

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.