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.

2. Under the heading “Select Your Business Category”, click Form 225.
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.

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 (i.e., the location at which you will be storing and using them). When finished with this section, click the “Next” button.
5. Complete personal information on Page 2 and click “Next” when finished.

6. 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.
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.

8. In Section 4, answer all four questions regarding background information. Click “Next” when finished.
9. If you answered "Yes" to any of the questions in the preceding step, provide an explanation in the space provided for supplemental information.
10. Select the appropriate drug codes following the directions on the screen.

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.
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.