



UNIVERSITY OF
NOTRE DAME

Controlled Substance Program



Controlled Substance Program

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1.0 Purpose

This procedure is to provide guidance and resource information for University faculty and staff who utilize controlled substances in teaching and research. This procedure outlines the compliance requirements with U.S. Drug Enforcement Administration (DEA) and the Indiana Board of Pharmacy. Compliance with federal and state regulations is accomplished by proper procurement, distribution, use, inventory, recordkeeping, storage and disposal of controlled substances used in research and teaching protocols.

2.0 Scope

This document applies to the use of controlled substances in research laboratories at the University.

3.0 Responsibilities

3.1. Principal Investigators (PIs) who are registered controlled substance users shall have responsibility for:

- 3.1.1. Ensuring that Controlled Substances are licensed and registered for use in their labs and maintained in the manner that is indicated on the license.
- 3.1.2. Working within the scope of the current license/registration.
- 3.1.3. Managing the use of Controlled Substances in their labs.
- 3.1.4. Understanding and complying with all federal and state laws.
- 3.1.5. Restricting access only to users they authorize.
- 3.1.6. Maintaining proper record keeping in accordance with this procedure.
- 3.1.7. Properly disposing of Controlled Substances in accordance with Section 15 of this procedure.
- 3.1.8. Reporting any theft or loss of controlled substances in accordance with Section 13 of this procedure.
- 3.1.9. Designating appropriate authorized users to carry out the duties under the Controlled Substance Program on their behalf (see Appendix F).
- 3.1.10. Notifying Notre Dame Research Compliance (NDRC) of inspections and notifications of inspections by the DEA or Indiana Board of Pharmacy.
- 3.1.11. Working through ND Research Compliance (NDRC) on communications with the DEA or Indiana Board of Pharmacy.

3.2. Authorized Users shall have responsibility for:

- 3.2.1. Understanding and complying with all federal and state laws regarding the use of controlled substances as well as adhering to university and department requirements.
- 3.2.2. Working only within the scope of the registration/license/protocol for which they are authorized.

3.3. Notre Dame Research Compliance shall have responsibility for:

- 3.3.1. Developing and maintaining the Controlled Substances Program and providing guidance to individuals on licensing and registration, procurement, use, record keeping, storage, security and disposal of controlled substances used in research.
- 3.3.2. Serving as the primary point of contact between the university and IBOP and DEA regarding compliance with state and federal requirements.
- 3.3.3. Conducting semi-annual audits of laboratories that use Controlled Substances.
- 3.3.4. Providing informational materials to licensees and authorized users.
- 3.3.5. Assisting licensees and authorized users in the disposal of Controlled Substances and providing options for proper disposal.
- 3.3.6. Maintaining a record of all researchers that hold DEA registrations at the University of Notre Dame.
- 3.3.7. Reporting or referring any known loss, theft or diversion of controlled substances to Notre Dame Security Police. It remains the responsibility of the licensee to notify both the DEA and Indiana Board of Pharmacy of any loss, theft and diversion.

3.4. Notre Dame Security Police shall have responsibility for:

- 3.4.1. Assisting RMS and the Controlled Substance License holder as the sworn officer observing and acknowledging the destruction of a controlled substance.
- 3.4.2. Investigating all matters regarding the loss, theft or diversion of controlled substances used in research at the university.
- 3.4.3. Notifying NDRC of any known loss, theft or diversion and enlist their assistance as necessary.

4.0 Definitions (see Appendix A)

5.0 Controlled Substance Registration and Licensing

- 5.1. Any person who engages in research with controlled substances shall acquire an Indiana Board of Pharmacy (IBOP) controlled substance license and a DEA registration to receive, distribute, store, and administer controlled substances for research purposes at the University.
- 5.2. No person required to be registered shall engage in any activity for which registration is required until the application for registration is granted and a Certificate of Registration is issued and received by IBOP and DEA.



- 5.3. The Indiana Board of Pharmacy license shall be obtained before applying for a DEA registration.
- 5.4. The Indiana Board of Pharmacy license and DEA registration shall be active for the location (building and room number) where controlled substances are delivered, stored, and administered. A separate license is required for each principal place of business.
- 5.5. The activities and controlled substances used shall be limited to those described in the protocol(s) approved in the Indiana Board of Pharmacy Controlled Substance Registration and DEA Registration.

6.0 Initial Application

6.1. Indiana Board of Pharmacy Application

- 6.1.1. Any person considering obtaining an Indiana Board of Pharmacy Controlled Substance Registration (CSR) number shall first contact Notre Dame Research Compliance (574-631-1461) for guidance and information on the IBOP license application requirements.
- 6.1.2. NDRC shall consult with the person considering applying for a license to confirm that the substances to be used are not exempt from regulations by the federal government (for exempted lists, visit http://www.deadiversion.usdoj.gov/21cfr/cfr/1308/1308_24.htm), and that no alternative substances could be used (thus not requiring to apply for a license.)
- 6.1.3. If the proposed substances used are not listed on the DEA's exempt list and alternative substitutes are not feasible, the applicant shall prepare the application and submit it, and all other required documentation, to Notre Dame Research Compliance to review for completeness and accuracy. Upon
- 6.1.4. NDRC approval, the applicant shall submit the application, and all other required documentation, to IBOP and provide a copy of the final submission to NDRC (see Appendix B).
- 6.1.5. Upon receipt of a completed new application, fee (if applicable) and all requested documentation, the IBOP office will contact the individual listed on the application to schedule an on-site inspection prior to issuance of any license. Refer to Appendix D for on-site inspection items.
- 6.1.6. Notification of a scheduled inspection by the Indiana Board of Pharmacy shall be reported to Notre Dame Research Compliance (574-631-1461) prior to the inspection. NDRC shall participate on all on-site inspections conducted by IBOP.
- 6.1.7. Once the application is approved by the IBOP, the licensee shall be issued a Controlled Substance Registration number and license. The licensee shall provide NDRC a copy of the Controlled Substance Registration and, after

consulting with NDRC for guidance and information on the DEA license application requirements, shall then apply for DEA registration.

6.2. Drug Enforcement Agency Application

- 6.2.1. The licensee shall prepare an application for DEA registration and submit it to NDRC for review for completeness and accuracy. See Appendix G for example cover letter.
- 6.2.2. Upon NDRC approval, the applicant shall submit the application to DEA and provide a copy of the final submission to NDRC (see Appendix C).
- 6.2.3. Upon receipt of a completed new application, fee and all requested documentation, the DEA office may contact the individual listed on the application to schedule an on-site inspection prior to issuance of any license. Refer to Appendix D for on-site inspection items.
- 6.2.4. Notification of a scheduled inspection by the Drug Enforcement Agency shall be reported to Notre Dame Research Compliance (574-631-1461) prior to the inspection. NDRC shall participate on all on-site inspections conducted by the DEA.
- 6.2.5. Once the application is approved by the DEA, the licensee shall receive a certificate and DEA number. The licensee shall provide a copy of the certificate DEA number to NDRC.

7.0 License Renewal

7.1. Indiana Board of Pharmacy Renewal Process

- 7.1.1. Controlled Substances Registrations (CSR) for non-practitioners and facilities expire December 31 of odd-numbered years and shall be renewed every two years by the licensee (not NDRC).
- 7.1.2. License renewal shall be completed online at MyLicense (<https://mylicense.in.gov/EGov/Login.aspx>).
- 7.1.3. Once the renewal process is complete, the licensee will be issued a certificate with revised expiration dates. The licensee shall maintain copies of renewals with all other required controlled substance records. The licensee shall provide NDRC with a copy of the new registration information.

7.2. Drug Enforcement Agency Renewal Process

- 7.2.1. Researchers already possessing licensure shall renew their DEA registration every year by completing and submitting the online DEA Form 225a (<https://www.deadiversion.usdoj.gov/webforms/jsp/regapps/common/renewalAppLogin.jsp>).
- 7.2.2. Once the renewal process is complete, the licensee shall be issued a certificate with revised expiration dates. The licensee shall maintain copies of renewals with all other required controlled substance records. The licensee shall provide NDRC a copy of the new registration information.

8.0 Modification of Registration

8.1. Indiana Board of Pharmacy:

- 8.1.1. After notification to NDRC, any licensee may apply to modify his/her registration to authorize the handling of additional controlled substances or to change the name or address by submitting a letter of request to the Indiana Board of Pharmacy.
- 8.1.2. The letter shall contain the licensee's name, address, registration number, and the substances and/or schedule to be added to his registration or the name or address and shall be signed by the same person who signed the most recent application for registration or re-registration.
- 8.1.3. If the licensee seeks to handle additional Schedule I controlled substances, the licensee shall:
 - Obtain a Federally approved research protocol describing each research project involving the additional substances, or
 - Provide the IBOP with two copies of a statement describing the nature, extent, and duration of such instructional activities, as appropriate.
- 8.1.4. The request for modification shall be handled in the same manner as an application for registration with copies of all related documentation provided to NDRC.
- 8.1.5. If the modification of registration is approved, the Indiana Board of Pharmacy will issue a new certificate of registration to the licensee, who shall maintain it with the old certificate of registration until the expiration date. The licensee shall provide a copy of the new certificate to NDRC.

8.2. Drug Enforcement Agency:

- 8.2.1. After notification to NDRC, any licensee may apply to modify his/her registration to authorize the handling of additional controlled substances or to change his/her name or address by submitting a written request to the DEA Field Office or submitted on-line at (<https://www.deadiversion.usdoj.gov/webforms/jsp/regapps/common/updateLogin.jsp>).
- 8.2.2. The request shall contain:
 - The licensee's name, address, and registration number as printed on the certificate of registration;
 - The substances and/or schedules to be added to the registration or the new name or address; and
 - A signature.
- 8.2.3. If the licensee is seeking to handle additional controlled substances listed in Schedule I for the purpose of research or instructional activities, the licensee shall attach three copies of a research protocol describing each research project involving the additional substances, or two copies of a statement



describing the nature, extent, and duration of such instructional activities, as appropriate.

- 8.2.4. Copies of all documentation submitted to DEA shall be provided to NDRC.
- 8.2.5. If the modification is approved, the DEA will issue a new certificate of registration and, if requested, new Schedule I-II order forms (DEA Form 222) when applicable. The licensee shall provide a copy of the new certificate to NDRC.

9.0 Denial, Suspension or Revocation of Registration

- 9.1. Under the Controlled Substance Act, the DEA has the authority to deny, suspend, or revoke a DEA registration upon a finding that the licensee has:
 - 9.1.1. Materially falsified any application filed.
 - 9.1.2. Been convicted of a felony relating to a controlled substance or a List I chemical.
 - 9.1.3. Had their state license or registration suspended, revoked, or denied.
 - 9.1.4. Committed an act which would render the DEA registration inconsistent with the public interest.
 - 9.1.5. Been excluded from participation in a Medicaid or Medicare program.

10.0 Termination of Registration

- 10.1. Any licensee desiring to discontinue business activities altogether or with respect to controlled substances (without transferring such business activities to another person) shall first notify Notre Dame Research Compliance and return for cancellation his/her certificate of registration, and any unexecuted order forms (DEA Form 222) in his/her possession, to the Registration Unit, Drug Enforcement Administration (see mailing address below). Any controlled substances in his/her possession shall be disposed of in accordance with Section 15 of this procedure. Licensee shall also notify the Indiana Board of Pharmacy (IBOP) at the address below.

DEA Mailing Address:
Drug Enforcement Administration, Attn: Administrator
8701 Morrissette Drive
Springfield, VA 22152

IBOP Mailing Address:
Indiana Board of Pharmacy
402 West Washington Street, Room W072
Indianapolis, Indiana 46204

- 10.2. Any licensee desiring to discontinue business activities altogether or with respect to controlled substances (by transferring such business activities to another person) shall submit in person or by registered or certified mail, return receipt requested, to



the Special Agent in Charge in his/her area, at least 14 days in advance of the date of the proposed transfer (unless the Special Agent in Charge waives this time limitation in individual instances), the following information:

- 10.2.1. The name, address, registration number, and authorized business activity of the registrant discontinuing the business (registrant-transferor);
 - 10.2.2. The name, address, registration number, and authorized business activity of the person acquiring the business (registrant-transferee);
 - 10.2.3. Whether the business activities will be continued at the location registered by the person discontinuing business, or moved to another location (if the latter, the address of the new location should be listed);
 - 10.2.4. Whether the registrant-transferor has a quota to manufacture or procure any controlled substance listed in Schedule I or II (if so, the basic class or class of the substance should be indicated); and
 - 10.2.5. The date on which the transfer of controlled substances will occur.
- 10.3. Any termination of registration by a licensee shall prompt an internal NDRC audit to ensure all requirements of this section and [21 CFR 1301.52](#) are satisfied.

11.0 Purchasing & Receiving Controlled Substances

- 11.1. Only researchers with a current IBOP license and DEA registration shall purchase controlled substances for use in research.
- 11.2. All purchases of controlled substances shall be accompanied by registration and license information and delivered solely to the address on the DEA registration.
- 11.3. Ordering of controlled substances for research shall be done only through approved distributors or manufacturers approved to distribute controlled substances. A sample list identifying acceptable suppliers is provided in Appendix E.
- 11.4. Schedule I or II Substances
 - 11.4.1. These controlled substances shall only be ordered by the licensee.
 - 11.4.2. Any person licensed and registered to conduct research with Schedule I or II controlled substances shall complete and send, in triplicate, DEA Form 222. This form shall only be obtained through the DEA. See Appendix E Instructions for Ordering Controlled Substances.
 - 11.4.3. Any DEA Form 222s with corrections shall be voided and kept on file with the rest of the DEA Form 222 records. Voided forms shall not be discarded as all forms must be accounted for.
 - 11.4.4. A copy of the executed DEA Form 222 shall be maintained and kept separate from all other records.
 - 11.4.5. Unused DEA Order Forms shall be kept in a secure location to prevent theft.

11.5. Schedule III-IV Substances

- 11.5.1. These controlled substances shall only be ordered by the licensee or an authorized agent of the licensee. These substances shall be purchased by contacting a commercial supplier. See Appendix E Instructions for Ordering Controlled Substances.
- 11.5.2. A copy of the licensee's DEA registration shall be provided to the supplier. Otherwise, the supplier will not process the order request.

11.6. Invoices for schedules I and II shall be maintained separately from schedules III-V.

11.7. Purchasing records shall contain the following and a record of receipt log maintained for all controlled substances (Appendix H):

- 11.7.1. A handwritten date and signature of receipt on the invoice;
- 11.7.2. The name, address, and DEA number of the company from which the controlled substance was purchased;
- 11.7.3. The name, address, and DEA number of the purchaser;
- 11.7.4. The name of the controlled substance purchased and package size;
- 11.7.5. The size and strength of the controlled substance purchased;
- 11.7.6. The amount purchased, which shall also match the amount received.

12.0 Storage, Security & Access

12.1. All licensees shall provide effective physical security controls and operating procedures to guard against theft and diversion of controlled substances.

12.2. Access to controlled substances shall be restricted to the minimum number of employees needed. Those employees having access shall be listed with documentation provided to IBOP and DEA. Records of those having access shall be maintained with the licensee's controlled substance records (see Appendix F). This access list shall be revised and updated whenever persons are added or removed.

12.3. Regardless of schedules, all controlled substances shall be kept under lock and key, in a substantially constructed cabinet or safe, and accessible only to authorized personnel. Storage cabinets must be heavy enough to be essentially immovable, or built into the structure of the building. Doors must not be prone to being forced opened by prying tools, or easily removable at the hinges.

12.4. Controlled substances shall be kept locked in their storage locations except for the time required for authorized staff to remove, work with, and replace them.

12.5. The room in which the storage container is located shall have limited access during working hours and provide security (e.g., locked door or locked door and alarm)



after hours. The controlled substance shall not be located near a glass panel where they are visible from the outside.

- 12.6. An overall evaluation of the security measures in place shall be made by the IBOP and DEA during the application review to ensure the controlled substances are stored securely.
- 12.7. Controlled substances listed in Schedule I-V shall be stored in a securely locked, substantially constructed cabinet ([21 CFR 1301.75](#)).
- 12.8. The DEA may require a vault meeting the design specification requirements, including thickness, type of material used, and an alarm system for larger storage quantities of Schedule I and II substances (DEA does not provide a definition for "larger" and the DEA will determine based upon all the security measures in place).
- 12.9. Licensees authorized to possess carfentanil, etorphine hydrochloride, and diprenorphine shall store these substances in a safe or steel cabinet equivalent to a U.S. Government Class V security container.
- 12.10. A licensee shall not employ an agent or individual who has had his or her application for registration with DEA denied or revoked at any time, and who, as a result of employment, will have access to controlled substances.
- 12.11. Any applicant or licensee who wants to know whether or not a proposed security system substantially complies with DEA requirements as prescribed by the regulations shall submit plans, blueprints and/or sketches of the proposed system to the appropriate DEA Field Office. Even with preliminary Field Office approval of the proposed system, final approval shall only be given at the time the system is completed and can be inspected at the location where it is to be used.
- 12.12. Physical security controls and procedures shall be expanded and extended accordingly if existing systems become inadequate as a result of a controlled substance being transferred to a different schedule, being placed in a schedule, or if there is a significant increase in the quantity of controlled substances in the possession of a licensee during normal business operations.

13.0 Theft, Loss, or Unauthorized Use

- 13.1. Thefts, suspected thefts or any significant loss of any controlled substance shall be reported immediately to Notre Dame Security Police and Research Compliance. In addition, any unauthorized person who gains access to a controlled substance for the purpose of diversion or theft shall be reported to the Notre Dame Security Police and shall be subject to university discipline policies.



13.2. The licensee shall notify in writing the Indiana Board of Pharmacy of any theft or significant loss of any controlled substances upon discovery of such theft or loss. Thefts must be reported whether or not the controlled substances are subsequently recovered and/or the responsible parties are identified and action taken against them.

13.3. Licensees shall also notify the DEA Field Division Office in their area, in writing, of the theft or significant loss of any controlled substance within one business day of discovery of such loss or theft. The licensee shall also complete and submit to the Field Division Office in their area, DEA Form 106, "Report of Theft or Loss of Controlled Substances" regarding the theft or loss (<https://www.deadiversion.usdoj.gov/webforms/dtlLogin.jsp>). The address for the DEA Field Division Office is:

DEA Diversion
Merrillville Resident Office
1571 East 85th Avenue, Suite 200
Merrillville, IN 46410

13.4. DEA controlled substance licensees are strongly encouraged to complete and submit the DEA Form 106 online (<https://www.deadiversion.usdoj.gov/webforms/dtlLogin.jsp>). If a licensee does not have internet access, a paper copy of the DEA-106 form can be requested by writing to:

Drug Enforcement Administration
Attn: Regulatory Section/ODG
8701 Morrissette Drive
Springfield, VA 22152

13.5. When a diversion has occurred, an inspection from the DEA is likely to occur. The facility and personnel security measures outlined above shall be followed to reduce the chances of loss, theft, or misuse of controlled substances.

14.0 Abandoned Substances

14.1. Under no circumstances are controlled substances to be abandoned by a DEA registrant.

14.2. A licensee shall ensure all substances are properly accounted for and disposed of at the time of termination of registration.

14.3. However, in the event that an abandoned controlled substance is discovered, NDRC shall be notified immediately upon discovery.

- 14.4. The licensee's department shall make every effort to contact the licensee. If unsuccessful, RMS shall provide guidance to the department on how to handle disposal.
- 14.5. Controlled substances left by a licensee (even if their license is expired or if they have left the university) are still legally the licensee's responsibility. Any licensee that abandons a controlled substance may be subject to the civil penalties outlined in the [United States Code \(USC\) Codified CSA, Section 842](#).

15.0 Destruction of Controlled Substances

- 15.1. Licensees shall account for all controlled substances upon their disposal.
- 15.2. Substances that are expired, unused, or contaminated substances shall be stored under lock and key until ready for disposal.
- 15.3. When substances are ready for disposal, the licensee shall notify RMS and prepare DEA Form 41 (http://www.deadiversion.usdoj.gov/21cfr_reports/surrend/). The form shall be completed in its entirety with exception to listing the names of witnesses for destruction and a copy forwarded to Risk Management and Safety for review.
- 15.4. The date of destruction noted on DEA Form 41 shall be at a minimum two weeks beyond the current date in which the form is submitted to the DEA Field Office. When identifying the date of destruction, the licensee shall coordinate with RMS to ensure availability on the date decided upon.
- 15.5. After review and approval from RMS, the licensee shall submit DEA Form 41 either electronically or via fax to the local DEA Field Office for review.
- 15.6. Typically, the DEA Field Office will contact the licensee approving of the disposal.
- 15.7. The destruction of the controlled substance shall only be conducted on the day noted on the DEA Form 41. If destruction cannot be performed on the day listed, then a separate DEA Form 41 shall be re-submitted to the local DEA Field Office with a revised destruction date.
- 15.8. During the destruction process, there shall be at minimum two witnesses to the destruction, of which, one shall be a sworn officer from NDSP.
- 15.9. RMS shall perform the physical destruction process by dispensing the controlled substances into a chemical solution comprised of mixed solvents. After dispensing any chemical controlled substances, each container shall be rinsed with water and the rinsate poured into the disposal container.

15.10. Upon completion of disposal, both witnesses shall print, sign and date DEA Form 41. The licensee shall fax two copies of the form to the local DEA Field Office, place one copy with the licensee's controlled substance records, and provide RMS with one copy.

16.0 **Inventorying of Controlled Substances**

- 16.1. Every licensee shall maintain complete and accurate accounting of all controlled substances, from the time they are manufactured or received until they are administered, disposed of or returned (see Appendix J).
- 16.2. Inventories and records shall be kept at the premises where the licensed activity is conducted, and shall be readily available for inspections for a minimum of two years.
- 16.3. Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the licensee.
- 16.4. Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the licensee or in such form that the information required is readily retrievable from the ordinary business records of the licensee.
- 16.5. Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location for at least two years from the date that the inventory was conducted.
- 16.6. Each inventory shall contain the following information:
- 16.6.1. Whether the inventory was taken at the beginning or close of business;
 - 16.6.2. Names of controlled substances;
 - 16.6.3. Each finished form of the substances (e.g., 100 milligram tablet);
 - 16.6.4. The number of dosage units of each finished form in the commercial container (e.g., 100 tablet bottle);
 - 16.6.5. The number of commercial containers of each finished form (e.g., four 100 tablet bottles); and
 - 16.6.6. Disposition of the controlled substances.
- 16.7. Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the licensee.
- 16.8. A separate inventory shall be made for each registered location and each independent activity registered.

- 16.9. The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.
- 16.10. Initial inventory date – Every licensee required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the dispensing of controlled substances. In the event a person commences business with no controlled substances on hand, he/she shall record this fact as the initial inventory. This shall be done when the Licensee receives their initial DEA registration and shall indicate that there are no controlled substances on hand.
- 16.11. Biennial inventory date – After the initial inventory is taken, the licensee shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory shall be taken on any date which is within two years of the previous biennial inventory date (see Appendix K).
- 16.12. Inventory date for newly controlled substances – When adding a new substance to any schedule of controlled substances, each licensee shall take an inventory of all stocks of the substance on hand.
- 16.13. Each person registered or authorized to dispense or conduct research with controlled substances shall document his/her inventory using Appendix I.
- 16.14. Every licensee shall maintain all records and inventories for at least 2 years from the date of such inventory or records.

17.0 Training

- 17.1. All licensees and persons working under the licensee shall be familiar with and adhere to all federal and state controlled substances rules and regulations.
- 17.2. Licensees, or their designees, shall provide appropriate training to all Authorized Users working under the license.
- 17.3. This training shall include a review of this procedure and safety information specific to the substance and application.

18.0 Internal Auditing

- 18.1. NDRC shall conduct semi-annual audits of laboratories that use Controlled Substances to evaluate and assess the laboratory's compliance with applicable state and federal requirements.



- 18.2. The audits shall include one paperwork audit and one field audit per year for each applicable laboratory.
- 18.3. Participation from the licensee or designee shall only be required during field audits.
- 18.4. Audits shall be documented providing details of inspection results, including corrective action recommendations.
- 18.5. Audit reports shall be distributed to the licensee, Director of Research Compliance and Notre Dame Research.

19.0 Record Retention

- 19.1. Each licensee shall maintain controlled substance records and documents in accordance with Appendix L.
- 19.2. Failure to comply with federal controlled substance recordkeeping requirements may result in a civil penalty not to exceed \$10,000 ([Title 21 USC Codified CSA, Section 842\(a\)\(5\) and 842\(c\)\(B\)](#)).

20.0 References/Resources

Indiana Board of Pharmacy
<http://www.in.gov/pla/pharmacy.htm>

United States Department of Justice, Drug Enforcement Administration, Office of Diversion Control
<http://www.dea.gov/diversion/>

Revision History Table

History	Effective Date
<p>Section 3.0 Responsibilities – added 3.1.11 and reworded 3.3.2 to include RMS as the primary point of contact between the university and the IBOP and DEA.</p> <p>Section 10.0 Termination of Registration – Reworded 10.1 and 10.2 to include requirements for terminating registration with or without transferring business activities to another person. Added 10.3 that any termination of registration by a licensee shall prompt an internal RMS audit. A hyperlink to the federal regulations was added.</p> <p>Reworded Section 12.7 to reflect requirements provided in 21 CFR 1301.75. Section 12.9 was struck and included in the revised Section 12.7.</p> <p>Section 14.0 Abandoned Substances – revised wording in section.</p> <p>Section 16.0 Inventorying of Controlled Substances – reworded 16.1. Added two year recordkeeping requirement in 16.2. Reworded 16.5. Added a new 16.6 detailing the information each inventory must contain.</p> <p>Section 19.0 Record Retention – added 19.2.</p>	<p>July 2015</p>
<p>Section 10.0 Termination of Registration – added Licensee shall also notify the Indiana Board of Pharmacy (IBOP) at the address below. IBOP Mailing Address: Indiana Board of Pharmacy 402 West Washington Street, Room W072 Indianapolis, Indiana 46204</p>	<p>February 2017</p>

Appendix A Definitions

Administer – Direct application of a controlled substance to the body of a patient or research subject by a practitioner (or, in his/her presence, by his/her authorized agent), or the patient or research subject at the direction and in the presence of the practitioner, whether such application be by injection, inhalation, ingestion, or any other means.

Authorized User – A faculty or laboratory member (staff, graduate student, or visiting scientist) who is authorized by a Licensee to possess or use controlled substances in the course of their research. Authorized Users must be listed on the Authorized User Form (see Appendix F).

Controlled Substance – A drug or other substance, or immediate precursor, indicated in Schedule I-V of the Controlled Substances Act, Code of Federal Regulations 21 CFR, part 1300 to end (<http://www.deadiversion.usdoj.gov/21cfr/cfr/>). The term does not include distilled spirits, wine, malt beverages, or tobacco.

Dispense – Delivering a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling, or compounding necessary to prepare the substance for such delivery. The term "dispenser" means a practitioner who so delivers a controlled substance to an ultimate user or research subject.

Disposal - Disposal of expired, excess and unwanted controlled substances. Disposal also refers to controlled substances that are residual (often referred to as waste) or have been contaminated through use.

Distribute – Delivering (other than by administering or dispensing) a controlled substance or a listed chemical. The term "distributor" means a person who so delivers a controlled substance or a listed chemical.

Drug Enforcement Administration (DEA) - The agency within the United States Department of Justice that enforces the controlled substances laws and regulations.

Indiana Board of Pharmacy (IBOP) – The agency within the State of Indiana that enforces the controlled substance laws and regulations.

Licensee – The person that holds both a Indiana Board of Pharmacy license and DEA registration to work with controlled substances.

Listed Chemical – Any List I chemical or any List II chemical.

List I Chemical - A chemical specified by regulation of the Attorney General as a chemical that is used in manufacturing a controlled substance in violation of 21 CFR Subchapter I and is important to the manufacture of the controlled substance. (See http://www.deadiversion.usdoj.gov/21cfr/cfr/1310/1310_02.htm#a for the names of List I chemicals.)

List II Chemical – A chemical (other than a List I chemical) specified by regulation of the Attorney General as a chemical that is used in manufacturing a controlled substance in violation of 21 CFR Subchapter I. (See http://www.deadiversion.usdoj.gov/21cfr/cfr/1310/1310_02.htm#b for the names of List II chemicals.)

Location - A room or designated area where controlled substances are stored or used. A location is managed by a single University employee, has a single address and has a DEA Licensee with which it is associated.

Narcotic Drug – Any of the following whether produced directly or indirectly by extraction from sources of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis: A) Opium, opiates, derivatives of opium and opiates, including their isomers, esthers, ethers, salts, and salts of isomers, esthers, and ethers. This does not include the isoquinoline alkaloids of opium. B) Poppy straw and concentrate from poppy straw. C) Coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed. D) Cocaine, its salts, optical and geometric isomers, and salts of isomers. E) Ecgonine, its derivatives, their salts, isomers, and salts of isomers. F) Any compound, mixture, or preparation which contains any quantity of any of the substances referred to in A) through E).

Opiate – Any drug or other substance having an addition-forming or addition-sustaining liability similar to morphine or being capable of conversion into a drug having such addition-forming or addition-sustaining liability.

Practitioner – A physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

Readily Retrievable - The keeping of certain records by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing in the records.



Schedules – The groupings of controlled substances assigned by the Drug Enforcement Administration, or DEA, based on their potential to be habit forming, and usefulness in medicine as a drug.

Schedule I – Drugs, or other substances, that having a high potential for abuse, no current accepted medical use in the United States, and have an accepted lack of safety under medical supervision.

Schedule II – Drugs, or other substances, having a high potential for abuse, currently have an accepted medical use in treatment in the United States, or has a currently accepted medical use with severe restrictions.

Schedule III – Drugs, or other substances, having a potential for abuse less than Schedule I or II substances, with currently accepted medical use in treatment in the United States. Schedule III drugs might lead to moderate or low physical and high psychological dependence.

Schedule IV – Drugs, or other substances, having a low potential for abuse relative to those listed in Schedule III. These drugs have currently accepted medical use in the United States, and abuse of them may lead to limited physical or psychological dependence relative to those in Schedule III.

Schedule V – Drugs, or other substances, having a low potential for abuse relative to Schedule IV. These drugs have currently accepted medical use in the United States, and abuse of them may lead to limited physical or psychological dependence relative to those in schedule IV.

Appendix B

Indiana Board of Pharmacy Application Instructions

The following instructions are provided for completing an initial non-practitioner Controlled Substance Registration (CSR) application with the Indiana Board of Pharmacy (IBOP). Prior to submitting any formal application to the IBOP, the applicant shall contact Risk Management and Safety at 574-631-5037 for review.

Application Requirements

The following lists all that is required from researchers for application submission to the IBOP:

- [Completed CSR application](#);
- A list of procedures to be performed;
- Types and quantities of drugs to be stored on site (formulary) organized by Schedule number;
- Specific protocols for monitoring drug usage, inventory control, destruction, security, storage, and access;
- A one page summary of research objectives, research protocol, and curriculum vitae.

Application Instructions

1. Retrieve the [Application Form](#)
2. Complete Section I:
 - a. Check the box for “Researcher”

SECTION I (All applicants must complete this section. Practitioners should use State Form 34617.)			
<i>Please check one box.</i>			
<input type="checkbox"/> Analytical Laboratory	<input type="checkbox"/> K9 Training	<input type="checkbox"/> Non-Practitioner Owner	<input type="checkbox"/> Surgery Center
<input type="checkbox"/> Correctional Facility	<input type="checkbox"/> Law Enforcement	<input type="checkbox"/> Pharmacy	<input type="checkbox"/> Wholesale Distributor
<input type="checkbox"/> Hospital / Clinic	<input type="checkbox"/> Limited Permit	<input type="checkbox"/> Out Patient Clinic	<input type="checkbox"/> Other _____
<input type="checkbox"/> Humane Society	<input type="checkbox"/> Manufacturer	<input type="checkbox"/> Researcher	

- b. Enter “University of Notre Dame”, (Insert Building Name here) in the “Name of Facility” field.
- c. Leave the “DBA (if applicable)” field empty.
- d. In the field for “Name of the pharmacy manager or person responsible for controlled substances”, enter the name of the licensee/PI who will be assuming legal responsibility for the controlled substances.
Note: *a curriculum vitae must be attached to the application for the individual listed in this field.*
- e. For the “Physical Address of controlled premises”, enter the address (including city, state and zip code) to which the controlled substances will be delivered, stored and used.



Note: If using Freimann Life Science Center lock boxes, do not include a room number.

- f. Enter the Name of the contact person, his/her Title, Telephone Number, and E-mail address.

Name of facility					
DBA (if applicable)					
Name of pharmacy manager or person responsible for controlled substances (attach curriculum vitae)					
Physical address of controlled premises (number and street)		City	State	ZIP code	County
Name of contact person		Title			
Telephone number ()		E-mail address			

- g. For the “Drug schedules” field, check all that apply to what is needed. If one is applying for schedule 2 or 3 substances, check both “2” and “2 Narcotic” or “3” and “3 Narcotic”. If one is applying for both schedules 2 and 3, check all four of the check boxes for schedules 2 and 3 substances.

Drug schedules (check all that apply) 1 2 2 Narcotic 3 3 Narcotic 4 5

- h. Answer the four questions at the bottom of the first page following the instructions provided.

<p>If your answer is "Yes" to any of the following, explain fully in a signed and notarized statement, including all related details. Include violation, location, date and disposition. Letters from attorneys or insurance companies are not accepted in lieu of your statement. Falsification of any of the following is grounds for permanent revocation of a registration issued pursuant to this application.</p>	
<p>1. Except for arrests or convictions that have been expunged by a court, has the applicant, any of the agents or listed pharmacist ever been convicted of, pled guilty or nolo contendere to a violation of any federal, state or local law relating to the use, manufacturing, distribution or dispensing of controlled substances?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>2. Except for minor violations of traffic laws resulting in fines, and arrests or convictions that have been expunged by a court, has the applicant, any of the agents or listed pharmacist ever been convicted of, pled guilty or nolo contendere to any offense, misdemeanor or felony in any state?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>3. Have you ever had any action, discipline or revocation on a DEA (US Drug Enforcement Administration) registration or entered into a Memorandum of Understanding (MOU) on said registration?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>4. Has the applicant, any of the agents, or the listed pharmacist been treated for drug or alcohol abuse?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No

- 3. Complete Section II:
 - a. List the procedures to be performed directly involving use of controlled substances.
 - b. List the substance names, types and quantities of drugs to be stored on site (formulary), organized by Schedule number.
- 4. Complete Section III:
 - a. Include the IACUC or IBC protocol to be used, including the approval page. If not applicable, submit a one page summary of procedures to be performed using the controlled substances, the types and quantities of drugs to be stored on site, and animals used.
 - b. Include specific protocols for monitoring drug usage, inventory control, destruction, security, storage, and access.



- c. Submit the names, dates of birth, and Notre Dame ID Numbers of individuals who will be handling or have access to the CS and/or records thereof. (Authorized Users Form)
5. Complete Section IV and Affirmation
 - a. All applications for shall be signed by the responsible party or practitioner who assumes legal responsibility for the controlled substances.

The application fee must be made payable to "Professional Licensing Agency". Certain facilities are exempt from registration and renewal fees. Please see below for additional information on exemptions.

Registration and renewal fees are waived for the following applicants:

- Any official or agency of the U.S. Army, Navy, Marine Corps, Air Force, Coast Guard, Veterans' Administration or Public Health Service who or which is authorized to procure or purchase controlled substances for official use; and
- Any official, employee, or other civil officer of the United States, or any State, or any political subdivision or agency thereof, who or which is authorized to purchase controlled substances, to obtain such substances from official stocks, to dispense or administer such substances, to conduct research, instructional activities, or chemical analysis with such substances in the course of his or its official duties or employment.

In order to claim exemption from payment, the applicant or licensee must put the request in writing and state why they believe they are exempt. Exemption from payment does not relieve the applicant or licensee of any other requirements or duties prescribed by law.

Note: the address listed on your registration must match the address to which the Controlled Substances will be delivered (ie: the location at which you will be storing and using them).

Application, fee, and documentation shall be mailed to the following address:

Professional Licensing Agency
402 W Washington Street, Room W072
Indianapolis, IN 46204

Appendix C

Drug Enforcement Agency Application Checklist

The following instructions are provided for completing an initial application with the Drug Enforcement Agency (DEA). Prior to submitting any formal application to the DEA, the applicant shall contact Risk Management and Safety at 574-631-5037 for review.

Note: You may not apply for DEA registration until you have received Indiana CSR approval.

Schedule II – V Controlled Substances

The following are instructions on how to apply for Schedule II-V Controlled Substances.

1. Use DEA Form 225, available at:
<https://www.deadiversion.usdoj.gov/webforms/jsp/regapps/common/newAppLogin.jsp>
2. Under the heading “Select Your Business Category”, click Form 225.

Select Your Business Category

- Form 224** - Practitioners(MD,DO,DDS,DMD,DVM,DPM), Mid Level Practitioners (NP, PA, OD, etc.), Pharmacies, Hospitals/Clinics, Teaching Institutions
- Form 225** - Manufacturers, Import/Export, Distributors, Researchers, Dog Handlers, Labs
- Form 510** - Chemical: Manufacturers, Import/Export, Distributors
- Form 363** - Narcotic Treatment Clinics

3. In the drop-down menu under “Select One Business Activity,” select “Researcher.(II-V).” and click on “Begin”. Note: This application process does not include application for Schedule I substances. Application for Schedule I substances are listed below.

Select One Business Activity

Applying for a registration with the wrong Business Category/Activity will cause either delay in processing your application or the withdrawal of your application. If you are not certain of your Business Category/Activity, please contact DEA Customer Service at 1-800-882-9539.

Please do not ating this form.

- Please Select -

- Please Select -

MANUFACTURER (\$3,047 / 1 YRS)

MANUF (BULK) (\$3,047 / 1 YRS)

DISTRIBUTOR (\$1,523 / 1 YRS)

CHEMPACK/SNS DISTRIBUTOR (\$1,523 / 1 YRS)

RESEARCHER (II-V) (\$244 / 1 YRS)

CANINE HANDLER (\$244 / 1 YRS)

ANALYTICAL LAB (\$244 / 1 YRS)

IMPORTER (\$1,523 / 1 YRS)

IMPORTER (C.I.I) (\$1,523 / 1 YRS)

EXPORTER (\$1,523 / 1 YRS)

REVERSE DISTRIB (\$1,523 / 1 YRS)

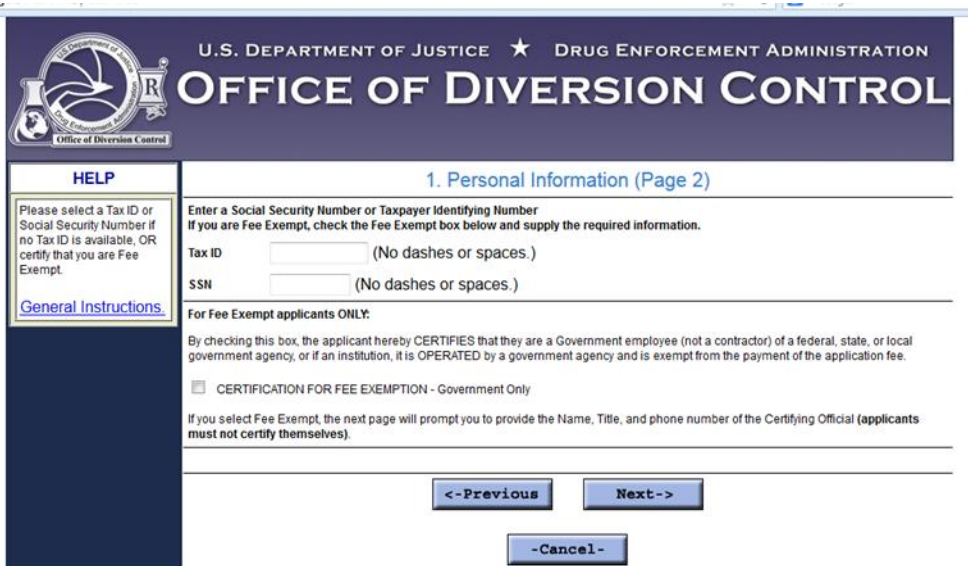
- Form 224** Approved OMB Form No. 1117-0014 Expires: 01/31/2016 (12 minutes)
- Form 225** Approved OMB Form No. 1117-0012 Expires: 04/30/2015 (15 minutes)
- Form 510** Approved OMB Form No. 1117-0031 Expires: 04/30/2016 (15 minutes)
- Form 363** Approved OMB Form No. 1117-0015 Expires: 04/30/2015 (15 minutes)

4. Complete the required fields for Section 1 General Information. **NOTE:** The address on your registration must match the address to which your controlled substances will be

delivered (ie: the location at which you will be storing and using them). When finished with this section, click the “Next” button.

HELP	1. General Information (Page 1)
<p>Please make any required changes to the address information on this page. If you have not changed your address, please select Next to continue.</p> <p>General Instructions.</p>	* Last Name <input type="text"/>
	* First Name, Middle Initial, (Degree) <input type="text"/>
	Additional Company Information <input type="text"/>
	* Business Address Line 1 <input type="text"/>
	Address (Line 2) <input type="text"/>
	* City <input type="text"/>
	* State <input type="text" value="-State-"/>
	* Zip <input type="text"/> - <input type="text"/>
	* Business Phone Number (<input type="text"/>) <input type="text"/> - <input type="text"/> Ex. <input type="text"/>
	Fax Number (<input type="text"/>) <input type="text"/> - <input type="text"/>
	* Business Email Address <input type="text"/>
	Contact Name <input type="text"/>
	Mailing Address <input type="checkbox"/> (Check if same as business address)
	Additional Company Information <input type="text"/>
	*Mail to: Address Line 1 <input type="text"/>
	Mailing Address (Line 2) <input type="text"/>
	* City <input type="text"/>
	* State <input type="text" value="-State-"/>
* Zip <input type="text"/> - <input type="text"/>	
<input type="button" value="-Cancel-"/> <input type="button" value="Next->"/>	

- Complete personal information on Page 2 and click “Next” when finished.



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OFFICE OF DIVERSION CONTROL

HELP
Please select a Tax ID or Social Security Number if no Tax ID is available, OR certify that you are Fee Exempt.
[General Instructions.](#)

1. Personal Information (Page 2)

Enter a Social Security Number or Taxpayer Identifying Number
If you are Fee Exempt, check the Fee Exempt box below and supply the required information.

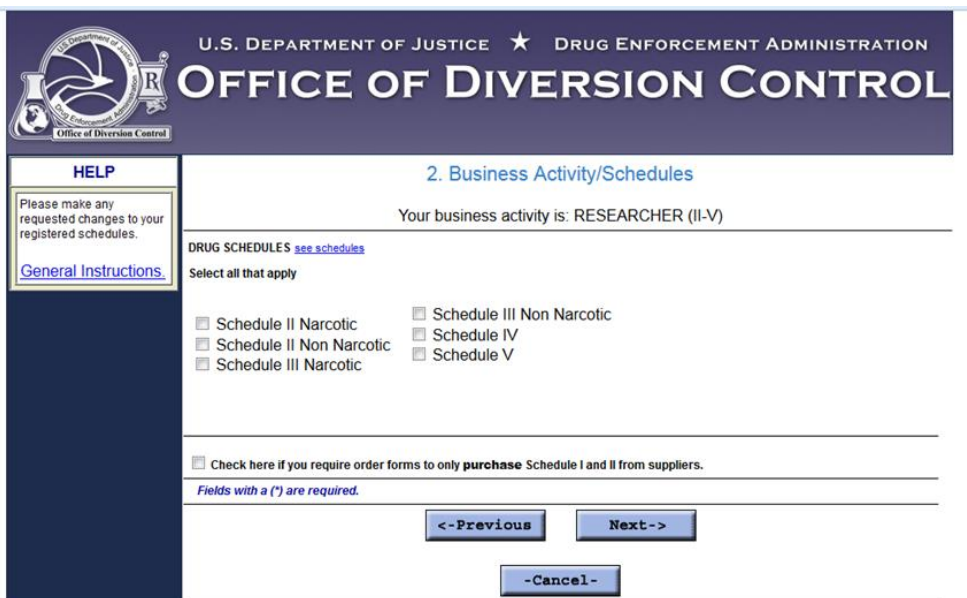
Tax ID (No dashes or spaces.)
SSN (No dashes or spaces.)

For Fee Exempt applicants ONLY:
By checking this box, the applicant hereby CERTIFIES that they are a Government employee (not a contractor) of a federal, state, or local government agency, or if an institution, it is OPERATED by a government agency and is exempt from the payment of the application fee.

CERTIFICATION FOR FEE EXEMPTION - Government Only

If you select Fee Exempt, the next page will prompt you to provide the Name, Title, and phone number of the Certifying Official (applicants must not certify themselves).

- In Section 2, select the appropriate drug schedules for which you are applying for. Click “Next” when finished. Note: There is a checkbox that can be clicked if order forms for Schedule I or II substances is required.



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OFFICE OF DIVERSION CONTROL

HELP
Please make any requested changes to your registered schedules.
[General Instructions.](#)

2. Business Activity/Schedules

Your business activity is: RESEARCHER (II-V)

DRUG SCHEDULES [see schedules](#)

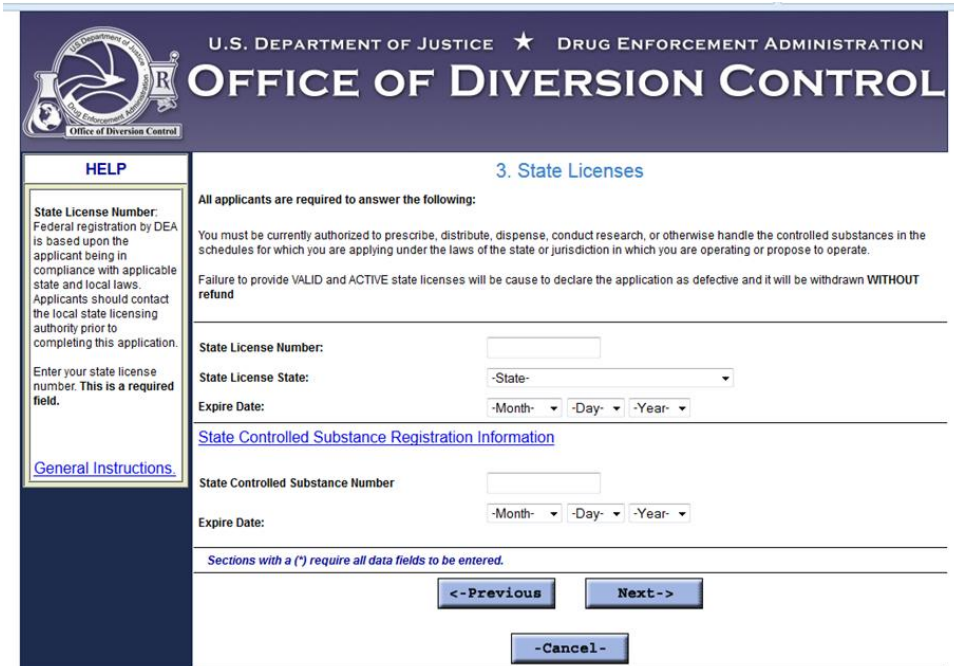
Select all that apply

Schedule II Narcotic Schedule III Non Narcotic
 Schedule II Non Narcotic Schedule IV
 Schedule III Narcotic Schedule V

Check here if you require order forms to only purchase Schedule I and II from suppliers.

Fields with a (*) are required.

7. In Section 3, enter the state license information. The state license number is the number received from the IBOP controlled substance registration. Click “Next” when finished.



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HELP

State License Number:
Federal registration by DEA is based upon the applicant being in compliance with applicable state and local laws. Applicants should contact the local state licensing authority prior to completing this application.
Enter your state license number. This is a required field.
[General Instructions.](#)

3. State Licenses

All applicants are required to answer the following:
You must be currently authorized to prescribe, distribute, dispense, conduct research, or otherwise handle the controlled substances 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.
Failure to provide VALID and ACTIVE state licenses will be cause to declare the application as defective and it will be withdrawn WITHOUT refund

State License Number:

State License State:

Expire Date:

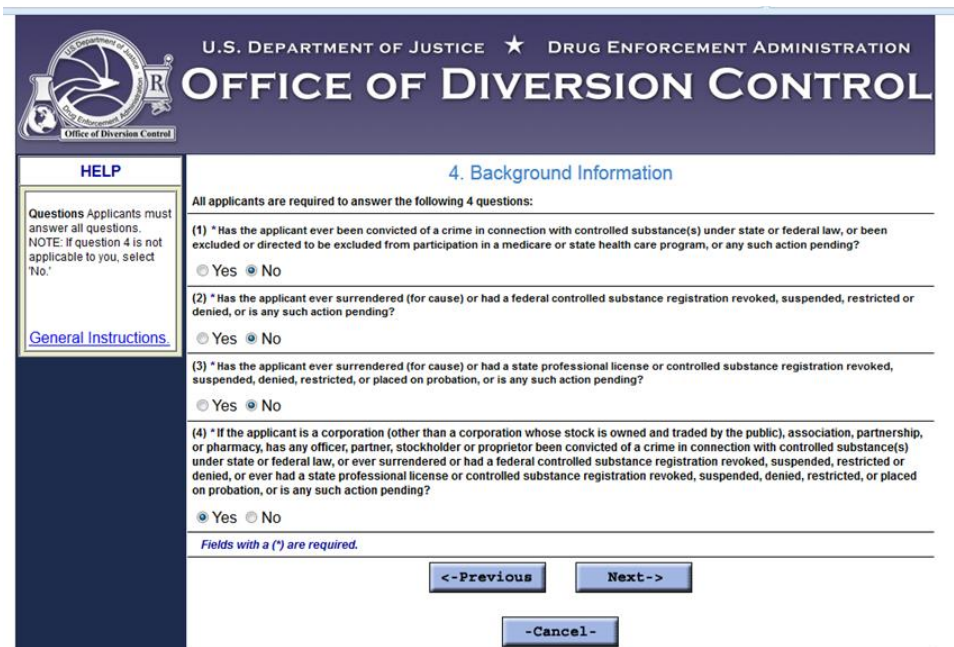
[State Controlled Substance Registration Information](#)

State Controlled Substance Number

Expire Date:

Sections with a (*) require all data fields to be entered.

8. In Section 4, answer all four questions regarding background information. Click “Next” when finished.



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HELP

Questions Applicants must answer all questions. NOTE: If question 4 is not applicable to you, select 'No.'
[General Instructions.](#)

4. Background Information

All applicants are required to answer the following 4 questions:

(1) * Has the applicant ever been convicted of a crime in connection with controlled substance(s) under state or federal law, or been excluded or directed to be excluded from participation in a medicare or state health care program, or any such action pending?
 Yes No

(2) * Has the applicant ever surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted or denied, or is any such action pending?
 Yes No

(3) * Has the applicant ever surrendered (for cause) or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or 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 or had a federal controlled substance registration revoked, suspended, restricted or denied, or ever had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?
 Yes No

Fields with a (*) are required.

9. If you answered "Yes" to any of the questions in the preceding step, provide an explanation in the space provided for supplemental information.

HELP

Explanations to Questions Applicants must provide at least one explanation for each "Yes" answer. Some explanations already on record are not listed in detail for privacy reasons.

[General Instructions](#)

Background Information, Supplement to question 4

No explanations have been entered. Please provide an explanation below.

ADD NEW EXPLANATION FOR 'YES' ANSWER TO QUESTION 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 or had a federal controlled substance registration revoked, suspended, restricted or denied, or ever had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?

Date:

Location:

Nature:
500 characters or less ... Number of Characters Entered:

Result:
500 characters or less ... Number of Characters Entered:

You must have at least one COMPLETE explanation for each question answered with a 'yes'. Please EDIT any existing answers which indicate a need for additional information. To provide a NEW explanation for question 4 please fill in the above fields and click Add New

10. Select the appropriate drug codes following the directions on the screen.

Select a schedule to add drug codes for that schedule.

Schedule I * Select Drug Codes

Schedule II Narcotic * You have not selected any schedules which require drug code input. You may select "Next" below to continue.

Schedule II Non Narcotic * More details regarding drug schedules can be found in [21 CFR 1308](#).

Schedule III Narcotic *

Schedule III Non Narcotic *

Schedule IV *

Schedule V *

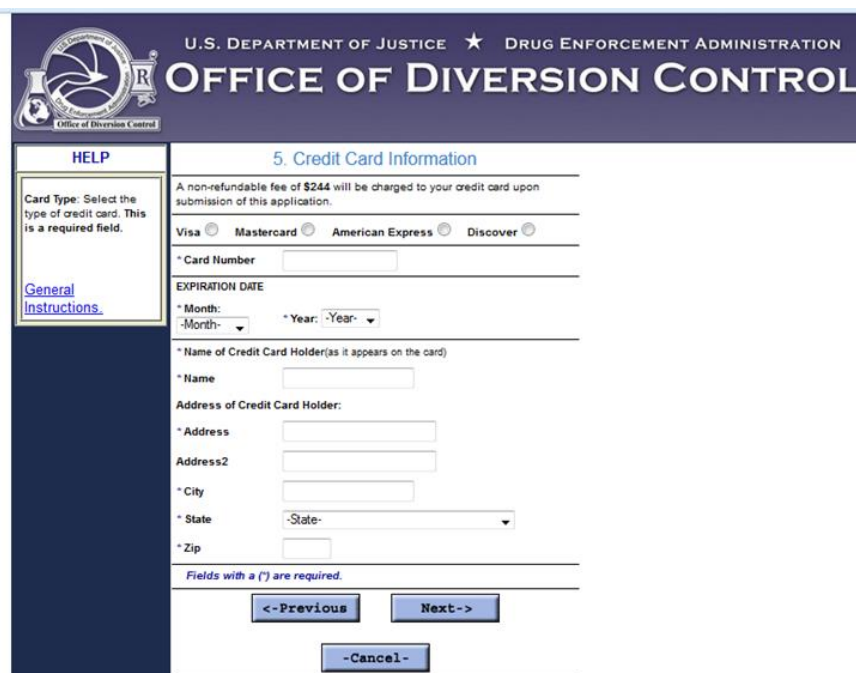
List I Chemicals *

Schedules marked with a "*" do not require drug codes to be entered.

You have not selected any schedules which require drug code input. You may select "Next" below to continue.

Drug Codes Selected
- No Codes Selected -

11. Complete Section 5 regarding payment information and click "Next" when finished. According to DEA regulations, the University is not fee exempt and you are required to pay the annual fee of \$244. A credit card may be used or checks can be made payable to "Drug Enforcement Administration". Third-party checks or checks drawn on foreign banks will not be accepted. FEES ARE NON-REFUNDABLE.



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HELP 5. Credit Card Information

Card Type: Select the type of credit card. This is a required field.
[General Instructions](#)

A non-refundable fee of \$244 will be charged to your credit card upon submission of this application.

Visa
 Mastercard
 American Express
 Discover

* Card Number

EXPIRATION DATE

* Month: * Year:

* Name of Credit Card Holder(as it appears on the card)

* Name

Address of Credit Card Holder:

* Address

Address2

* City

* State

* Zip

Fields with a (*) are required.



In addition to the application, the applicant shall include the IACUC or IBC protocol to be used, including the approval page. If those are not applicable, the applicant shall submit a one page summary (see Appendix G for example) which shall include the following:

- The procedures to be performed using the controlled substances
- The types and quantities of drugs to be stored on site
- Specific protocols for monitoring drug usage, inventory control, destruction, security, storage, and access.
- A formal statement that the applicant understands the recordkeeping requirements, including the use of DEA Form 41 for inventory of drugs surrendered, and the use of DEA Form 106 for reporting theft or loss.
- The names, dates of birth, and Notre Dame ID Numbers of individuals who will be handling or have access to the controlled substances.

After the initial registration period, subsequent renewals shall expire 12 months from the previous expiration date.

Schedule I Controlled Substances

The following are instructions on how to apply for Schedule I Controlled Substances. A protocol to conduct research with controlled substances listed in Schedule I shall be in the following form and contain the following information, where applicable:

1. Information on Investigator
 - a. Name, address, and DEA registration number, if any.
 - b. Institutional affiliation.
 - c. Qualifications, including curriculum vitae and an appropriate bibliography (list of publications).
2. Information on Research Project
 - a. Title of project.
 - b. Statement of the purpose.
 - c. Name of the controlled substances or substance involved and the amount of each needed.
 - d. Description of the research to be conducted, including the number of species of research subjects, the dosage to be administered, the routine method of administration, and the duration of the project.
 - e. Location where the research will be conducted.
 - f. Statement of the security provisions for storing the controlled substances and for dispensing the controlled substances in order to prevent diversion.
3. Authority
 - a. Institutional approval.
 - b. Approval of a Human Research Committee for human studies.
 - c. Indication of an approved active Notice of Claimed Investigational Exemption for a New Drug (number).
 - d. Indication of an approved funded grant (number), if any.

Appendix D

Facility Inspection Preparation Checklist

The following is a list of inspection questions covered during a typical on-site inspection conducted by either the Indiana Board of Pharmacy or the DEA. This list shall be used as guidance in preparation to an inspection conducted for a new applicant seeking registration through the IBOP and DEA.

Facility Security Questions:

1. Is the Controlled Substance storage mechanism proper and secure?
2. Is security lighting utilized at the facility?
3. Is an alarm system utilized at the facility?
4. Are motion detectors utilized at the facility?
5. Is the door lock system sufficient for storage of Controlled Substances?
6. Are there walls and/or fences utilized at the facility?
7. Do storage provisions comply with the Controlled Substances Act?

Facility Operations Questions:

1. How is the inventory maintained?
2. Are DEA Form 222 stored in a secure manner?
3. Are DEA Form 222 executed properly when ordering Controlled Substances?
4. Are Controlled Substance invoices signed at time of receipt?
5. Are Controlled Substance invoices separated from Non-Controlled invoices?
6. How many individuals have access to Controlled Substances within the facility?



Appendix E

Instructions for Ordering Controlled Substances

This reference document provides details regarding information necessary to place orders for DEA Controlled Substances.

Ordering Schedule I and II Controlled Substances

Orders for these items must include a complete DEA Form 222. These forms are accessible only through the DEA by visiting the DEA website or by calling the DEA. Order forms shall not be altered or incomplete. The address on the DEA Form 222 must match the address on your DEA registration certificate. Upon completion of the DEA 222 Form, the licensee shall submit Copy 1 and 2 to the supplier and retain Copy 3 with the licensee's records and follow the instructions provided on the form. An order that shows any alteration, erasure or change in description shall be rejected by the supplier.

Ordering Schedule III, IV, & V Controlled Substances

These drugs can be ordered directly from the manufacturer (DEA Form 222 is not needed). You will be asked to provide a copy of your DEA Registration before your order will be prepared and shipped. The "ship to" address must exactly correspond to your name and address on the DEA registration.

The following is a brief list of sources from which controlled substances can be purchased. This list is provided as an example for planning purposes only.

- Henry Schein – Veterinary Division – henryschein.com
- MWI Veterinary Supply – mwivet.com
- Butler Schein, Inc. – henryscheinvet.com
- Sigma-Aldrich, Inc. – sigmaaldrich.com



Appendix G Controlled Substance Use/Storage Letter (Example)



UNIVERSITY OF
NOTRE DAME

AEROSPACE AND MECHANICAL ENGINEERING

365 Fitzpatrick Hall
Notre Dame, Indiana
46556-5637 USA

Telephone (574) 631-5430
Facsimile (574) 631-8341
E-mail amedept@nd.edu
Web site <http://ame.nd.edu>

Scott A. Nowland
1571 E. 85th Ave., Suite 200
Merrillville, IN 46410

January 1, 2015

Dear Mr. Nowland:

This letter is to support my application for a controlled substances (CS) license with the DEA. I have attached a copy of my license issued by the State of Indiana and the requested pages from protocol number 15-001 approved by the Institutional Animal Care and Use Committee (IACUC) at the University of Notre Dame. This protocol is simply for euthanasia of three animals. We expect to purchase (1) 100 ml bottle of Euthesol® (Schedule 2N) to be administered at 0.22 mg/kg for 3 animals at a body weight of 3-4 kg each. Please note that I expect to modify my application within 6-12 months for planned protocol involving live animal experiments and analgesics (Schedule 3).

In regards to security measures, the CS are stored in room 403 of the Freimann Life Science Center (FLSC), where each PI is issued a locked box. Room 403 is locked during non-operational hours. Access into FLSC is limited and controlled with access cards.

The drug inventory is performed by the individual registrant. Minimally, there will be a biennial inventory, however, more frequent intervals may be recommended. The inventory will be witnessed by another registrant and both will sign the log.

Drugs will be ordered by the PI or a designated person. Documentation will be maintained for those select FLSC staff authorized to use my DEA registrant number to make purchase



of CS. It has been arranged through the University Procurement Department to have all CS shipments sent directly to FLSC via an overnight carrier rather than to be delivered to the Central Receiving Warehouse. Documentation will be maintained for those select FLSC staff authorized to receive packages on my behalf. FLSC staff will then call the PI when a package is received. The PI must open the package to ascertain that the contents are correct and logged into their CS inventory. All invoices will be held for a minimum of two years.

The following FLSC staff will have access to administer CS to animals for the approved IACUC protocol:

Name	DOB	Notre Dame ID
John Doe	12/05/1958	123456789
Jane Doe	01/15/1960	000111222
Garfield Cat	02/08/1965	135792468
Santa Clause	03/02/1981	555555555

Finally, I declare that I understand the methods of local recordkeeping and the use of DEA Form 41 for inventory of any drugs surrendered and Form 106 for reporting theft or loss.

Sincerely,
(Signature)
(Name)
(Title)

Appendix L

Checklist of Controlled Substance Forms to be Submitted & Retained

Document	Frequency of Completion	Submitted with Application	Record Retention Requirement	Submitted to NDRC
Purchasing records of all CS received	Perpetual		≥ 2 yrs	
Receipt/invoice with handwritten date for each order	Perpetual		≥ 2 yrs	
Record of DEA Form 222 use (Schedules I & II only)	Perpetual		≥ 2 yrs	
CS administered/dispensed logs (one per CS)	Perpetual		≥ 2 yrs	
Complete CS inventory	At least biennially		≥ 2 yrs	
List of authorized users/individuals with CS access	At least annually	X	≥ 2 yrs	X
Application or renewal form(s)	Upon renewal*	X		X
List of CS type and quantity to be stored on site (formulary) organized by schedule number	Upon renewal*	X		X
IACUC protocol, IBU protocol, or 1 pg summary of research methods/objectives	Upon renewal*	X		X
Protocol for CS monitoring/storage/access/etc.	Upon renewal*	X		X
Registrant's curriculum vitae	Upon renewal*	X		X
Drug codes for Schedule I & II substances	Upon renewal*	X		X
Explanation/resolution details for "yes" on criminal history questions (if applicable)	Upon renewal*	X		X
Copy of relevant licenses	Upon renewal*	X	≥ 2 yrs	X
Letter detailing use/storage/access controls	Upon renewal*	X	≥ 2 yrs	X
Statement of knowledge of policies & Forms 41 & 106	Upon renewal*	X	≥ 2 yrs	X
Authorization for ordering designee (if applicable)	Upon renewal*	X	≥ 2 yrs	X

Authorization for receiving designee (if applicable)	Upon renewal*	X	≥ 2 yrs	X
DEA Form 41 for disposal	As needed		≥ 2 yrs	X
DEA Form 106 for theft or loss	As needed		≥ 2 yrs	X
Change in registration documentation (name, address)	As needed		≥ 2 yrs	X
Initial CS inventory (volumes = 0)	Once		≥ 2 yrs	
Termination of registration documentation (if applicable)	Once, if needed		≥ 2 yrs	X
Training records for all applicable personnel	Initially and as needed		30 yrs plus current	X

*The phrase “upon renewal” means upon initial application for or renewal of registration or licensing.