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”
   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.

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.

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

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