

## Definitions for Controlled Substances Used in Research

**Authorized User-** An Authorized User is an individual who has the complete trust of a DEA registrant, and who is authorized by the DEA registrant to oversee the ordering, dispensing and control of controlled substances in the absence of the DEA registrant. Completion of the ORC&S Controlled Substances Used in Research Registration Form should be on file with the DEA registrants records and readily available for audits and inspections.

**Clinical Setting-** A setting where a Controlled Substance is used in a medical or veterinary application.

**Controlled Substance-** A drug or other substance, or immediate precursor, included in Schedule I, II, III, IV, or V of Part B of U.S.C. Title 21 Subchapter I. The current official schedule of controlled substances can be found in Section 1308 of the most recent issue of Title 21 Code of Federal Regulations Part 1308 ([21 CFR 1308](#)).

**Loss or Significant Loss-** When determining whether a loss is significant, a registrant should consider, among others, the following factors: (1) The actual quantity of controlled substances lost in relation to the type of business; 2) The specific controlled substances lost; 3) Whether the loss of the controlled substances can be associated with the access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances; 4) A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,; 5) Whether the specific controlled substances are likely candidates for diversion; 6) Local trends and other indicators of the diversion potential of the missing controlled substance.

**Non-Clinical Setting-** A setting where a Controlled Substance is used in research, teaching, or testing, which is not a clinical usage of the Controlled Substance.

**Power of Attorney-** A DEA registrant may authorize one or more individuals to issue orders for Schedule I and II controlled substances on their behalf by executing a power of attorney for each such individual. Details [here](#).

**Reverse Distributor-** A person or entity who receives controlled substances acquired from another DEA registrant for the purpose of returning unwanted, unusable, or outdated controlled substances to the manufacturer or the manufacturer's agent, or, where necessary, processing such substances or arranging for processing such substances for disposal.

**Schedule I-** Drugs with no currently accepted medical use and a high potential for abuse.  
Examples: heroin, lysergic acid diethylamide (LSD), marijuana (cannabis), 3,4-methylenedioxymethamphetamine (ecstasy), methaqualone, and peyote.

**Schedule II-** Drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence. These drugs are also considered dangerous.  
Examples: combination products with less than 15 milligrams of hydrocodone per dosage unit (Vicodin), cocaine, methamphetamine, methadone, hydromorphone (Dilaudid), meperidine (Demerol), oxycodone (OxyContin), fentanyl, Dexedrine, Adderall, and Ritalin.

**Schedule III-** Drugs with a moderate to low potential for physical and psychological dependence.

Schedule III drugs abuse potential is less than Schedule I and Schedule II drugs but more than Schedule IV.

Examples: products containing less than 90 milligrams of codeine per dosage unit (Tylenol with codeine), ketamine, anabolic steroids, testosterone.

**Schedule IV-** drugs with a low potential for abuse and low risk of dependence.

Examples: Xanax, Soma, Darvon, Darvocet, Valium, Ativan, Talwin, Ambien, Tramadol.

**Schedule V-** Drugs with lower potential for abuse than Schedule IV and consist of preparations containing limited quantities of certain narcotics. Schedule V drugs are generally used for antidiarrheal, antitussive, and analgesic purposes.

Examples: cough preparations with less than 200 milligrams of codeine or per 100 milliliters (Robitussin AC), Lomotil, Motofen, Lyrica, Parepectolin.