OLD DOMINION UNIVERSITY

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Policies and Procedures for Using Controlled Substances in Research

Administered by
Office of Research
&
Environmental Health and Safety Office

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Old Dominion University
Policies and Procedures for Using Controlled Substances in Research

Table of Contents

Section **Page**

I. Purpose……3

II. Definitions……3

III. Responsibilities……5

IV. Procedures for Using Controlled Substances ……6

Appendix

A: Controlled Substances Protocol Review Form……9

B: Schedules of Controlled Substances……11

I. PURPOSE

In conducting research and teaching activities with controlled substances, Old Dominion University's (ODU) registrants and authorized personnel shall comply with Federal and State laws and regulations regarding their uses, including registration with the Drug Enforcement Administration (DEA) and the Virginia Board of Pharmacy (VBP), specified storage requirements, inventory maintenance and substance disposal. Failure to comply with this policy can result in disciplinary action, as well as suspension or termination of research by the University. The Office of Research and the Environmental Health and Safety Office (EHSO) are responsible for monitoring compliance.

II. DEFINITIONS

Authorized Personnel:
Any employee authorized to use controlled substances under the direct supervision of a Registrant.

Controlled Substance:
Any substance listed in the Controlled Substances Act, Code of Federal or Substance Regulations (21 CFR, part 1300 to end), Virginia Statue §54.1 3422, and the Virginia Board of Pharmacy Policies and Procedures.

Department:
A Department is any administrative unit or structure that by size, location, or nature of activity requires separate registration.

Disposal:
The removal and destruction of controlled substances that are in their original containers or original form and that are outdated, surplus or no longer intended for use. Disposal also applies to small quantities of controlled substances that are residual (often referred to as "waste") or that have been adulterated through use.

Disposition Records:
An accurate, continuous and current record used to track the acquisition, use and disposal of controlled substances.

Drug Enforcement Administration (DEA):
The section of the United States Department of Justice that establishes regulations for the handling and use of controlled substances.

Employee/Member of the University:
This term refers to faculty, staff, and any other individuals employed by ODU or ODU Research Foundation who use ODU resources or facilities or receive funds administered by ODU, and volunteers and representatives who may speak or act as agents for ODU. Members do not include students taking courses, attending classes or enrolled in an academic program unless they meet one of the other criteria.

Environmental Health and Safety Office (EHSO):
The Old Dominion University Environmental Health and Safety Office.

Institutional Animal Care and Use Committee (IACUC):
The Institutional Animal Care and Use Committee for review of projects using animal subjects.

Institutional Review Board (IRB):
The Institutional Review Board for review of research involving human subjects.

Location:
A building, room, or set of contiguous or adjacent rooms where controlled substances are stored or used.

Office of Research:
The Office of Research is responsible for ensuring compliance with internal research policies and with local, State and Federal regulations related to research.

Registration:
Formal grant of specific authority by the DEA and/or Virginia Board of Pharmacy (VBP).

Registrant:
A University employee authorized by his/her Department to hold both a VBP registration and DEA license to obtain controlled substances and to store, use and properly dispose of controlled substances at a single location.

Research:
Any investigative activity conducted by ODU personnel using University facilities or resources regardless of funding source.

Teaching:
Teaching activities include classroom demonstrations, laboratory exercises and research projects that are required for completion of a course at the undergraduate, graduate or professional level. This policy does not cover any teaching activity performed within a clinical environment. However, clinical teaching activities must still comply with DEA and VBP regulations applicable to practitioners and pharmacies.

Virginia Board of Pharmacy (VBP):
The agency authorized by the Virginia statute to regulate controlled substances.

III. RESPONSIBILITIES

Authorized Personnel
Must properly use and maintain disposition records of controlled substances in accordance with this policy.

Environmental Health and Safety Office (EHSO)
1. Coordinates disposal activities for waste or unused controlled substances.
2. Approves security of storage facilities of all registrants; guards against theft or diversion.
3. Conducts annual audit of the Office of Research activities pertaining to use of controlled substances in research.
4. Serves as back-up program coordinator to the Office of Research.

Department Chair
Determines whether to give an individual university employee in his/her Department authorization to maintain a VBP registration and DEA license to obtain controlled substances and to store, use and properly dispose of controlled substances at a single location.

Registrant
1. Maintains a VBP registration.
2. Maintains a DEA license.
3. Submits protocol review form to Department Chair for approval and signature.
4. Submits protocol review form to the Office of Research for review and approval.
5. Shall have protocol approved by the IRB and/or IACUC, if applicable.
6. Shall properly store and use controlled substances, maintain appropriate disposition records, supervise use by authorized personnel, and conduct an annual inventory of controlled substances used at that location.
7. Uses appropriate record keeping in accordance with regulatory requirements.
8. Notifies Department Chair and Office of Research of discrepancies found in the inventory.
9. Can exercise signature authority to purchase and dispose of controlled substances used within that Department and for which a justification is on record

Office of Research
1. Maintains a current list of all registration holders.
2. Monitors acquisition of controlled substances and verifies registration and justification for use. Provides training in controlled substances policies and procedures.
3. Promulgates instructions on the use, storage, disposal, and reporting of the theft or loss of controlled substances.
4. Conducts inspection when a registration holder or registration address becomes inactive.
5. Conducts annual review of registrant’s purchasing process, disposition and inventory records, and security measures.
6. Reviews research protocols involving the use of controlled substances.
7. Performs periodic site reviews.

Old Dominion University Research Foundation (ODURF)
Requires that the Research Proposal Transmittal Form include a category for the use of controlled substances in research and that the Office of Research is sent a copy of research proposals that involve the use of controlled substances for review and comment.

IV. PROCEDURES FOR USING CONTROLLED SUBSTANCES

Registration

Any Principal Investigator intending to use controlled substances for research or teaching must be registered with both the Drug Enforcement Agency (DEA) and the Virginia Board of Pharmacy (VBP). The Registrant shall purchase controlled substances using his/her own registration number. The Registrant shall not purchase controlled substances for other personnel.

For DEA registration, researchers should use Form 225 "New Application for Manufacturer, Distributor, Researcher, Analytical Laboratory, Importer, Exporter." DEA registration can be completed online or printable forms can be obtained at:
http://www.deadiversion.usdoj.gov/drugreg/reg_apps/index.html/

For VBP registration, researchers should use "Application for a Controlled Substance for Various Entities." This form can be obtained online at:
http://www.dhp.virginia.gov/Pharmacy/pharmacy_forms.htm#csr

Application for Use

Controlled substances may not be procured, possessed, stored or used by an individual until the Office of Research has approved the registrant's "Controlled Substances Protocol Review Form" (See Appendix A). Authorization to possess and use controlled substances expires two years from the date of final approval. Amendments to the original approval requested prior to the expiration date of the original authorization must be submitted to the Office of Research using the "Controlled Substances Protocol Review Form." Actions requiring amendments include:

1. Addition of controlled substance(s) to the experimental protocol
2. Significant change(s) in the experimental design
3. Change(s) in the location(s) or storage and/or use
4. Change(s) in Authorized Personnel

Purchasing

A Federal DEA license and DEA requisition number are required for purchasing controlled substances. The Federal Drug Administration (FDA), in the Controlled Substances Act, has established strict ordering procedures that must be followed before a vendor is permitted to fill an order. Orders must be accompanied by the appropriate DEA Form, which can be obtained from the DEA's Diversion Control Program Office.

Orders for DEA Schedule I and Schedule II drugs must be accompanied by DEA Form 222. This form is numbered sequentially and issued only to holders of DEA registration numbers.

Schedule III and IV controlled substances can be purchased by citing the DEA requisition number from Form 223. The three-part form must be completed as the directions on the back of the form specify.
The licensee must keep Part 3 of the form and have it available for inspection by enforcement

officers for a period of two years from the date the order was placed. Space is provided on Part 3 for receiving information.

For assistance with registration or purchases, contact the Old Dominion University Office of Research at 757-683-3460.

Storage

The Registrant must provide effective controls and procedures to guard against theft and diversion of controlled substances. Controlled substances must be stored separate from other drugs or materials. Controlled substances should be stored in a securely locked, substantially constructed cabinet as stipulated in 21CFR Section 1301.75. Expired or unwanted controlled substances must be separated from the working stock, and "outdated" or "expired" shall be written in indelible ink on each vial, bottle or container to be discarded and on any outer container in which the item is placed. These substances can be placed in a bag or box and put in the same storage space as the working stock.

Maintenance of Records and Inventories

The VBP Controlled Substance Registration (CSR) Certificate must be posted in a conspicuous location within the facility in which the controlled substances are used, such as in the Registrant's office or laboratory.

The Registrant must keep accurate, continuing and current records of the acquisition, use and disposal of controlled substances at each location. Inventories and other records shall be kept and made available for inspection for at least two years from the date of such inventories or records. The Registrant must maintain separate inventories and records for each registered location and for each independent activity for which he/she is registered.

The schedules of Controlled Substances are listed in Appendix B. There are six schedules (I through VI). Inventories and records of Schedule I and II controlled substances must be maintained separate from all other records. Inventories and records of controlled substances listed in Schedules III – V must be maintained either separately from all other records of the Registrant or in such form that the information required is readily retrievable from the ordinary business records of the Registrant. The Registrant must conduct an annual inventory and reconciliation of all stocks of controlled substances on hand. The date and time of the inventory and the Registrant's signature must be recorded. To prevent unauthorized persons from ordering controlled substances, DEA order forms must be numbered for each schedule drug, and the numbers must be recorded on a separate sheet. Both the DEA forms and the record of numbers must be stored in the safe/cabinet with the controlled substances.

The Registrant must include the following information in the inventory:

- Name of the substance for each finished form of the substance
- Number of units or total volume of each finished form in each commercial container
- Number of commercial containers of each finished form received
- Expiration date and lot numbers of the containers received
- Name, address and registration number of source from which the containers were received

- Amount of each finished form transferred or used, including the name and address of the person(s) to whom it was given, the date of transfer, the name of the individual who used the substance and the reason it was used
- If controlled substances are compounded or aliquotted, each new container must be labeled and tracked as with the original container. Federal law and IACUC guidelines prohibit use of non-pharmaceutical grade drugs for anesthesia, analgesia, euthanasia or for any survival procedures in live animals, unless there is no adequate commercial preparation available.
- Number of units or volume of finished forms and/or commercial containers disposed of in any other manner, as well as the date and manner of disposal

Security Controls
Rooms where controlled substances are used and/or stored shall be secured at all times. Access to these areas shall be limited to the registrant and authorized personnel. Door locks shall not be keyed to the University's master key system. A combination lock is preferable.

Persons who have been convicted of a felony offense relating to controlled substances or who, at any time, had an application for registration with the DEA denied, had a DEA registration revoked, or surrendered a DEA registration for case are prohibited from using controlled substances.

Theft or Loss
If a Registrant discovers a theft or any other unusual loss of any controlled substances, he/she must immediately report such theft or loss to the University Police and to the Office of Research and/or EHSO. The Office of Research or EHSO will then contact DEA. Further, the Registrant must file a DEA Form-106 "Report of Theft of Controlled Substances" with the DEA. This form can be obtained online at:
http://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html

Disposal
To minimize waste, DEA registrants should only purchase quantities they intend to use. Damaged, expired, unwanted, unusable, or non-returnable Controlled Substances must be accounted for, retained, and disposed of in accordance with applicable State and Federal regulations. (http://www.deadiversion.usdoj.gov/21cfr/cfr/1307/1307_21.htm).

Environmental Health & Safety personnel are NOT DEA registered and therefore cannot collect, hold or dispose of Controlled substances without proper DEA paperwork from the PI (DEA form 41).

DEA controlled substances must be disposed of through an authorized **Reverse Distributor** or **On-Site Disposal**. Reverse distributors are companies licensed and permitted to recycle and/or destroy controlled substances. Contact Office or Research or EHSO to help determine disposal method.

A Registrant Record of Controlled Substances Destroyed (DEA Form 41) must be completed prior to disposing of any DEA controlled substance. Copy of Form 41 should be retained by the registrant for at least 2 years.

Controlled substances that are mixed with radioactive waste, chemical waste or regulated medical waste are not eligible for disposal under these guidelines. Such substances must be disposed of through the EHSO as radioactive waste, chemical waste, or regulated medical waste, respectively. Contact the EHSO to help determine disposal method.

Oversight

The Office of Research reviews each Registrant's purchasing and disposition records, and inventory and security measures on an annual basis and conducts a final inspection when the Registrant becomes inactive. This oversight review is required for the continued use of controlled substances in research.

APPENDIX A

CONTROLLED SUBSTANCES PROTOCOL REVIEW FORM
OLD DOMINION UNIVERSITY

Directions: Researchers planning to use controlled substances as part of their research must complete this form. Researchers must have a current DEA license and VBP Registration. This form should be returned to the Office of Research, Attention Research Compliance Coordinator. The Research Compliance Coordinator will review the application and contact the applicant if there are any questions or concerns. The applicant will receive confirmation to proceed with the project.

Administrative Information	
Name of Researcher	
Type of Application ☐ Initial Application ☐ Renewal Application ☐ Amendment	
Department	
Campus Address	
Office Phone	Emergency/After Hours Phone
Fax	Email
Title of Research or Teaching Project	
Please list all personnel authorized to work with controlled substances under your supervision.	
Proposed Starting Date	
Grant Number (if applicable)	
Does the research involve the administration of drugs to live animals? ☐ Yes ☐ No If yes, has the project been reviewed by the IACUC? ☐ Yes (indicate the protocol number) ☐ No	
Does the research involve the administration of drugs to human subjects? ☐ Yes ☐ No If yes, has the project been reviewed by the IRB? ☐ Yes (indicate the protocol number) ☐ No	
Controlled Substances	
Current DEA license expiration date	Current VBP registration expiration date

List the name(s) and amount(s) of controlled substance(s) to be used in the research project.

Which controlled substance schedule(s) are you planning to use? (Please check all that apply)
☐ I ☐ II ☐ III ☐ IV ☐ V ☐ VI

Where will the controlled substances be stored? (Please include building name(s) and room number(s)).

Describe security measures to prevent theft or loss of controlled substances.

Is a securely locked, substantially constructed cabinet used for storage of controlled substances?
☐ Yes
☐ No

Where will the controlled substances be used? (Please include building name(s) and room number(s)).

Describe security measures to prevent theft or loss of controlled substances during use.

Describe the proposed use(s) of the controlled substance in research. Please include the number and species of research subjects, dose to be administered, the route and method of administration, and duration of the project. (Attach an extra sheet if necessary.)

Certification

The signature below affirms that the researcher will comply with all of the rules and regulations outlined in the Old Dominion University Policy and Procedures for Using Controlled Substances in Research.

Signature	Date

Authorization by Department Chair

I authorize the use of controlled substances as outlined in this protocol submission and certify that the researcher possesses appropriate licensure through DEA and VBP.

Signature	Date

Authorization by Office of Research

Signature	Date

APPENDIX B
SCHEDULES OF CONTROLLED SUBSTANCES
VIRGINIA CODE OF LAW

Be sure to check the following links for updated Schedules:
DEA: http://www.deadiversion.usdoj.gov/schedules/
VA Board of Pharmacy: http://www.dhp.virginia.gov/Pharmacy/

§ 54.1-3446. Schedule I.

1. Any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation:

Acetylmethadol;
Allylprodine;
Alphamethylfentanyl;
Alphacetylmethadol (except levo-alphacetylmethadol, also known as levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM);
Alphameprodine;
Alphamethadol;
Benzethidine;
Betacetylmethadol;
Betameprodine;
Betamethadol;
Betaprodine;
Clonitazene;
Dextromoramide;
Diampromide;
Diethylthiambutene;
Difenoxin;
Dimenoxadol;
Dimepheptanol;
Dimethylthiambutene;
Dioxaphetylbutyrate;
Dipipanone;
Ethylmethylthiambutene;
Etonitazene;
Etoxeridine;
Furethidine;
Hydroxypethidine;
Ketobemidone;
Levomoramide;
Levophenacylmorphan;
Morpheridine;
Noracymethadol;
Norlevorphanol;
Normethadone;
Norpipanone;
Phenadoxone;
Phenampromide;

Phenomorphan;
Phenoperidine;
Piritramide;
Proheptazine;
Properidine;
Propiram;
Racemoramide;
Trimeperidine.

2. Any of the following opium derivatives, their salts, isomers and salts of isomers, unless specifically excepted, whenever the existence of these salts, isomers and salts of isomers is possible within the specific chemical designation:

Acetorphine;
Acetyldihydrocodeine;
Benzylmorphine;
Codeine methylbromide;
Codeine-N-Oxide;
Cyprenorphine;
Desomorphine;
Dihydromorphine;
Drotebanol;
Etorphine;
Heroin;
Hydromorphinol;
Methyldesorphine;
Methyldihydromorphine;
Morphine methylbromide;
Morphine methylsulfonate;
Morphine-N-Oxide;
Myrophine;
Nicocodeine;
Nicomorphine;
Normorphine;
Phoclodine;
Thebacon.

3. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of its salts, isomers, and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation (for purposes of this subdivision only, the term "isomer" includes the optical, position, and geometric isomers):

Alpha-ethyltryptamine (some trade or other names: Monase;a-ethyl-1H-indole-3-ethanamine; 3-]2-aminobutyl[indole; a-ET; AET);
4-Bromo-2,5-dimethoxyphenethylamine (some trade or other names: 2-]4-bromo-2,5-dimethoxyphenyl[-1-aminoethane;alpha-desmethyl DOB;2C-B; Nexus);
3,4-methylenedioxy amphetamine;
5-methoxy-3,4-methylenedioxy amphetamine;
3,4,5-trimethoxy amphetamine;
Bufotenine;
Diethyltryptamine;
Dimethyltryptamine;

4-methyl-2,5-dimethoxyamphetamine;
2,5-dimethoxy-4-ethylamphetamine (DOET);
Ibogaine;
Lysergic acid diethylamide;
Mescaline;
Parahexyl (some trade or other names: 3-Hexyl-1-hydroxy-7, 8, 9, 10-tetrahydro-6, 6, 9-trimethyl-6H-dibenzo]b,d[pyran; Synhexyl);
Peyote;
N-ethyl-3-piperidyl benzilate;
N-methyl-3-piperidyl benzilate;
Psilocybin;
Psilocyn;
Tetrahydrocannabinols, except as present in marijuana and dronabinol in sesame oil and encapsulated in a soft gelatin capsule in a drug product approved by the U.S. Food and Drug Administration;
Hashish oil (some trade or other names: hash oil; liquid marijuana; liquid hashish);
2,5-dimethoxyamphetamine (some trade or other names: 2,5-dimethoxy-a-methylphenethylamine; 2,5-DMA);
3,4-methylenedioxymethamphetamine (MDMA), its optical, positional and geometric isomers, salts and salts of isomers;
3,4-methylenedioxy-N-ethylamphetamine (also known as N-ethyl-alpha-methyl-3,4 (methylenedioxy)phenethylamine, N-ethyl MDA, MDE, MDEA);
4-bromo-2,5-dimethoxyamphetamine (some trade or other names: 4-bromo-2,5-dimethoxy-a-methylphenethylamine; 4-bromo-2,5-DMA);
4-methoxyamphetamine (some trade or other names: 4-methoxy-a-methylphenethylamine; paramethoxyamphetamine; PMA);
N-ethyl analog of phencyclidine;
Pyrrolidine analog of phencyclidine;
Thiophene analog of phencyclidine.

4. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers and salts of isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:
Gamma hydroxybutyric acid (some other names include GHB; gamma hydroxybutyrate; 4-hydroxybutyrate; 4-hydroxybutanoic acid; sodium oxybate; sodium oxybutyrate);
Mecloqualone;
Methaqualone.

5. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers and salts of isomers:
Aminorex (some trade or other names; aminoxaphen; 2-amino-5-phenyl-2-oxazoline; 4, 5-dihydro-5-phenyl-2-oxazolamine);
Fenethylline;
Ethylamphetamine;
Cathinone (some trade or other names: 2-amino-1-phenyl-1-propanone, alpha-aminopropiophenone, 2-aminopropiophenone, norephedrone), and any plant material from which Cathinone may be derived;
Methcathinone (some other names: 2-(methylamino)-propiophenone; alpha-(methylamino) propiophenone; 2-(methylamino)-1-phenylpropan-1-one; alpha-N-methylaminopropiophenone; monomethylpropion; ephedrone; N-methylcathinone; methylcathinone; AL-464; AL-422; AL-463 and UR 1432).

6. Any material, compound, mixture or preparation containing any quantity of the following substances:

3-methylfentany-(N-]3-methyl-1-(2-phenyethyl)-4-piperidyl[N-phenylpropanamide), its optical and geometric isomers, salts, and salts of isomers;
1-methyl-4-phenyl-4-propionoxypiperidine (MPPP), its optical isomers, salts and salts of isomers;
1-(2-phenylethyl)-4-phenyl-4-acetyloxypiperidine (PEPAP), its optical isomers, salts and salts of isomers;
N-]1-(1-methyl-2-phenyl)ethyl-4-piperidyl[-N-phenylacetamide (acetyl-alpha-methylfentanyl), its optical isomers, salts and salts of isomers;
N-]1-(1-methyl-2-2-thienyl)ethyl-4 piperidyl[-N-phenylpropanamide (alpha-methylthiofentanyl), its optical isomers, salts and salts of isomers;
N-]1-benzyl-4-piperidyl[-N-phenylpropanamide (benzylfentanyl), its optical isomers, salts and salts of isomers;
N-]1-(2-hydroxy-2-phenyl) ethyl-4-piperidyl[-N-phenylpropanamide (beta-hydroxyfentanyl), its optical isomers, salts and salts of isomers;
N-]3-methyl-1-(2-hydroxy-2-phenyl)ethyl-4-piperidyl[-N-phenylpropanamide (beta-hydroxy-3-methylfentanyl), its optical and geometric isomers, salts and salts of isomers;
N-]3-methyl-1-(2-2-thienyl)ethyl-4-piperidyl[-N-phenylpropanami de (3-methylthiofentanyl), its optical and geometric isomers, salts and salts of isomers;
N-]1-(2-thienyl)methyl-4-piperidyl[-N-phenylpropanamide(thenylf entanyl), its optical isomers, salts and salts of isomers;
N-]1-(2-2-thienyl)ethyl-4-piperidyl[-N-phenylpropanimide(thiofe ntanyl), its optical isomers, salts and salts of isomers.
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§ 54.1-3448. Schedule II.

1. Any of the following substances, except those narcotic drugs listed in other schedules, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by combination of extraction and chemical synthesis:

Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate, excluding apomorphine, thebaine-derived butorphanol, dextrorphan, nalbuphine, nalmefene, naloxone naltrexone and their respective salts, but including the following:

Raw opium;
Opium extracts;
Opium fluid extracts;
Powdered opium;
Granulated opium;
Tincture of opium;
Codeine;
Ethylmorphine;
Etorphine hydrochloride;
Hydrocodone;
Hydromorphone;
Metopon;
Morphine;
Oxycodone;
Oxymorphone;
Thebaine.

Any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in this subdivision, but not including the isoquinoline alkaloids of opium.

Opium poppy and poppy straw.

Coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extractions which do not contain cocaine or ecgonine; cocaine or any salt or isomer thereof.

Concentrate of poppy straw, the crude extract of poppy straw in either liquid, solid or powder form, which contains the phenanthrene alkaloids of the opium poppy.

2. Any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation:

Alfentanil;
Alphaprodine;
Anileridine;
Bezitramide;
Bulk dextropropoxyphene (nondosage forms);
Dihydrocodeine;
Diphenoxylate;
Fentanyl;
Isomethadone;
Levo-alphacetylmethadol (levo-alpha-acetylmethadol)
(levomethadyl acetate) (LAAM);
Levomethorphan;
Levorphanol;
Metazocine;
Methadone;
Methadone - Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane;
Moramide - Intermediate, 2-methyl-3-morpholino-1, 1-diphenyl-propane-carboxylicacid;
Pethidine;
Pethidine - Intermediate - A, 4-cyano-1-methyl-4-phenylpiperidine;
Pethidine - Intermediate - B, ethyl-4-phenylpiperidine-4-carboxylate;
Pethidine - Intermediate - C, 1-methyl-4-phenylpiperidine-4-carboxylic acid;
Phenazocine;
Piminodine;
Racemethorphan;
Racemorphan;
Remifentanil.

3. Any material, compound, mixture or preparation which contains any quantity of the following substances having a potential for abuse associated with a stimulant effect on the central nervous system:
Amphetamine, its salts, optical isomers, and salts of its optical isomers;
Phenmetrazine and its salts;

Any substance which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers;
Methylphenidate.

4. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

Amobarbital;
Glutethimide;
Secobarbital;
Pentobarbital;
Phencyclidine.

5. The following hallucinogenic substance:
Nabilone.

6. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances which are immediate precursors to amphetamine and methamphetamine or phencyclidine:
Phenylacetone;
1-phenylcyclohexylamine;
1-piperidinocyclohexanecarbonitrile.
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§ 54.1-3450. Schedule III.

A. Unless specifically exempted or listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:

Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid, except those substances which are specifically listed in other schedules;

Any compound, mixture or preparation containing amobarbital, secobarbital, or pentobarbital or any salt of amobarbital, secobarbital, or pentobarbital and one or more other active medicinal ingredients which are not listed in Schedules II through V;

Any suppository dosage form containing amobarbital, secobarbital, or pentobarbital or any salt of amobarbital, secobarbital, or pentobarbital and approved by the Food and Drug Administration for marketing only as a suppository;
Chlorhexadol;

Any drug product containing gamma hydroxybutyric acid, including its salts, isomers, and salts of isomers, for which an application is approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C § 355);

Ketamine, its salts, isomers, and salts of isomers (some other names for ketamine: [±] -2-[2-chlorophenyl]-2-[methylamino]-cyclohexanone);
Lysergic acid;
Lysergic acid amide;
Methyprylon;
Sulfondiethylmethane;
Sulfonethylmethane;
Sulfonmethane;
Tiletamine - zolazepam or any salt thereof;

B. Nalorphine

C. Unless specifically excepted or unless listed in another schedule:

1. Any material, compound, mixture, or preparation containing any of the following narcotic drugs or their salts thereof: Buprenorphine.

2. Any material, compound, mixture, or preparation containing limited quantities of any of the following

narcotic drugs, or any salts thereof:

Not more than 1.8 grams of codeine, or any of its salts, per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium;

Not more than 1.8 grams of codeine, or any of its salts, per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

Not more than 300 milligrams of dihydrocodeinone, or any of its salts, per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium;

Not more than 300 milligrams of dihydrocodeinone, or any of its salts, per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

Not more than 1.8 grams of dihydrocodeine, or any of its salts, per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

Not more than 300 milligrams of ethylmorphine, or any of its salts, per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more ingredients in recognized therapeutic amounts;

Not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

Not more than 50 milligrams of morphine, or any of its salts, per 100 milliliters or per 100 grams with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

D. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

Benzphetamine;
Chlorphentermine;
Clortermine;
Phendimetrazine.

E. The Board may except by regulation any compound, mixture, or preparation containing any stimulation or depressant substance listed in subsection A from the application of all or any part of this chapter if the compound, mixture, or preparation contains one or more active medicinal ingredients not having a stimulant or depressant effect on the central nervous system, and if the admixtures are included therein in combinations, quantity, proportion, or concentration that vitiate the potential for abuse of the substances which have a stimulant or depressant effect on the central nervous system.

F. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts of isomers is possible within the specific chemical designation:

Anabolic steroids, including, but not limited to:
Boldenone (Dehydrotestosterone);
Clostebol (4-Chlorotestosterone) (Chlorotestosterone);

Dromostanolone (Drostanolone);
Ethylestrenol;
Fluoxymesterone;
Formyldienolone (Formebolone);
Mesterolone;
Methandriol (methylandrostenediol);
Methandrostenolone (Methandienone) (Dehydromethyltestosterone);
Methenolone;
17-Methyltestosterone (Methyltestosterone);
Mibolerone;
Nandrolone (19-Nortestosterone);
Norethandrolone;
Oxandrolone;
Oxymesterone (Oxymestrone);
Oxymetholone (Anasterone);
Stanolone (4-Dihydrotestosterone) (Dihydrotestosterone);
Stanozolol (Androstanazole);
Testolactone (1-Dehydrotestololactone);
Testosterone;
Trenbolone (Trienbolone) (Trienolone); and

Any salt, ester, or isomer of a drug or substance described or listed in this paragraph, if that salt, ester, or isomer promotes muscle growth. However, such term does not include an anabolic steroid which is expressly intended for administration through implants to cattle or other nonhuman species and which has been approved by the United States Secretary of Health and Human Services for such administration. If any person prescribes, dispenses, or distributes any such steroid for human use, such person shall be considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of this subsection.

G. Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a drug product approved by the U.S. Food and Drug Administration.

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§ 54.1-3452. Schedule IV.

1. Any material, compound, mixture, or preparation which contains any quantity of the following substances having a potential for abuse associated with a depressant effect on the central nervous system:

Alprazolam;
Barbital;
Bromazepam;
Camazepam;
Chloral betaine;
Chloral hydrate;
Chlordiazepoxide;
Clobazam;
Clonazepam;
Clorazepate;
Clotiazepam;
Cloxazolam;
Delorazepam;
Diazepam;
Dichloralphenazone
Estazolam;

Ethchlorvynol;
Ethinamate;
Ethyl loflazepate;
Fludiazepam;
Flunitrazepam;
Flurazepam;
Halazepam;
Haloxazolam;
Ketazolam;
Loprazolam;
Lorazepam;
Lormetazepam;
Mebutamate;
Medazepam;
Methohexital;
Meprobamate;
Methylphenobarbital;
Midazolam;
Nimetazapam;
Nitrazepam;
Nordiazepam;
Oxazepam;
Oxazolam;
Paraldehyde;
Petrichloral;
Phenobarbital;
Pinazepam;
Prazepam;
Quazepam;
Temazepam;
Tetrazepam;
Triazolam;
Zaleplon;
Zolpidem.

2. Any compound, mixture or preparation which contains any quantity of the following substances including any salts or isomers thereof:
Fenfluramine.

3. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

Cathine (+)-norpseudoephedrine;
Diethylpropion;
Fencamfamin;
Fenproprex;
Mazindol;
Mefenorex;
Modafinil;
Phentermine;
Pemoline (including organometallic complexes and chelates thereof);

Pipradrol;
Sibutramine;

SPA (-)-1-dimethylamino-1,2-diphenylethane.

4. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:

Dextropropoxyphene (alpha-(+)-4-dimethylamino-1,2-diphenyl-3-methyl-2-propionoxy butane);

Not more than 1 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

5. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including their salts:
Butorphanol (including its optical isomers);
Pentazocine.

6. The Board may except by regulation any compound, mixture, or preparation containing any depressant substance listed in subdivision 1 from the application of all or any part of this chapter if the compound, mixture, or preparation contains one or more active medicinal ingredients not having a depressant effect on the central nervous system, and if the admixtures are included therein in combinations, quantity, proportion, or concentration that vitiate the potential for abuse of the substances which have a depressant effect on the central nervous system.
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§ 54.1-3454. Schedule V.

1. Any compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, which also contains one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation, valuable medicinal qualities other than those possessed by the narcotic drug alone:

Not more than 200 milligrams of codeine, or any of its salts, per 100 milliliters or per 100 grams;

Not more than 100 milligrams of dihydrocodeine, or any of its salts, per 100 milliliters or per 100 grams;

Not more than 100 milligrams of ethylmorphine, or any of its salts, per 100 milliliters or per 100 grams;

Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit;

Not more than 100 milligrams of opium per 100 milliliters or per 100 grams;

Not more than 0.5 milligrams of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

The Board may except by regulation any compound, mixture or preparation containing any depressant substance listed in subdivision 1 from the application of all or any part of this chapter and such substances so excepted may be dispensed pursuant to § 54.1-3416.

2. Unless specifically excepted or listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers:
Pyrovalerone.

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§ 54.1-3455. Schedule VI.

1. Any compound, mixture, or preparation containing any stimulant or depressant drug exempted from Schedules III, IV or V and designated by the Board as subject to this section.

2. Every drug, not included in Schedules I, II, III, IV or V, or device, which because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not generally recognized among experts qualified by scientific training and experience to evaluate its safety and efficacy as safe for use except by or under the supervision of a practitioner licensed to prescribe or administer such drug or device.

3. Any drug, not included in Schedules I, II, III, IV or V, required by federal law to bear on its label prior to dispensing, at a minimum, the symbol "Rx only," or which bears the legend "Caution: Federal Law Prohibits Dispensing Without Prescription" or "Caution: Federal Law Restricts This Drug To Use By Or On The Order Of A Veterinarian" or any device which bears the legend "Caution: Federal Law Restricts This Device To Sales By Or On The Order Of A _____ ." (The blank should be completed with the word "Physician," "Dentist," "Veterinarian," or with the professional designation of any other practitioner licensed to use or order such device.)