applicant obtained the substance, if known; and
   (iv) Name, address, and registration number, if known, of the person who possessed the CS prior to the applicant, if known.

(b) The Special Agent in Charge shall authorize and instruct the applicant to dispose of the controlled substance in one of the following manners:

1) By transfer to person registered under the Act and authorized to possess the substance;

2) By delivery to an agent of the Administration or to the nearest office of the Administration;
(3) By destruction in the presence of an agent of the Administration or other authorized person; or
(4) By such other means as the Special Agent in Charge may determine to assure that the substance does not become available to unauthorized persons.

(c) In the event that a registrant is required to dispose of controlled substances regularly, the Special Agent in Charge may authorize the registrant to dispose of such substances, in accordance with paragraph (b) of this section, without prior approval of the Administration in each instance, on the condition that the registrant keep records of such disposals and file periodic reports with the Special Agent in Charge summarizing the disposals made by the registrant. In granting such authority, the Special Agent in Charge may place such conditions, as he/she deems proper on the disposal of controlled substances, including the method of disposal and the frequency and detail of reports.

(d) This section shall not be construed as affecting or altering in any way the disposal of CS through procedures provided in laws and regulations adopted by any State.

Note: DEA recommends disposition of controlled substances through "Reverse Distributors"

8.7 Record keeping Procedures for Controlled Substances

a) The registrants (Controlled Substance Officer) must adequately document all controlled substance usage, waste, and damaged material. Each time a quantity of a controlled substance is taken from stock, an entry is to be made in the Controlled Substance Disposition Record (CSDR) (Appendix 8)/ log-book. This form notes the date, quantity used, quantity wasted, and the signature of the individual authorized to handle the controlled substance. The record of receipt (including original invoices from suppliers or the source of acquisition) must be maintained. Records should include the date of receipt, the supplier, the quantity and dose of the controlled substance received, the expiration date, and the date when the controlled substance was exhausted or discarded as expired. Records must be retained for a period of two (2) years following disposition of the controlled substance.

b) Any time supplies are wasted; this information must be documented on the CSDR/log-book. A second authorized person, listed on the Controlled Substance Use Authorization Application form or Controlled Substance Use Authorization Update, must verify witnessing the wastage by signing their name in the verification column of the CSDR. "Wasting" of supplies may occur if the substance removed from the original container have become contaminated or have otherwise become unusable. Materials are generally wasted into the sanitary sewer. "Disposal" of controlled substances applies to generally larger quantities of unused controlled
substances that have expired or are no longer required or authorized. See Section above on Disposition of CS.

c) An accurate perpetual balance for each controlled substance container is to be maintained at all times on the CSDR/log-book.

d) If there is not enough space on the original CSDR to account for all dispensing of a given substance, additional copies are to be properly completed and attached to the original CSDR. CSDR for each controlled substance is to be returned to CSSO after research has been completed (whether or not unused portions of the substances remain), or when all the supply of the controlled substance has been used. The total number of sheets is to be indicated at the bottom of all CSDR forms.

e) Separate, more detailed laboratory records may be used to record other information pertinent to the administration of CS, such as the observed effects caused by the controlled substance, other related procedures, etc. The CSDR/log-book may serve as a useful experimental record, which be kept by the researcher. Copies of the records should be forwarded to CSSO upon completion of the authorized use for the controlled substance.

Controlled Substance Spill Record Form (Appendix 9) must be completed for controlled substance wastes due to spill.
9.0 BIENNIAL INVENTORY

Federal regulations require an inventory of all CS be performed at least once every two years. This inventory is conducted to verify the perpetual balances maintained on the CSDR for individual CS. The performance of these inventories will be coordinated by the CSSO.

1. The following procedures are to be followed by authorized users when conducting the biennial inventory:

   a) Only individuals who are registered with the CSSO and have on file a Controlled Substance Use Authorization Application Form and the CSSO may conduct the biennial inventory. No other individual has the authority to conduct this inventory.

   b) A Biennial CS Inventory Form (Appendix 10) shall be used to record the information from the inventory. For each substance in stock, the inventory agent must list the name and dose form of the controlled substance, the total quantity of the substance in metric units or the total number in finished dose form, and the date when registrant purchased the controlled substance. The total amount of each substance shown as the perpetual balance on its CSDR form is to be listed next to the inventoried amount. If there are any discrepancies, these must be explained on the Inventory Record.

   c) The Controlled Substance Inventory Record is to be signed by the Department Chair or Director and submitted to the CSSO no later than two days after completion of the inventory.
10.0 U.S. CHEMICAL CONTROL

The federal Chemical Diversion and Trafficking Act of 1988 (CDTA) was enacted to control the manufacture, distribution, export and import of 12 precursor chemicals and 8 essential chemicals and certain equipment used in the manufacture of controlled substances. The Domestic Chemical Diversion and Control Act of 1993 (DCDCA) eliminated the CDTA terminology of “precursors” and “essential” for chemicals regulated under that act and replaced them with the terms “List I” and “List II” chemicals. The DCDCA required that all manufacturers, distributors, importers, and exporters of List 1 chemicals be registered with the DEA and that bulk manufacturers of List I and List II chemicals report on the total quantity of listed chemicals produced during the year. After passing the Comprehensive Methamphetamine Control Act of 1996 the attorney General published Special Surveillance List that contains listed chemicals and equipment found at the clandestine drug laboratories. Currently, List I and List II of Controlled Substance Act contain 38 chemicals (Appendix 11). If you notice that these chemicals are being ordered or used in unusually high quantities, or unusual applications, please contact the CSSO or the Public Safety. The vendors of listed chemicals may request clearance from responsible University official (e.g., Director EH&S or Vice President for Research) when such listed chemicals are purchased. The CSSO will also send the list of such chemicals to the Purchasing to monitor any unusual activity.

It is responsibility of the registrants to comply with the DEA regulation when making any purchases of controlled substances or listed chemical through purchase orders or the use of the Pro-Card.

The CSSO will routinely monitor purchasing data to verify that threshold quantities of precursor and essential chemicals are not exceeded. Purchasing Department shall make pertinent data available for analysis by CSSO.
11.0 Inspections

1. Records and inventories of CS are subject to unannounced inspection by representatives of EH&S. All records and CS must be immediately available for review. Representatives of State and Federal agencies may also wish to inspect how you are storing, maintaining, safeguarding, using, disposing and keeping records of CS under your control.

2. At the time of inspection, the following items are subject to evaluation:

   a) Proper storage and security arrangements.

   b) Accuracy and completeness of your Controlled Substance Disposition Records and all other relevant records.

   c) Ensuring that workers handling CS are only those listed on the Controlled Substance Disposition Records and approved Controlled Substance Update Form.

   d) Deficiencies found during previous inspections have been corrected.

   e) Procedures for use and disposal of the CS in compliance with State and Federal regulations.

3. A representative from EH&S will inspect each laboratory or research facility using CS on at least an annual basis using the Controlled Substance Inspection checklist (Appendix 12). In addition, department or individual researchers are encouraged to perform periodic self-evaluation surveys. If you need assistance or have any questions regarding proper handling procedures, you may contact the CSSO at X70489/72621.
12.0 SEPARATION PROCEDURES

Authorized users of restricted materials (controlled substance, select agents and radioactive materials) are required to comply with certain procedures for safe disposition of these materials and/or handing over safe custody of these before they separate from FIU. Given below are the separation procedures:

1. Employees of the University—faculty, researchers or staff members- who have any CS under their control must notify the CSSO and the Division of Human Resources immediately if they are separating from employment with FIU. These individuals are responsible for completing a “Separation Clearance Form” that includes specific provisions designed to ensure compliance with federal and state laws and regulations relating to controlled substances.
2. The employee will complete inventory and disposition of the material per regulations.
3. The employee will return the key of the CS safe to the CSSO. If the CSSO is not available the employee will seal the keys in envelop and request the Public Safety to collect the keys and hold for the CSSO.
4. The CSSO will visit the lab and confirm that the inventory has been compiled.
5. The CSSO will complete EH & S’ portion of the “Separation Clearance Form.”
6. The employee will submit the completed form to DHR which will process it accordingly upon receipt.
APPENDIX 1 - QUESTIONNAIRE FOR EMPLOYEES OR INDIVIDUALS WORKING AT FIU WHO WILL HAVE ACCESS TO SUBSTANCES REGULATED BY THE DRUG ENFORCEMENT AGENCY OF THE UNITED STATES OF AMERICA

The Drug Enforcement Agency requires that any person who will have access to controlled substances as a result of his or her status as employee or agent of the Florida International University answer the following questions. Any false information may jeopardize your position with respect to employment. Information revealed by this questionnaire will not necessarily preclude, but will be considered as part of the overall evaluation of your qualification. The responses on this questionnaire will be held in strictest confidence.

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

   ☐ Yes  ☐ No

2. In the past three years, have you ever knowingly used narcotics, amphetamines or barbiturates, other than those prescribed to you by a physician? If the answer is “Yes,” furnish details.

   ☐ Yes  ☐ No

Name (Print)  Signature  Date

Name (Print)  Signature  Date

Principal Investigator/Permit Holder

Reference: 21 CFR 1309.90
APPENDIX 2 - Security Screening Information

Background Checks for Personnel with Access to Controlled Substances

Full Name _____________________________________________________________
Home Address __________________________________________________________
City ___________________ State ____ Zip _________ Home Phone Number ________________
Business Phone Number ___________________ Social Security Number __________________
Date of Birth ___________ Place of Birth ___________________ Country of birth _____________
Race __________________ Gender ____________ Height ___________ Weight _____________
Hair Color ______________ Eye Color ______________
Driver’s License Number ____________________________ Issuing State ________________
Job Title ____________________________ Length of Employment __________________
DEA Number (if applicable) _________________________________
State License [ ] MD [ ] DDS [ ] DMD [ ] DVM [ ] DO [ ] RN [ ] LPN [ ] RPh
[ ] Other __________________________________________
Expiration Date _____________________________
Signature __________________________________ Date _____________

Privacy Act Information Sheet
[ ] DEA-224 Application for Registration
[ ] DEA-225 Application for Registration

Authority: Section 302 and 303 of the CS Act of 1970 (Public Law 91-513).

Routine Uses: The CS Act Registration Records produces special reports as required for statistical analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated:

A. Other federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.
B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.
C. Persons registered under the Controlled Substances Act (PL 91-513) for the purpose of verifying the registration of customers and practitioners.

Effect: Failure to complete the form will preclude processing of the application
## RESEARCHER INFORMATION

**Registrant Department:** ___________________________________________________________________

**Authorized User (Registrant/Primary CS Officer):** ____________________________ **Title:** ______________

**Phone:** _______________________ **Fax:** ___________________ **E-mail:** ________________________________

**Alternate CS Officer:** ____________________________ **Title:** ____________ **Phone:** _____________________

**Registered Address:**

**Project Name:**

**Dates of Project:**

## FACILITY INFORMATION

**Controlled substance storage location:**

<table>
<thead>
<tr>
<th>Building</th>
<th>Room</th>
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**Controlled substance use location:** (if different than storage location)

<table>
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<tr>
<th>Building</th>
<th>Room</th>
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Describe completely the storage cabinet or safe, and locking device for the controlled substances (CS), include specific security containers dimension, make & model, if known.

## STAFF & PERSONNEL INFORMATION

**Indicate who will have total responsibility for all record keeping & security (Registrant/Primary and Alternate Controlled Substance Officer):**

<table>
<thead>
<tr>
<th>Name of responsible person for record keeping and security</th>
<th>Campus phone</th>
<th>E-mail address</th>
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</table>

**List all individuals for whom you are requesting authorization to access the CS:**

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Campus Phone</th>
<th>E-Mail Address</th>
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<tbody>
<tr>
<td>1:</td>
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### CONTROLLED SUBSTANCES INFORMATION

Indicate what type of record keeping forms you are planning to use:

- [ ] EH&S CS Use Log
- [ ] Other (Please attach sample copy)

Name of CS to be used: (DEA drug codes can be found at: [www.deadiversion.usdoj.gov/schedules/schedules.htm](http://www.deadiversion.usdoj.gov/schedules/schedules.htm))

<table>
<thead>
<tr>
<th>Name of the controlled substance and Schedule</th>
<th>DEA drug code</th>
<th>Quantity/packaging size (e.g., Number of Containers, Units per Container, Quantity per Unit)</th>
<th>Purchase frequency</th>
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☐ Check this box, if you are attaching additional controlled substance information on a separate sheet.

**Name of CS supplier:**

- [ ] Fisher Scientific
- [ ] Sigma
- [ ] Abbott
- [ ] Henry-Schein
- [ ] Other: Please give information below

<table>
<thead>
<tr>
<th>Name of the supplier</th>
<th>Supplier’s address</th>
<th>Phone number</th>
<th>DEA # (if known)</th>
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<tbody>
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☐ Check this box, if you are attaching additional supplier information on a separate sheet.

**CS use information**

Please provide a brief description of the purpose of the research and the purpose of the controlled substance in the research:

____________________________________________________________________________________________________________________________________________________
Certification (Applicant must sign)
I certify that I have read and understood the FIU Procedure for the use, storage and disposal of CS in research and academic instruction. I further certify that, to the best of my knowledge, the information provided in this application is complete and accurate. I will notify the Controlled Substance Safety Officer of any loss of CS or discrepancies in recordkeeping immediately upon discovery.

Name: _________________________ Signature: ________________ Date: __________
(Primary Controlled Substance Officer)

Name: _________________________ Signature: ________________ Date: __________
(For whom authorization is requested)

Name: _________________________ Signature: ________________ Date: __________
(For whom authorization is requested)

Name: _________________________ Signature: ________________ Date: __________
(For whom authorization is requested)

Verification and Approvals

Name: _________________________ Signature: _________________ Date: _________
(Department Chair or Director)

Name: _________________________ Signature: _________________ Date: _________
(Registrant, if the user is not the registrant)

Environmental Health & Safety:

Workplace storage location has been inspected: _______
Name: _____________________________ Signature: _________________ Date: _____

IMPORTANT:

Please attach the following:

- Curriculum vitae and appropriate bibliography
- DEA Questionnaire form
- Security Screening Information form for everyone with access to CS
- Research protocol
- Controlled Substances Fact Sheet
- Are you planning to use Schedule I substances? YES ☐ NO ☐ EH&S will contact you for further information if you are planning to use Schedule I substances.
## APPENDIX 4 - CONTROLLED SUBSTANCE USE AUTHORIZATION UPDATE

### Section 1 — To be Completed by Controlled Substance Authorized User (Please Type or Print):

<table>
<thead>
<tr>
<th>Registrant/Primary and Alternate CS Officer:</th>
<th>Phone:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lab Manager</td>
<td>Phone:</td>
</tr>
</tbody>
</table>

| Department: |

- [ ] There have been no significant changes in the types of controlled substances (CS) or procedures used in my research or instructional activities.

- [ ] The authorized persons listed on my original APPLICATION or on most recent UPDATE have changed. Add or delete the following names as indicated:

<table>
<thead>
<tr>
<th>Add/Delete</th>
<th>Name</th>
<th>Title and Phone #</th>
<th>Signature and Date</th>
</tr>
</thead>
<tbody>
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</tr>
</tbody>
</table>

- [ ] I wish to change the types of drugs I use, or significantly change the type or purpose of drug use. The changes are described below:

<table>
<thead>
<tr>
<th>Registrant/ Primary and Alternate CS Officer:</th>
<th>Name</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>
## Section 2 - Project Description


## Section 3 - Certification (Applicant must sign)

I certify that I have read and understood the FIU Procedure for the Use of CS in Research and Academic Instruction. I further certify that, to the best of my knowledge, the information provided in this application is complete and accurate. I will notify the Controlled Substance Safety Officer of any loss of CS or discrepancies in recordkeeping immediately upon discovery.

<table>
<thead>
<tr>
<th>Registrant/ Primary and Alternate CS Officer:</th>
<th>Name</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
</table>

## Section 4 - Verification and Approvals

<table>
<thead>
<tr>
<th>Department Chair:</th>
<th>Name</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registrant</td>
<td>Name</td>
<td>Signature</td>
<td>Date</td>
</tr>
</tbody>
</table>

### Environmental Health & Safety

<table>
<thead>
<tr>
<th>Workplace storage location has been inspected Controlled Substance Safety Officer:</th>
<th>Name</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
</table>
APPENDIX 5 - Controlled Substances Fact Sheet

Use of DEA controlled substances (CS) requires responsible and detailed legal and record keeping activities. The following is a summary of certain facts concerning these responsibilities and activities.

1. Research or instructional use of CS at FIU may only be done under the Environmental Health & Safety (EH&S) authorization and Drug Enforcement Administration (DEA) Registration Certificate. Personal Registration Certificates, though available through DEA, may not be used to order, receive, use, transfer or dispose of controlled materials at FIU.

2. Use of CS is governed by Federal and State laws, as well as guidelines established by the university's procedure. (See Chapter II of Title 21 of the Code of Federal Regulations (parts 1300 to the end and www.fiu.edu/~ehs controlled substances).

3. Some CS have a high potential for abuse, and this abuse may lead to severe psychological or physical dependence.

4. FIU personnel who participate in illicit activities in the use of CS are subject to federal and state prosecution, as well as university action such as suspension or termination of employment.

5. Procedures for ordering, receiving, storage, security, use, disposal and record keeping of CS are detailed in the FIU Controlled Substance Safety Manual.

6. Controlled Substance Safety Officer must be notified of any loss of CS or discrepancies in recordkeeping immediately upon discovery.

7. Questions concerning controlled substances may be directed to the Controlled Substance Safety Officer at Environmental Health and Safety, extension 70489/72621.

Please sign below:

- I certify that I have read and understood this CS Fact Sheet.
- I understand that CS are dangerous. I have read proper procedures for their use.
- I will abide by federal, State and University procedures and regulations regarding CS.
- I will comply with security and access control to CS.
- I will follow procedures for disposal of CS while in the University and when I separate from the University.

Name: ____________________________ Signature: ____________ Date: ____________
Appendix 6: Letter of Exemption for Purchase of Controlled Substances

Ms. Suzanne Stacknik  
Department of Health  
Bureau Statewide Pharmaceutical Services  
2818-A Mahan Drive  
Tallahassee, FL 32308

Dear Ms. Stacknik:

RE: Letter of Exemption for Purchase of Controlled Substances

I am writing to request a letter of exemption under which I plan to obtain (name the controlled substances) for the purpose of (research, teaching, testing) at Florida International University. The work will involve (describe research projects, testing, etc.). The estimated completion date of this project is (months/years).

My (My department’s) DEA permit number is ______________. All purchases of controlled substances will be made in my name (my department’s name. I am Primary Controlled Substance Officer for my department). I plan to purchase no more than (______) quantity of (____________) and (____________) quantity of (____________) at any one time, and expect to purchase this quantity no more frequently than (______) times per year. Purchases will be made from the following companies:

(List suppliers and, if available Florida License Number)

By signature below, I certify that the above referred controlled substances will be secured, and access restricted to the authorized individuals only. The controlled substances will not be sold and will only be used in (room, building) at Florida International University. I understand that I am responsible for all legal and regulatory compliance issues associated with the purchase, use, storage and disposal of controlled substances I acquire under this exemption letter.

Sincerely,

Your name, Title  
Department  
Florida International University  
Address

Forwarded through: SK Dua, Controlled Substance Safety Officer  
EH&S, FIU

CC:  
Director  
Environmental Health and Safety, FIU
## APPENDIX 7 - Controlled Substance Order/ Receipt Record

Principal Investigator: _______________________________ Department______________________  
Location: ____________________________ DEA License No.: _________________________  
Date: _________________________________ Page _________ of _____________________

<table>
<thead>
<tr>
<th>Ser. No.</th>
<th>Order Date</th>
<th>Receipt Date</th>
<th>Controlled Substance (Name and Code) and Purchase Order (Tracking) No.</th>
<th>Lot No.</th>
<th>Form/Strength</th>
<th>Quantity/Amount</th>
<th>Running Total</th>
</tr>
</thead>
<tbody>
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</table>
APPENDIX 8 - Controlled Substance Disposition Record (CSDR)

**Permit holder:** ______________________  **Dept.** ____________________  **DEA Registration No.** ____________

**CS Name:** ___________________  **Schedule:** _____  **Controlled Substance Tracking No.** ____________  **PO No.:** ____________

**Strength or Dosage Form:** ____________  **Lot/ID No.** ________________  **Manufacturer (Supplier):** ______________________

Total amount of drug (adding all bottles or containers) received from supplier for a lot: _____________________________________

**INSTRUCTIONS:** A separate CSDR is to be maintained for each order of a given drug received from a vendor or supplier (designated by an EH&S Controlled Substance Tracking Number), regardless of the number of containers received. Record the disposition of each unit quantity (i.e. gram or ampoule), and maintain a perpetual balance of the amount you possess. The CSDR may refer to more detailed lab records the exact dosage used (such as given to individual animals), as long as an entry is documented on this record each time a quantity is removed from the container(s) in your possession. Only wasted quantities need verification signatures. Indicate additional pages at the bottom.

<table>
<thead>
<tr>
<th>DATE</th>
<th>QUANTITIES</th>
<th>SIGNATURE</th>
<th>ENTIRE DISPENSED QUANTITY USED (YES/NO), if No attach a sheet for detailed use</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>DISPENSED</td>
<td>WASTED (spilled/expired/disposed)</td>
<td>BALANCE</td>
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Florida International University  
Environmental Health & Safety  
**Controlled Substance Safety Manual**  
Controlled Substance Safety Officer: S.K. Dua  
Origination Date: 06/01/2004  
Revision Number: 3  
Revision Date: 06/02/2014  
Page 1 of 1
## APPENDIX 9 - CONTROLLED SUBSTANCE SPILL RECORD

Use one Record per Unit (vial/bottle, etc.)

| Authorized User/Permit holder: ___________________________ | Department: ___________________________ |
| DEA Registration Number: ___________________________ | Controlled Substance: ___________________________ |
| Schedule No.: ______ | Finished Form: ______ | Manufacturer (Supplier): ___________________________ |
| DEA license No.: ___________________________ | Lot/ID No.: ___________________________ | Purchase Order #: ___________________________ |
| Number of Containers: ______ | Units per Containers: ______ | Quantity in a Unit: ___________________________ |
| Date Received: ______ | Lab Location: ___________________________ |

Date of Spill:
Quantity spilled:
Describe the incident below:

Name: ___________________________ Signature: ___________________________ Date: ______

Verified by:

Name: ___________________________ Signature: ___________________________ Date: ______
APPENDIX 10 - Controlled Substances Biennial Inventory Form

The Biennial Inventory is a requirement of the Federal Drug Enforcement Administration (21 CFR 1304.11).

Please return this form to the Controlled Substances Safety Officer at EH&S

Registrant: ____________________________ Department: ____________________________ Registration No. ______________
Storage location: ____________________________ CS Name ____________________________ Schedule ___________

Instructions: List all Controlled Substances in possession. Fill out separate forms for each CS. Tracking number is a combination of the CS code number, purchase requisition number and the bottle number, if more than one bottle is purchased at a time. The numbers are separated by a hyphen (-). Example: 2270-XXXXX XX- 1, 2270-XXXXX XX- 2, for a Pentobarbital (code 2270), purchase requisition number XXXXXXX and bottle 1 and 2, respectively.
<table>
<thead>
<tr>
<th>Line Item</th>
<th>Lot No.</th>
<th>Tracking No.</th>
<th>Date</th>
<th>Unopened Containers</th>
<th>Opened Containers</th>
<th>Finished Form‡</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Qty</td>
<td>Container size</td>
<td>Qty</td>
</tr>
<tr>
<td>1</td>
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</tbody>
</table>

Number of completed line items in table: __________________________ (write “Zero” if none)

**By signing below,** I agree the information listed here represents the actual amount of controlled substances existing in inventory as of the close of business on ______ ______ (Biennial Inventory Date).

Principal Investigator Signature: __________________________ Date: _______

* Measure in weight (powder or crystals) or volume (liquids) or number of units (tablets or capsules). For opened containers: If the substance is listed in Schedule I or II, make an exact count or measure of the contents. If the substance is listed in Schedule III, IV or V, make an estimated count or measure of the contents unless the container holds more than 1,000 tablets or capsules, in which case an exact count must be made.

‡ For DEA Drug Code and Schedule number, refer to DEA Controlled Substances website (above). DEA Drug Code is a 4-digit number. Controlled Substance Schedule number is expressed in Roman numerals, I through V; N denotes the item is non-narcotic and only applies to schedules II and III.

Florida International University
Environmental Health & Safety
Controlled Substance Safety Manual
Controlled Substance Safety Officer: S.K. Dua
Origination Date: 06/01/2004
Revision Number: 3
Revision Date: 06/02/2014
Page 2 of 2
## APPENDIX 11 - Listed Chemicals Regulated Under the Controlled Substances Act and DEA Code Number

See 21 C.F.R. 1309, 1310, and 1313 for details

### October 31, 2001

- **R** = Reagent
- **P** = Precursor
- **S** = Solvent

### List I

<table>
<thead>
<tr>
<th>Controlled Substance Produced</th>
<th>Thresholds In Kilograms</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Domestic</td>
</tr>
<tr>
<td>1. N-Acetylanthranilic acid $^\zeta$</td>
<td>8522</td>
</tr>
<tr>
<td>2. Anthranilic acid $^\zeta$</td>
<td>8530</td>
</tr>
<tr>
<td>3. Benzaldehyde</td>
<td>8256</td>
</tr>
<tr>
<td>4. Benzyl cyanide</td>
<td>8735</td>
</tr>
<tr>
<td>5. Ephedrine $^\zeta$ $^\zeta$</td>
<td>8113</td>
</tr>
<tr>
<td>6. Ergonovine $^\zeta$</td>
<td>8675</td>
</tr>
<tr>
<td>7. Ergotamine $^\zeta$</td>
<td>8676</td>
</tr>
<tr>
<td>8. Ethylamide</td>
<td>8678</td>
</tr>
<tr>
<td>9. gamma-Butyrolactone (GBL) (other names include: GBL; Dihydro-2 (3H) furanone; 1,2- Butanolid; 1,4- Butanolid; 4-Hydroxybutanoic acid lactone; gamma-hydroxybutyric acid lactone)</td>
<td></td>
</tr>
<tr>
<td>10. Hydriodic acid</td>
<td>6695</td>
</tr>
</tbody>
</table>

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*Florida International University*
*Environmental Health & Safety*
*Controlled Substance Safety Manual*  
Controlled Substance Safety Officer: S.K. Dua
<table>
<thead>
<tr>
<th>11. Hypophosphorous acid&lt;sup&gt;1&lt;/sup&gt; (including ammonium hypophosphite, calcium hypophosphite, iron hypophosphite, potassium hypophosphite, manganese hypophosphite, magnesium hypophosphite, and sodium hypophosphite)</th>
<th>R</th>
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<th>0</th>
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<tbody>
<tr>
<td>12. Isosafrole 8704</td>
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<tr>
<td>13. Methylamine&lt;sup&gt;1&lt;/sup&gt; 8520</td>
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<td>1</td>
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<tr>
<td>14. 3,4-Methylenedioxyphenyl -2-propanone 8502</td>
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<td>4</td>
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<tr>
<td>15. N-Methylephedrine&lt;sup&gt;3&lt;/sup&gt; 8115</td>
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<tr>
<td>16. N-Methylpseudoephedrine&lt;sup&gt;3&lt;/sup&gt; 8119</td>
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<tr>
<td>17. Nitroethane 8256</td>
<td>P</td>
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<td>2.5</td>
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<td>18. Norpseudoephedrine&lt;sup&gt;3&lt;/sup&gt; 8317</td>
<td>P</td>
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<td>2.5</td>
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<tr>
<td>19. Phenylacetic acid&lt;sup&gt;2&lt;/sup&gt; 8791</td>
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<tr>
<td>20. Phenylpropanolamine&lt;sup&gt;x&lt;/sup&gt; &amp;&lt;sup&gt;2&lt;/sup&gt; 1225</td>
<td>P</td>
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<td>2.5</td>
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<tr>
<td>21. Phosphorous (Red) 6795</td>
<td>R</td>
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<td>22. Phosphorous (white or yellow) 6796</td>
<td>R</td>
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<tr>
<td>23. Piperidine&lt;sup&gt;1&lt;/sup&gt; 2704</td>
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<td>0.500</td>
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<td>24. Piperonal 8750</td>
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<td>25. Propionic anhydride 8328</td>
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<td>0.001</td>
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<td>26. Pseudoephedrine&lt;sup&gt;x&lt;/sup&gt; &amp;&lt;sup&gt;2&lt;/sup&gt; 8112</td>
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<tr>
<td>27. Safrole 8323</td>
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</table>
### List II

R = Reagent  
P = Precursor  
S = Solvent

<table>
<thead>
<tr>
<th>#</th>
<th>Chemical</th>
<th>AMP</th>
<th>CCA</th>
<th>CMC</th>
<th>EBR</th>
<th>HMD</th>
<th>MDA</th>
<th>MEB</th>
<th>MNA</th>
<th>NVIDIA</th>
<th>4-MT</th>
<th>PN</th>
<th>PCP</th>
<th>PQ</th>
<th>MEK/MEK</th>
<th>Domestic</th>
<th>Imports &amp; Exports</th>
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</thead>
<tbody>
<tr>
<td>28.</td>
<td>Acetic anhydride 8519</td>
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<td>29.</td>
<td>Acetone 6532</td>
<td>S</td>
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<td>30.</td>
<td>Benzyl chloride 8570</td>
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<td>31.</td>
<td>Ethyl ether 6584</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>S</td>
<td>S</td>
<td>S</td>
<td>S</td>
<td>S</td>
<td>S</td>
<td></td>
<td></td>
</tr>
<tr>
<td>32.</td>
<td>Hydrochloric acid 5 &amp; 6 6545</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>N/C</td>
<td>222.3</td>
</tr>
<tr>
<td>32a. Hydrogen chloride gas 5 &amp; 6</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0</td>
<td>27</td>
<td></td>
</tr>
<tr>
<td>33.</td>
<td>Iodine 6699</td>
<td>R</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.4</td>
<td>N/C</td>
</tr>
<tr>
<td>34.</td>
<td>Methyl ethyl ketone (or MEK or 2-Butanone) 6714</td>
<td>S</td>
<td></td>
<td>S</td>
<td>S</td>
<td>S</td>
<td>S</td>
<td>S</td>
<td>S</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>35.</td>
<td>Methyl isobutyl ketone 6715</td>
<td>S</td>
<td></td>
<td>S</td>
<td>S</td>
<td>S</td>
<td>S</td>
<td>S</td>
<td>S</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>N/C</td>
</tr>
<tr>
<td>36.</td>
<td>Potassium permanganate 6579</td>
<td>R</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>55</td>
<td>500</td>
</tr>
<tr>
<td>37.</td>
<td>Sulfuric acid 6 &amp; 6 6552</td>
<td>R</td>
<td></td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>N/C</td>
<td>347</td>
</tr>
<tr>
<td>38.</td>
<td>Toluene 6594</td>
<td>S</td>
<td>S</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>S</td>
<td>S</td>
<td>S</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>159</td>
<td>1,591</td>
</tr>
</tbody>
</table>

1. and its salts  
2. and its salts and esters  
3. and its salts, optical isomers, and salts of optical isomers  
4. Exports only, to all Western Hemisphere except Canada.  
5. Exports to all South American countries & Panama - Domestic for HCl gas.  
6. Threshold for HCl acid and sulfuric acid is 50 gallons, the equivalent weight in kilograms is shown.  
7. For pseudoephedrine, phenylpropanolamine, and combination ephedrine drug products, see 21 USC §§ 802(39)(A)(iv), 802(45), and Historical and Statutory Notes following 21 USC § 802 on Public Law 104-237 § 041(f).

N/C = Not Controlled.
APPENDIX 12- CONTROLLED SUBSTANCE INSPECTION CHECKLIST

A. Laboratory Specifications:

<table>
<thead>
<tr>
<th>Principal investigator or Lab manager:</th>
<th>Phone:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department:</td>
<td>Bldg/room:</td>
</tr>
<tr>
<td>Storage location/room #:</td>
<td></td>
</tr>
<tr>
<td>Security arrangement:</td>
<td></td>
</tr>
<tr>
<td>Persons present for inspection:</td>
<td>Date of inspection:</td>
</tr>
</tbody>
</table>

B. Controlled Substances (CS) Use and Security

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
<td></td>
<td>All users have completed background check and a statement to that effect is in the EH&amp;S file.</td>
</tr>
<tr>
<td>2.</td>
<td></td>
<td></td>
<td>Entrance door is labeled with the name and phone numbers of the PI/ Lab Manager.</td>
</tr>
<tr>
<td>3.</td>
<td></td>
<td></td>
<td>The stocks of CS are stored in a locked secure facility.</td>
</tr>
<tr>
<td>4.</td>
<td></td>
<td></td>
<td>Prepared solutions of CS are stored and secured against theft/misuse.</td>
</tr>
<tr>
<td>5.</td>
<td></td>
<td></td>
<td>Access to the CS is restricted at all times to only those individuals who are listed on the current Authorization Form on file with the CSSO.</td>
</tr>
<tr>
<td>6.</td>
<td></td>
<td></td>
<td>Locks and/or safe combinations have been rekeyed/ changed whenever personnel changes have occurred.</td>
</tr>
<tr>
<td>7.</td>
<td></td>
<td></td>
<td>All CS are stored according to their labeled instructions.</td>
</tr>
<tr>
<td>8.</td>
<td></td>
<td></td>
<td>All flip-off tops or other types of seals are intact on those items that have not yet been used.</td>
</tr>
<tr>
<td>9.</td>
<td></td>
<td></td>
<td>Receipts/original invoices of the CS have been filed.</td>
</tr>
<tr>
<td>10.</td>
<td></td>
<td></td>
<td>Separate records of Schedule I and II CS have been maintained from schedule III, IV and V CS.</td>
</tr>
<tr>
<td>11.</td>
<td></td>
<td></td>
<td>CS have not been loaned or shared with other laboratories or individuals not otherwise authorized to receive them nor transferred to other accounts.</td>
</tr>
<tr>
<td>12.</td>
<td></td>
<td></td>
<td>Inventory is kept for the receipt/use of Forms 222 used for purchase of schedule I and II CS.</td>
</tr>
<tr>
<td>13.</td>
<td></td>
<td></td>
<td>Photo copy of the order/receipt record received Semi-annually.</td>
</tr>
<tr>
<td>14.</td>
<td></td>
<td></td>
<td>Disposal of any expired materials or empty containers have been via proper channel.</td>
</tr>
<tr>
<td>15.</td>
<td></td>
<td></td>
<td>Records of any material disposed have been maintained and a copy provided to EH&amp;S.</td>
</tr>
<tr>
<td>16.</td>
<td></td>
<td></td>
<td>The Controlled Substance Disposition Record (CSDR) is completed and current.</td>
</tr>
</tbody>
</table>
17. □ □ □ Details of the use of the CS have been documented.

18. □ □ □ A new and/or completed CSDR has been submitted within the last 12 months.

19. □ □ □ Unavoidable loss (material sticking to the hypodermic needle or to the syringe) has been accounted for.

20. □ □ □ A CS Authorization Update has been submitted to EH&S each time an addition or deletion from the list of authorization personnel has been made.

21. □ □ □ All CSDR’s are accurate and current; they account for the quantity utilized for each use and/or any waste or damaged materials.

22. □ □ □ The perpetual balance on the CSDR accurately matches the quantity on hand stated in the Biennial Controlled Substances Inventory Form.

23. □ □ □ All losses or discrepancies in recordkeeping have been promptly reported to EH&S upon discovery.

24. □ □ □ The CSDR(s) form(s) include information about the time, date and quantity of the use of the controlled substance(S) and the names of the lab personnel conducting the experiment.

25. □ □ □ The area users are aware of the administrative requirements, which pertain to controlled substances, as outlined by the use of Controlled Substances Safety Manual in Research and Instruction at FIU.

26. □ □ □ A copy of the FIU CS Safety Manual is on file in the research area.

27. □ □ □ Standard Operating Procedures (SOP) and safety guidelines are developed for use of CS and documented.

Comments:
____________________________________________________________________________
____________________________________________________________________________
____________________________________________________________________________
____________________________________________________________________________
____________________________________________________________________________
____________________________________________________________________________

☐ How and when deficiencies were corrected?
____________________________________________________________________________
____________________________________________________________________________
____________________________________________________________________________

Recommended Action from PI:
☐ No action required
☐ Please respond by __________ regarding implementation status of the recommended measures

Inspected By: _____________________ Signature: ___________ Date: ______
INSTRUCTIONS for DEA Form 41
Registrants Inventory of Drugs Surrendered

1. List the name of the drug in column 1, the number of containers in column 2, the size of each container in column 3, and in column 4 the controlled substance content of each unit described in column 3; e.g., morphine sulfate tabs., 3 pkgs., 100 tabs., 1/4 gr. (16 mg.) or morphine sulfate tabs., 1 pkg., 83 tabs., 1/2 gr. (32mg.), etc.

2. All packages included on a single line should be identical in name, content and controlled substance strength.

3. Prepare this form in quadruplicate. Mail two (2) copies of this form to the Special Agent in Charge, under separate cover. Enclose one additional copy in the shipment with the drugs. Retain one copy for your records. One copy will be returned to you as a receipt. No further receipt will be furnished to you unless specifically requested. Any further inquiries concerning these drugs should be addressed to the DEA District Office which serves your area.

4. There is no provision for payment for drugs surrendered. This is merely a service rendered to registrants enabling them to clear their stocks and records of unwanted items.

5. Drugs should be shipped tape-sealed via prepaid express or certified mail (return receipt requested) to Special Agent in Charge, Drug Enforcement Administration, of the DEA District Office which serves your area. 
The instructions provided on the DEA Form 41 are incorrect. Please disregard instruction number 5. That instruction directs the registrant to ship the drugs to the Special Agent in Charge of the DEA office that serves the registrant’s area. Registrants should send the forms to DEA as detailed in instruction number 3, and await instructions on how to proceed.

PRIVACY ACT INFORMATION
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>PURPOSE:</td>
<td>To document the surrender of controlled substances which have been forwarded by registrants to DEA for disposal.</td>
</tr>
<tr>
<td>ROUTINE USES:</td>
<td>This form is required by Federal Regulations for the surrender of unwanted Controlled Substances. Disclosures of information from this system are made to the following categories of users for the purposes stated.</td>
</tr>
<tr>
<td></td>
<td>A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.</td>
</tr>
<tr>
<td></td>
<td>State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.</td>
</tr>
<tr>
<td>EFFECT:</td>
<td>Failure to document the surrender of unwanted Controlled Substances may result in prosecution for violation of the Controlled Substances Act.</td>
</tr>
</tbody>
</table>

Under the Paperwork Reduction Act, a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Drug Enforcement Administration, FOI and Records Management Section, Washington, D.C. 20537; and to the Office of Management and Budget, Paperwork Reduction Project no. 1117-0007, Washington, D.C. 20503.
The following schedule is an inventory of controlled substances which is hereby surrendered to you for proper disposition.

FROM: (Include Name, Street, City, State and ZIP Code in space provided below.)

<table>
<thead>
<tr>
<th>NAME OF DRUG OR PREPARATION</th>
<th>Number of Containers</th>
<th>CONTENTS (Number of grams, tablets, ounces or other units per container)</th>
<th>Controlled Substance Content, Unit (Each)</th>
<th>DISPOSITION</th>
<th>QUANTITY</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>4</td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>6</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>7</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Registrants will fill in Columns 1, 2, 3, and 4 ONLY.

Signature of applicant or authorized agent

Regrettant’s DEA Number

Regrettant’s Telephone Number

NOTE: CERTIFIED MAIL (Return Receipt Requested) IS REQUIRED FOR SHIPMENTS OF DRUGS VIA U.S. POSTAL SERVICE. See instructions on reverse (page 2) of form.

DEA Form 41 Previous edition dated 7/84 is usable. See instructions on reverse (page 2) of form.
### DEA-41 (6/1986) Pg. 2

<table>
<thead>
<tr>
<th>NAME OF DRUG OR PREPARATION</th>
<th>Number of Containers</th>
<th>CONTENTS (Number of grams, tablets, ounces or other units per container)</th>
<th>Controlled Substance Content, (Each Unit)</th>
<th>FOR DEA USE ONLY</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>DISPOSITION</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>QUANTITY</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>GMS.  MGS.</td>
</tr>
<tr>
<td>17</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5 6 7</td>
</tr>
<tr>
<td>18</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>19</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>21</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>22</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>23</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>24</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The controlled substances surrendered in accordance with Title 21 of the Code of Federal Regulations, Section 1307.21, have been received in _______packages purporting to contain the drugs listed on this inventory and have been: **(1) Forwarded tape-sealed without opening; (2) Destroyed as indicated and the remainder forwarded tape-sealed after verifying contents; (3) Forwarded tape-sealed after verifying contents.**

DATEDESTROYED BY:

**Strike out lines not applicable.**

**INSTRUCTIONS**

1. List the name of the drug in column 1, the number of containers in column 2, the size of each container in column 3, and in column 4 the controlled substance content of each unit described in column 3; e.g., morphine sulfate tabs., 3 pkgs., 100 tabs., 1/4 gr. (16 mg.) or morphine sulfate tabs., 1 pkg., 83 tabs., 1/2 gr. (32 mg.), etc.

2. All packages included on a single line should be identical in name, content and controlled substance strength.

3. Prepare this form in quadruplicate. Mail two (2) copies of this form to the Special Agent in Charge, under separate cover. Enclose one additional copy in the shipment with the drugs. Retain one copy for your records. One copy will be returned to you as a receipt. No further receipt will be furnished to you unless specifically requested. Any further inquiries concerning these drugs should be addressed to the DEA District Office which serves your area.

4. There is no provision for payment for drugs surrendered. This is merely a service rendered to registrants enabling them to clear their stocks and records of unwanted items.

5. Drugs should be shipped tape-sealed via prepaid express or certified mail (return receipt requested) to Special Agent in Charge, Drug Enforcement Administration, of the DEA District Office which serves your area.

**PRIVACY ACT INFORMATION**


PURPOSE: To document the surrender of controlled substances which have been forwarded by registrants to DEA for disposal.

ROUTINE USES: This form is required by Federal Regulations for the surrender of unwanted Controlled Substances. Disclosures of information from this system are made to the following categories of users for the purposes stated.

A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.
B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.

EFFECT: Failure to document the surrender of unwanted Controlled Substances may result in prosecution for violation of the Controlled Substances Act.

Under the Paperwork Reduction Act, a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Drug Enforcement Administration, FOI and Records Management Section, Washington, D.C. 20537; and to the Office of Management and Budget, Paperwork Reduction Project no. 1117-0007, Washington, D.C. 20503.
REPORT OF THEFT OR LOSS OF CONTROLLED SUBSTANCES

Federal Regulations require registrants to submit a detailed report of any theft or loss of Controlled Substances to the Drug Enforcement Administration. Complete the front and back of this form in duplicate. Forward the original and duplicate copies to the nearest DEA Office. Retain the duplicate copy for your records. Some states may also require a copy of this report.

1. Name and Address of Registrant (include ZIP Code)

2. Phone No. (Include Area Code)

3. DEA Registration Number

4. Date of Theft or Loss

5. Principal Business of Registrant (Check one)
   - Pharmacy
   - Distributor
   - Practitioner
   - Manufacturer
   - Methadone Program
   - Other (Specify)

6. County in which Registrant is located

7. Was Theft reported to Police?
   - Yes
   - No

8. Name and Telephone Number of Police Department (Include Area Code)

9. Number of Thefts or Losses Registrant has experienced in the past 24 months

10. Type of Theft or Loss (Check one and complete items below as appropriate)
    - Night break-in
    - Armed robbery
    - Employee pilferage
    - Customer theft
    - Other (Explain)
    - Lost in transit (Complete item 14)

11. If Armed Robbery, was anyone:
    - Killed? No Yes
    - Injured? No Yes
    - (How many)

12. Purchase value to registrant of Controlled Substances taken?

13. Were any pharmaceuticals or merchandise taken?
    - No
    - Yes (Est. Value)

14. IF LOST IN TRANSIT, COMPLETE THE FOLLOWING:
    A. Name of Common Carrier
    B. Name of Consignee
    C. Consignee's DEA Registration Number
    D. Was the carton received by the customer?
       - Yes
       - No
    E. If received, did it appear to be tampered with?
       - Yes
       - No
    F. Have you experienced losses in transit from this same carrier in the past?
       - No
       - Yes (How Many)

15. What identifying marks, symbols, or price codes were on the labels of these containers that would assist in identifying the products?

16. If Official Controlled Substance Order Forms (DEA-222) were stolen, give numbers.

17. What security measures have been taken to prevent future thefts or losses?

PRIVACY ACT INFORMATION

AUTHORITY: Section 361 of the Controlled Substances Act of 1970 (PL 91-513).
PURPOSE: Report theft or loss of Controlled Substances.
ROUTINE USES: The Controlled Substances Act authorizes the production of special reports required for statistical and analytical purposes. Disclosures of information from this form are made to the following categories of users for the purposes stated:
A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.
B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.
EFFECT: Failure to report theft or loss of controlled substances may result in penalties under Section 402 and 403 of the Controlled Substances Act.

Under the Paperwork Reduction Act, a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Records Management Section, Drug Enforcement Administration, Washington, D.C. 20537, and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.
LIST OF CONTROLLED SUBSTANCES LOST

<table>
<thead>
<tr>
<th>Trade Name of Substance or Preparation</th>
<th>Name of Controlled Substance in Preparation</th>
<th>Dosage Strength and Form</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Examples:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Desoxyn</td>
<td>Methamphetamine Hydrochloride</td>
<td>5 mg Tablets</td>
<td>3 x 100</td>
</tr>
<tr>
<td>Demerol</td>
<td>Meperidine Hydrochloride</td>
<td>50 mg/ml Vial</td>
<td>3 x 30 ml</td>
</tr>
<tr>
<td>Robitussin A-C</td>
<td>Codeine Phosphate</td>
<td>2 mg/cc Liquid</td>
<td>1 x Pints</td>
</tr>
</tbody>
</table>

I certify that the foregoing information is correct to the best of my knowledge and belief.

Signature

Title

Date

Florida International University
Environmental Health & Safety
Controlled Substance Safety Manual
Controlled Substance Safety Officer: S.K. Dua

Origination Date: 06/01/2004
Revision Number: 3
Revision Date: 06/02/2014
Page 2 of 2
SAMPLE DEA FORM 222

Place this sample with your blank DEA Form 222s for quick reference. Use this sample and the "7-Step Checklist" (below) to ensure your form is correct before mailing.

<table>
<thead>
<tr>
<th>LINE No.</th>
<th>No. of Packages</th>
<th>Size of Package</th>
<th>Name of Item</th>
<th>National Drug Code</th>
<th>Packages Shipped</th>
<th>Date Shipped</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>250 ML</td>
<td>Socumb, 6 Grain</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>20 ML</td>
<td>Hydromorphone Inj 2 MG</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>5x10ml</td>
<td>Morphine Sulfate 1MG</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>etc.</td>
<td>100</td>
<td>Morphine Tabs, 30 MG</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>.</td>
<td>20 ML</td>
<td>Morphine Sulfate, 15 MG</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>.</td>
<td>25 X 50 ML</td>
<td>Fentanyl CIT, 0.05 MG</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>.</td>
<td>20 ML</td>
<td>Demerol HCL, 100 MG</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>.</td>
<td>30 ML</td>
<td>Demerol HCL, 50 MG</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>.</td>
<td>100</td>
<td>Demerol Tabs, 50 MG</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>.</td>
<td>5</td>
<td>Fentanyl Patches *(see below)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>.</td>
<td>100ml</td>
<td>Sleepaway, 260 mg</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

▲ LAST LINE (must be 10 or less COMPLETED) 4*

SIGNATURE OF PURCHASER OR HIS ATTORNEY OR AGENT 5*

Date Issued: [Place the date in the blank]
DEA Registration No.: [Place the DEA registration number]

Schedules:
Registered as a: Form No.

U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II
SUPPLIER'S COPY 1
* Indicate Fentanyl Patches as 25mcg, 50mcg, 75mcg, or 100mcg

"7-Step Checklist"

1. Name of supplier, address, city and state are correct.
2. Form is dated.
3. Number of packages, size of package, and strength desired is correct.
4. The "NO. OF LINES COMPLETED" block is filled in.
5. Veterinarian has signed the form.
6. Form contains no erasures or alterations.
7. Remove the purchaser's copy (blue copy) and place in your records.
APPENDIX 17

Form-224
APPLICATION FOR REGISTRATION
Under the Controlled Substances Act

INSTRUCTIONS
1. To apply by mail, complete this application. Keep a copy for your records.
2. Print clearly, using black or blue ink, or use a typewriter.
3. Mail this form to the address provided in Section 7, or use enclosed envelope.
4. Include the correct payment amount. FEE IS NON-REFUNDABLE.
5. If you have any questions, call 505-382-9559 prior to submitting your application.

IMPORTANT: DO NOT SEND THIS APPLICATION AND APPLY ONLINE.

REGISTRATION INFORMATION:

$390.00

FEE IS NON-REFUNDABLE

SECTION 1
APPLICANT IDENTIFICATION

Last Name (if registration is for individual) OR Business or Facility Name (if registration is for business entity)

First Name (if registration is for individual)

Middle Initial

Business or Facility Name 2 ("doing business as", continuation of business name, or name of fee exempt institution)

Address Line 1 (street address)

Address Line 2

City

State

Zip Code

Business Phone Number

Business Fax Number

DEBT COLLECTION INFORMATION

Tax Identification Number (if registration is for business)

Social Security Number (if registration is for individual)

Provide SSN or TIN. See note #3 on bottom of page 2

SECTION 2
BUSINESS ACTIVITY

Check one box only

See page 3 for additional instructions

Hospital/Clinic

Ambulance Service

Practitioner (DDS, DMD, DO, DPM, DVM, MD or PHD)

Practitioner Military (DDS, DMD, DO, DPM, DVM, MD or PHD)

Mid-level Practitioner (MLP) (COM, HMD, MP, MD, NP, OD, PA, or RPH)

Central Fill Pharmacy

Teaching Institution

Professional Degree

Practitioners and MLPs: Enter your professional degree from list

Retail Pharmacy

Automated Dispensing System

Euthanasia Technician

FOR Automated Dispensing System

DEA Registration # of Retail Pharmacy for this ADS

An ADS is automatically fee-exempt. Skip Section 6 and Section 7 on page 2. You must attach a notarized affidavit.

SECTION 3
DRUG SCHEDULES

Check all that apply

Schedule II Narcotic

Schedule II Non-Narcotic

Schedule III Narcotic

Schedule III Non-Narcotic

Schedule IV

Schedule V

Check this box if you require official order forms for purchase of Schedule II narcotic/Schedule II non-narcotic controlled substances

Revision Date: 06/02/2014
APPENDIX 17

SECTION 4

Are you currently authorized to prescribe, distribute, dispense, conduct research, or otherwise handle the controlled substance(s) in the schedules for which you are applying under the laws of the state or jurisdiction in which you are operating or propose to operate?

NO

YES

STATE LICENSE(S)

Be sure to include both state license numbers if applicable

State License Number

State Controlled Substance License Number (if required)

SECTION 5

LIABILITY

1. Has the applicant ever been convicted of a crime in connection with controlled substance(s) under state or federal law?

YES

NO

IMPORTANT

All questions in this section must be answered.

2. Has the applicant ever surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted, or denied?

YES

NO

3. Has the applicant ever surrendered (for cause) or had a state professional license or controlled substance registration revoked, suspended, restricted, or placed on probation? Is any such action pending?

YES

NO

4. If the applicant is a corporation (other than a corporation whose stock is owned and traded by the public), association, partnership, or pharmacy, has any officer, partner, stockholder, or proprietor been convicted of a crime in connection with controlled substance(s) under state or federal law or ever surrendered, for cause, or had a federal controlled substance registration revoked, suspended, restricted, or placed on probation?

YES

NO

EXPLANATION OF "YES" ANSWERS

Date(s) of incident:

Location(s) of incident:

Nature of incident:

Result of incident:

Applicant who have answered "YES" to any of the four questions above must provide a statement to explain such answers.

Use this space or attach a separate sheet and return with application.

SECTION 6

CERTIFICATION OF EXEMPTION

from application fee

☐ Check this box if the applicant is a federal, state, or local government operated hospital, institution or official.

The undersigned hereby certifies that the applicant named hereon is a federal, state or local government operated hospital, institution or official, and is exempt from payment of the application fee.

Signature of certifying official (other than applicant):

Date:

Print or type name and title of certifying official:

Telephone No. (required for verification):

SECTION 7

METHOD OF PAYMENT

☐ Check the one form of payment only.

Mail this form with payment to:

Drug Enforcement Administration

P.O. Box 28653

Washington, DC 20038-8083

FEE IS NON-REFUNDABLE

American Express

Discover

Master Card

Visa

Credit Card Number:

Expiration Date:

Signature of Card Holder:

Printed Name of Card Holder:

SECTION 8

APPLICANT'S SIGNATURE

I certify that the foregoing information furnished on this application is true and correct.

Signature of applicant:

Date:

Print or type name and title of applicant

WARNING: Section 912(a)(40)(A) of Title 21, United States Code states that any person who knowingly or intentionally furnishes false or fraudulent information in any application is subject to imprisonment for not more than four years, a fine of not more than $20,000, or both.

1. No registration will be issued unless a completed application form has been received (21 CFR 1301.13).

2. In accordance with the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this collection is 1117-0044. Public reporting burden for this collection of information is estimated to average 12 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

3. The Drug Collection Improvement Act of 1986 (PL 104-134) requires that you furnish your taxpayer identifying number and/or Social Security Number on this application. This number is required for debt collection procedures should your fee become uncollectable.

4. PRIVACY ACT INFORMATION

AUTHORITY:

Section 302 and 303 of the Controlled Substances Act of 1970 (PL 91-513) and Drug Collection Improvement Act of 1996 (PL 104-134) (for taxpayer identifying number and/or social security number). This number will be used for purposes stated in the following:

I. Other federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.

II. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.

III. Persons registered under the Controlled Substances Act (PL 91-513) for the purpose of verifying the registration of customers.

Failure to complete form will result in processing of the application.

NEW - Page 2

Florida International University

Environmental Health & Safety

Controlled Substance Safety Manual

Controlled Substance Safety Officer: S.K. Dua

Origination Date: 06/01/2004

Revision Number: 3

Revision Date: 06/02/2014

Page 2 of 4
## DRUG SCHEDULES

Listed below are examples of the schedules with assigned drug code numbers. If you are in need of additional information, see 21 CFR 1308 or contact the DEA office serving your area.

### SCHEDULE I

<table>
<thead>
<tr>
<th>Basic Classes</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Narcotic &amp; Non-Narcotic</td>
<td>Acodeine</td>
</tr>
<tr>
<td></td>
<td>Morphine</td>
</tr>
<tr>
<td></td>
<td>Codeine</td>
</tr>
<tr>
<td></td>
<td>Hydromorphone</td>
</tr>
<tr>
<td></td>
<td>Meperidine</td>
</tr>
<tr>
<td></td>
<td>Oxycodone</td>
</tr>
<tr>
<td></td>
<td>Oxymorphone</td>
</tr>
<tr>
<td></td>
<td>Meperidine HCL</td>
</tr>
<tr>
<td></td>
<td>Hydrocodone</td>
</tr>
<tr>
<td></td>
<td>Hydromorphone HCL</td>
</tr>
<tr>
<td></td>
<td>Levorphanol</td>
</tr>
<tr>
<td></td>
<td>Diphenoxylate</td>
</tr>
<tr>
<td></td>
<td>Pholcine HCL</td>
</tr>
<tr>
<td></td>
<td>Methadone</td>
</tr>
<tr>
<td></td>
<td>Methadone HCL</td>
</tr>
<tr>
<td></td>
<td>Hydromorphone HCL</td>
</tr>
<tr>
<td></td>
<td>Levorphanol</td>
</tr>
<tr>
<td></td>
<td>Diphenoxylate</td>
</tr>
<tr>
<td></td>
<td>Pholcine HCL</td>
</tr>
<tr>
<td></td>
<td>Methadone</td>
</tr>
<tr>
<td></td>
<td>Methadone HCL</td>
</tr>
<tr>
<td></td>
<td>Hydromorphone HCL</td>
</tr>
<tr>
<td></td>
<td>Levorphanol</td>
</tr>
<tr>
<td></td>
<td>Diphenoxylate</td>
</tr>
</tbody>
</table>

### SCHEDULE II

<table>
<thead>
<tr>
<th>Basic Classes</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Narcotic Basic Classes</td>
<td>Acodeine</td>
</tr>
<tr>
<td></td>
<td>Morphine</td>
</tr>
<tr>
<td></td>
<td>Codeine</td>
</tr>
<tr>
<td></td>
<td>Hydromorphone</td>
</tr>
<tr>
<td></td>
<td>Meperidine</td>
</tr>
<tr>
<td></td>
<td>Oxycodone</td>
</tr>
<tr>
<td></td>
<td>Oxymorphone</td>
</tr>
<tr>
<td></td>
<td>Meperidine HCL</td>
</tr>
<tr>
<td></td>
<td>Hydrocodone</td>
</tr>
<tr>
<td></td>
<td>Hydromorphone HCL</td>
</tr>
<tr>
<td></td>
<td>Levorphanol</td>
</tr>
<tr>
<td></td>
<td>Diphenoxylate</td>
</tr>
<tr>
<td></td>
<td>Pholcine HCL</td>
</tr>
<tr>
<td></td>
<td>Methadone</td>
</tr>
<tr>
<td></td>
<td>Methadone HCL</td>
</tr>
<tr>
<td></td>
<td>Hydromorphone HCL</td>
</tr>
<tr>
<td></td>
<td>Levorphanol</td>
</tr>
<tr>
<td></td>
<td>Diphenoxylate</td>
</tr>
<tr>
<td></td>
<td>Pholcine HCL</td>
</tr>
<tr>
<td></td>
<td>Methadone</td>
</tr>
<tr>
<td></td>
<td>Methadone HCL</td>
</tr>
<tr>
<td></td>
<td>Hydromorphone HCL</td>
</tr>
<tr>
<td></td>
<td>Levorphanol</td>
</tr>
<tr>
<td></td>
<td>Diphenoxylate</td>
</tr>
</tbody>
</table>

Notice to Registrants Making Payment by Check

Authorization to Convert Your Check: If you send us a check to make your payment, your check will be converted into an electronic fund transfer. "Electronic fund transfer" is the term used to refer to the process in which we electronically instruct your financial institution to transfer funds from your account to our account, rather than processing your check. By sending your completed, signed check to us, you authorize us to copy your check and to use the account information from your check to make an electronic fund transfer from your account for the same amount as the check. If the electronic fund transfer cannot be processed for technical reasons, you authorize us to process the copy of your check.

Insufficient Funds: The electronic fund transfer from your account will usually occur within 24 hours, which is faster than a check is normally processed. Therefore, make sure there are sufficient funds available in your checking account when you send us your check. If the electronic fund transfer cannot be completed because of insufficient funds, we may try to make the transfer up to two times.

Transaction Information: The electronic fund transfer from your account will be on the statement account you receive from your financial institution. However, the transfer may be in a different place on your statement than the place where your checks normally appear. For example, it may appear under "other withdraws" or "other transactions." You will not receive your original check back from your financial institution. For security reasons, we will destroy your original check, but we will keep a copy of the check for record-keeping purposes.

Your Rights: You should contact your financial institution immediately if you believe that the electronic fund transfer reported on your account statement was not properly authorized or otherwise incorrect. Consumers have protections under Federal law called the Electronic Fund Transfer Act for unauthorized or incorrect electronic fund transfers.

NEW INST - Page 4

Florida International University
Environmental Health & Safety
Controlled Substance Safety Manual
Controlled Substance Safety Officer: S.K. Dua

Origination Date: 06/01/2004
Revision Number: 3
Revision Date: 06/02/2014
## APPLICATION FOR REGISTRATION

### Under the Controlled Substances Act

**INSTRUCTIONS**
1. To apply by mail, complete this application. Keep a copy for your records.
2. Print clearly, using black or blue ink, or use a typewriter.
3. Mail this form to the address provided in section 7 or use enclosed envelope.
4. Include the correct payment amount. FEE IS NON-REFUNDABLE.
5. If you have any questions, contact 1-800-355-9559 prior to submitting your application.

**REGISTRATION INFORMATION:**

- Fee for 1 year - see section 2
- FEE IS NON-REFUNDABLE

### SECTION 1 APPLICANT IDENTIFICATION

**Last Name (if registration is for Individual) - OR - Business or Facility Name (if registration is for business entity):**

- [ ]

**First Name (if registration is for Individual):**

- [ ]

**Middle Initial:**

- [ ]

**Business or Facility Name 2 ("doing business as", continuation of business name, or name of fee exempt institution):**

- [ ]

**Address Line 1 (street address):**

- [ ]

**Address Line 2:**

- [ ]

**City:**

- [ ]

**State:**

- [ ]

**Zip Code:**

- [ ]

**Business Phone Number:**

- [ ]

**Business Fax Number:**

- [ ]

### DEBT COLLECTION INFORMATION

**Mandatory pursuant to Debt Collection Improvements Act:**

- [ ]

### SECTION 2 BUSINESS ACTIVITY

**Check one box only:**

- [ ] Analytical Lab...
- [ ] Researcher w/Sched I...
- [ ] Researcher w/Sched II...
- [ ] Researcher-Dog...
- [ ] Importer...
- [ ] Distributor...
- [ ] Reverse Distributor...
- [ ] Manufacturer...
- [ ] Manufacturer BULK...
- [ ] Exporter...

**Provide SSB or TIN:**

- [ ]

**See note #3 on bottom of page 3**

### SECTION 3 DRUG SCHEDULES

**Check all that apply:**

- [ ] Schedule I
- [ ] Schedule II
- [ ] Schedule III Non-Narcotic
- [ ] Schedule III Narcotic
- [ ] Schedule IV
- [ ] Schedule V

**Enter drug codes on page 2:**

- [ ]

### MANUFACTURERS ONLY

**Mark each box with an "X" to indicate which drug schedule is handled in each manufacturing stage:**

- [ ] 1. Bulk synthesis / extraction
- [ ] 2. Dosage form manufacture
- [ ] 3. Package / Repackage
- [ ] 4. Non-human consumption

---

*Florida International University*

*Environmental Health & Safety*

**Controlled Substance Safety Manual**

*Controlled Substance Safety Officer: S.K. Dua*

*Origination Date: 06/01/2004*

*Revision Number: 3*

*Revision Date: 06/02/2014*

*Page 1 of 4*
### Appendix 18

**Controlled Substance Safety Manual**

*Florida International University*

**Origination Date:** 06/01/2004  
**Revision Number:** 3  
**Revision Date:** 06/02/2014

---

#### Schedule I

<table>
<thead>
<tr>
<th>Narcotic &amp; Non-Narcotic Basic Classes</th>
<th>Code</th>
<th>Bulk?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anabolic Steroids</td>
<td>4060</td>
<td></td>
</tr>
<tr>
<td>Benzphetamine</td>
<td>1228</td>
<td></td>
</tr>
<tr>
<td>Butelbital</td>
<td>2176</td>
<td></td>
</tr>
<tr>
<td>Caffeine</td>
<td>2160</td>
<td></td>
</tr>
<tr>
<td>Codeine</td>
<td>5064</td>
<td></td>
</tr>
<tr>
<td>Gamma-Hydroxybutyric Acid (GHB)</td>
<td>20/2</td>
<td></td>
</tr>
<tr>
<td>Hydrocodone up to 10 mg/5 ml or other</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ketamine</td>
<td>7200</td>
<td></td>
</tr>
<tr>
<td>Naltrexone</td>
<td>9400</td>
<td></td>
</tr>
<tr>
<td>Pentobarbital dosages forms</td>
<td>2271</td>
<td></td>
</tr>
<tr>
<td>Phenmetrazine</td>
<td>1515</td>
<td></td>
</tr>
<tr>
<td>Thiopental</td>
<td>2329</td>
<td></td>
</tr>
</tbody>
</table>

#### Schedule II

<table>
<thead>
<tr>
<th>Narcotic &amp; Non-Narcotic Basic Classes</th>
<th>Code</th>
<th>Bulk?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol</td>
<td>7400</td>
<td></td>
</tr>
<tr>
<td>Amphetamine</td>
<td>1100</td>
<td></td>
</tr>
<tr>
<td>Cocaine</td>
<td>5041</td>
<td></td>
</tr>
<tr>
<td>Codeine</td>
<td>5000</td>
<td></td>
</tr>
<tr>
<td>Codeine hydrochloride (bulk)</td>
<td>5273</td>
<td></td>
</tr>
<tr>
<td>Diphenoxylate</td>
<td>9110</td>
<td></td>
</tr>
<tr>
<td>Diphenylpropylamine (bulk)</td>
<td>9000</td>
<td></td>
</tr>
<tr>
<td>Diphenylpropylamine (bulk)</td>
<td>9000</td>
<td></td>
</tr>
<tr>
<td>Etofylline</td>
<td>8556</td>
<td></td>
</tr>
<tr>
<td>Hydrocodone</td>
<td>5193</td>
<td></td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>5100</td>
<td></td>
</tr>
<tr>
<td>Levonorgestrel</td>
<td>5220</td>
<td></td>
</tr>
<tr>
<td>Methadone</td>
<td>5250</td>
<td></td>
</tr>
<tr>
<td>Methcaine</td>
<td>5250</td>
<td></td>
</tr>
<tr>
<td>Methamphetamine</td>
<td>7762</td>
<td></td>
</tr>
<tr>
<td>Methamphetamine</td>
<td>1724</td>
<td></td>
</tr>
<tr>
<td>Methamphetamine</td>
<td>6360</td>
<td></td>
</tr>
<tr>
<td>Narcotic &amp; Non-Narcotic Basic Classes</td>
<td>6639</td>
<td></td>
</tr>
<tr>
<td>Opium (powdered)</td>
<td>6660</td>
<td></td>
</tr>
<tr>
<td>Opium (raw)</td>
<td>6660</td>
<td></td>
</tr>
<tr>
<td>THC (Delta-9)</td>
<td>6763</td>
<td></td>
</tr>
<tr>
<td>Thaline</td>
<td>6213</td>
<td></td>
</tr>
<tr>
<td>Thaline</td>
<td>6213</td>
<td></td>
</tr>
<tr>
<td>Trazodone</td>
<td>6213</td>
<td></td>
</tr>
<tr>
<td>Trazodone</td>
<td>6213</td>
<td></td>
</tr>
<tr>
<td>Trazodone</td>
<td>6213</td>
<td></td>
</tr>
<tr>
<td>Trazodone</td>
<td>6213</td>
<td></td>
</tr>
</tbody>
</table>

#### Schedule III

<table>
<thead>
<tr>
<th>Narcotic &amp; Non-Narcotic Basic Classes</th>
<th>Code</th>
<th>Bulk?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Codeine formulation product 90 mg/5 ml</td>
<td>5064</td>
<td></td>
</tr>
<tr>
<td>Chloral hydrate</td>
<td>2450</td>
<td></td>
</tr>
<tr>
<td>Chloral hydrate</td>
<td>2450</td>
<td></td>
</tr>
<tr>
<td>Chlorazepate</td>
<td>2744</td>
<td></td>
</tr>
<tr>
<td>Clozapine</td>
<td>2737</td>
<td></td>
</tr>
<tr>
<td>Clozapine</td>
<td>2737</td>
<td></td>
</tr>
<tr>
<td>Diazepam</td>
<td>2765</td>
<td></td>
</tr>
<tr>
<td>Fluoxetine</td>
<td>2767</td>
<td></td>
</tr>
<tr>
<td>Lorazepam</td>
<td>2885</td>
<td></td>
</tr>
</tbody>
</table>

#### Schedule IV

<table>
<thead>
<tr>
<th>Narcotic &amp; Non-Narcotic Basic Classes</th>
<th>Code</th>
<th>Bulk?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Codeine preparations 200 mg/10 ml or 100 gm</td>
<td>5102</td>
<td></td>
</tr>
<tr>
<td>Codeine preparations 200 mg/10 ml or 100 gm</td>
<td>5102</td>
<td></td>
</tr>
<tr>
<td>Diphenoxylate preparations 2.6 mg/25 mg or SLO</td>
<td>5171</td>
<td></td>
</tr>
<tr>
<td>Diphenoxylate preparations 2.6 mg/25 mg or SLO</td>
<td>5171</td>
<td></td>
</tr>
<tr>
<td>Pyrovalerone</td>
<td>1440</td>
<td></td>
</tr>
</tbody>
</table>

**Write in Additional Drug Codes**

You may write in additional drug codes in this section. Attach a separate sheet if additional drug codes must be reported.

---

NEW - Page 2