

Carnegie Mellon University Environmental Health and Safety (EHS) Controlled Substances Program

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EHS Controlled Substances

Carnegie Mellon University

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1. INTRODUCTION

State and Federal regulations have been promulgated concerning the use and handling of US Department of Justice Drug Enforcement Administration (DEA) controlled substances. These regulations are in place to address materials which are or have the potential to be addictive or habit forming. These substances have been categorized into "schedules" that have been created by the DEA to reflect their level of concern. The "Carnegie Mellon University DEA Controlled Substances Program" is intended to ensure that Carnegie Mellon University is in compliance with our regulatory requirements.

Required activities under the DEA include:

- Registration of your work with the DEA and with Carnegie Mellon's Department of Environmental Health and Safety (EHS). Under certain circumstances, registration with the Pennsylvania Department of Health may be required.
- Identifying and screening employees prior to authorizing them for work with the substance(s).
- Following proscribed ordering/purchasing procedures. For some materials, a DEA form is required.
- Maintaining an accurate running inventory and performing regular inventory audits of the substance(s).
- Properly document all use and dispensing of the controlled substances.
- Ensuring security of the substance(s).
- Ensuring proper disposal of the substance(s).

2. SCOPE AND APPLICABILITY

These procedures apply to all Carnegie Mellon University personnel who use these controlled substances in **DEA Schedules I through V**, while teaching or conducting research. A complete listing of these substances can be found in **Appendix G**, "**Controlled Substances Schedules**."

3. RESPONSIBILITIES

3.1 The Department of Environmental Health and Safety (EHS) is responsible for:

- Developing and implementing the written Controlled Substance program.
- Providing guidance to University departments and personnel for registering with state and federal agencies.
- Providing advice on storage of controlled substances.
- Facilitating disposal of controlled substances.
- Accompanying the Institutional Care and Use Committee (IACUC) on semi-annual inspections
- **3.2 Departmental units** that order controlled substances, or whose personnel use controlled substances while teaching or conducting research, are responsible for:
 - Assuring compliance with Federal and State Laws.
 - Having employees working with Controlled Substances complete an employee questionnaire, and assuring that only approved employees work with the substance.
 - Assuring Controlled Substances ordered through the department are secured and stored in a way that will
 not lead to theft or misuse.

- Completing the Carnegie Mellon University Notification of Controlled Substance Registration and returning it to EHS
- Maintaining proper record keeping for Controlled Substances.
- Reporting any loss or theft by co-workers of Controlled Substances.
- Properly disposing of Controlled Substances.
- Annually complete the Controlled Substances Self-Inspection form and return it to EHS.

4. REGISTRATION REQUIREMENTS

Use of Controlled Substances at Carnegie Mellon University requires registration with:

- The Federal Drug Enforcement Administration (required for <u>all</u> work with controlled substances)
- Carnegie Mellon University EHS (required for all work with controlled substances)

4.1 Federal Drug Enforcement Administration

All activities with Controlled Substances must be registered with the Drug Enforcement Administration (DEA). The specific registration requirements vary depending on the material and the way in which it will be used. Also, one registration type may not cover two different activities. For example *research* with controlled substances and *dispensing* of controlled substances require separate registration.

For **Research and/or Chemical analysis** of any DEA controlled substance, you will need to complete **Form 225** and submit it to the DEA. Work with any Schedule I substance must be registered separately from Schedule II – V substances. (Schedule II – V substances may be registered together on the same Form 225.)

For **Dispensing or Instructional Activity** involving any DEA controlled substance, you will need to complete **Form 224** and submit it to the DEA. Dispensing is defined as by private practitioners (such as physicians, dentists, veterinarians, nurse practitioners, hospitals and pharmacies) for clinical and hospital use.

The registrations are for one year. Renewal registration is done using **Form 225a** or **Form 224a**, depending on the form used for the initial registration.

Instructions on the DEA web site, where these forms are located, will indicate the required documents that must be submitted with the registration form. These may include:

- Investigator Name, address, institution and a qualifications statement including a curriculum vitae with bibliography.
- Project Title, statement of purpose, controlled substance name and amount needed, location of research, security statement and a technical description of the substance use.
- Authority Institutional approval from Department Heads of other Institutional Official and grant number if applicable.

The required forms and detailed instructions are available on the DEA website.

4.2. Carnegie Mellon University

In order to maintain supervision of the Carnegie Mellon University Controlled Substances Program, each person who registers with the DEA and/or the Commonwealth of Pennsylvania and must also fill out a "Carnegie Mellon University "Notification of Controlled Substance Registration (Appendix A)".

5. AUTHORIZED USE

The registrant (i.e., the researcher or instructor) is responsible for managing the controlled substances in accordance with the requirements of the regulations including inventory, record keeping and security provisions.

Employees of the registrant may engage in approved activities under the direction of the registrant. Authorized users names must be documented on the Carnegie Mellon University Controlled Substance Authorized Users List (Appendix B) and uploaded to BioRAFT annually.

5.2 Employee Questionnaire

The registrant is required to screen employees prior to authorization of work with controlled substances and to include the following questions on a questionnaire as part of the screening process (21 CFR 1301.90):

- Within the past five years, have you been convicted of a felony, or, within the past two years, any misdemeanor, or, are you presently charged with committing a criminal offense?
- In the past 3 years, have you knowingly used narcotics, amphetamines, or barbiturates otherthan those prescribed to you by a physician?

Fill out one questionnaire (Appendix C) for each employee who is authorized by the Principal Investigator (PI) to handle DEA controlled substances under that PI's supervision. (NOTE: THIS PI MUST BE REGISTERED with the Drug Enforcement Agency). Make copies of the form as needed for each employee who will be working with these substances. Keep these questionnaires on file in the lab. Keep a blank copy of this form in your files for new hires to complete before you allow them to handle DEA controlled substances.

6. ORDERING/PURCHASING/RETURN/TRANSFER

To order a controlled substance you must first have a DEA license.

The Controlled Substance Ordering Form (**DEA Form 222**) is a paper-based form used to order controlled substances and is REQUIRED when dealing with Schedule I or Schedule II materials. The form is requisitioned directly from the DEA and is required to be filled out in triplicate. The DEA Form 222 also allows the exchange of controlled substances from the registrant to another party registered with the DEA (typically used when a controlled substance is sent to a reverse distributor for credit or disposal).

Schedule I or II registrants can request <u>DEA Form 222 on-line</u>.

You will receive the maximum number of order form books allowed for your business activity.

Schedule III, IV, and V drug orders do not require a DEA Form 222. These drugs can be ordered directly from the manufacturer. However, you may be asked to provide a copy of your DEA Registration before your order will be prepared and shipped.

Use the <u>Carnegie Mellon University Record of DEA Form 222</u> (Appendix F) to maintain accountability of all DEA Form 222's.

Users of Schedule substances are required to maintain thorough Purchasing Records:

All Controlled Substances purchases must be kept on record. Purchasing records can be:

- A copy of the invoice
- A copy of the shipping document
- A copy of the packing slip

Purchasing records must contain:

- The name, address, and DEA number of the company from which the controlled substance was purchased
- The name of the controlled substance purchased
- The size and strength of the controlled substance purchased
- The amount purchased (which should match the amount received)

The purchasing record (invoice, shipping document, or packing slip) must be annotated with the handwritten date of receipt. The date written on this document must match the date entered in the "Date Received" column on your <u>Carnegie Mellon University Record of Controlled Substances Purchased Form</u> (Appendix B).

7. ADMINISTERING AND DISPENSING

The registrant is required to document all instances in which the registered substance is administered or dispensed.

Administering records must contain:

- Your DEA number, name, and address
- The recipient's DEA number, name, and address
- A complete description of the product and the quantity distributed
- The date of distribution by the selling registrant
- The handwritten date received by the receiving registrant

Dispensing records must contain:

- The name and address of person (research subject) to whom administered/dispensed
- The date administered/dispensed
- The initials of person administering or dispensing on behalf of registrant

- The name of the controlled substance
- The strength and size of the controlled substance
- The amount administered/dispensed (number of units or volume)

Use the Record of Controlled Substance Administered/Dispensed to record these activities.

8. INVENTORY PROCEDURES (CONTINUING RECORDS)

8.1 General requirements

Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant. A separate inventory shall be made for each registered location and each independent activity registered. In the event controlled substances in the possession or under the control of the registrant are stored at a location for which he/she is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. The Carnegie Mellon University Controlled Substance Physical Inventory Form (Appendix E) meets the DEA requirements for a Controlled Substance inventory record. Complete inventory requirements can be found on the Department of Justice DEA website.

8.2 Initial inventory date

Every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the manufacture, distribution, or dispensing of controlled substances,. In the event a person commences business with no controlled substances on hand, he/she shall record this fact as the initial inventory.

8.3 Biennial inventory date

After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.

9. SECURITY

Researchers are generally permitted to keep Controlled Substances in a securely locked, sturdy cabinet or safe.

- Schedules III-V, the Controlled Substance must be in a locked cabinet or safe.
- Schedules I and II, the Controlled Substance must in a locked cabinet, with the cabinet secured to a wall or otherwise not removable.

The DEA license holder must have complete accountability of all controlled substances stored or used in their area. This makes keeping good records essential so that any shortages or missing controlled substances will not go unnoticed. Theft or misuse of a controlled substance is a criminal act that must be reported to the Pittsburgh District DEA Office:

PITTSBURGH DISTRICT OFFICE

1781 McKees Rocks Road Pittsburgh, PA 15136

Diversion Number: (412) 777-6940 Diversion Fax: (412) 777-1880

Group Supervisor - Kurt Dittmer (412) 777-1871

Carnegie Mellon University Police Department: (412) 268-2323

Environmental Health and Safety: (412) 268-8182

In addition to the immediate phone reporting, a <u>Report of Theft or Loss of Controlled Substances</u> (DEA Form 106) must be completed and submitted to the Pittsburgh DEA office.

Reporting is also necessary if small quantities of controlled substances become unaccounted for on a reoccurring basis. Keep copies of <u>DEA Form 106</u> in your inventory records.

10. DISPOSAL

When a registrant has controlled substances that are expired or unwanted, one of the following protocols must be followed.

10.1 Use to completion/manufacturer return

The preferred method of disposal of Controlled Substances is complete use of the substance such that there is none left to dispose. If there is excess material at the completion of research, contact the manufacturer to return the remainder.

10.2 Disposal of Controlled Substances

To dispose of any of unwanted/expired controlled substances, the following procedures should be followed:

- Visit the <u>EHS website</u> and submit an Online Request for Hazardous Waste Pickup. Please indicate you are disposing of a controlled substance by typing "Controlled Substance" in the Special Handling Instructions text box.
- Visit the <u>Department of Justice DEA website</u> and complete Sections A and B of DEA Form41 (note: instructions are also online).
- Once completed, email a copy of DEA Form 41 to <u>safety@andrew.cmu.edu</u>.
- Once the onsite destruction has occurred, Section C and D will be completed and you will receive a copy of the form for your records. To maintain compliance with DEA Regulations, you are required to keep this form for a minimum of 2 years.

11. Revisions

Date	Documented Changes	Initials
10/1/2019	Reviewed document – no changes	
4/9/2021	Updated Format and Accessibility Update	MAS
11/2/2021	Updated Links	MAS

If you have any questions on these procedures, please contact EHS at (412)268-8182

Appendix A - Employee Questionnaire for Employees Who will Have Access to **Substances Regulated by the Drug Enforcement Agency**

Department:	Supervisor
substances regulated under Title 2 Mellon University undergo an emp the following question be answere	A) requires that any person who will have access to controlled 21 CFR Section 1300.01 as a result of employment at Carnegie bloyee screening process. This screening process requires that ed by such persons. The will be held in the strictest of confidence.
years, of any misdemeanor or are offense? (Do not include any traffic	ave you been convicted of a felony, or within the past two you presently formally charged with committing a criminal c violations, juvenile offenses or military convictions, except by er is yes, furnish details of conviction, offense, location, date
Yes No	
•	e you ever knowingly used any narcotics, amphetamines or scribed to you by a physician? If the answer is yes, furnish
Yes No	
Name (Signature):	(print):
Name PI/Supervisor (Signature):	(print):
Date:	

by

Appendix B - Carnegie Mellon University Record of Controlled Substance Purchases

Product Name	Amount Purchased	Date Received	Company (Purchased from & DEA Number)	Invoice or Shipping Document Number

Note: To ensure a comprehensive record, file a copy of the invoice or shipping document in folder. <u>Insure the date of receipt is recorded on the invoice or shipping document.</u>

Appendix C - Carnegie Mellon University Record of Controlled Substances Administered/Dispensed

Name of Controlled Substance: $_$	
Form:	
Strength:	
Size:	

Date	Animal Number	Species of Animal	Initials of Person Administering/ Dispensing	Previous Balance	Amount Administered/ Dispensed (or Purchased)	New Balance

Appendix D - Carnegie Mellon University Controlled Substance Authorized Users List

(Note: For security purposes, the number of individuals who have access to controlled substances should

Complete the information requested below, attach for each user listed and submit this form to Environmental Health and Safety ow is a current list of all persons designated by me, the DEA license holder, to access controstances at the above location address. Name (Print or Type) Signature (Legal Signature) (As Written on the			
Complete the information requested below, attach for each user listed and submit this form to Environmental Health and Safety low is a current list of all persons designated by me, the DEA license holder, to access contribstances at the above location address. Name Signature Initials (Print or Type) (Legal Signature) (As Written on the	rant Name:		
Environmental Health and Safety elow is a current list of all persons designated by me, the DEA license holder, to access contrabstances at the above location address. Name Signature Initials (Print or Type) (Legal Signature) (As Written on the	on Name:		
Initials (Print or Type) Convironmental Health and Safety Low is a current list of all persons designated by me, the DEA license holder, to access contribute the above location address. Convironmental Health and Safety Low is a current list of all persons designated by me, the DEA license holder, to access contribute the DEA license holder, to access the DEA license holder, to acc	on Address:		
Name (Print or Type) Signature (Legal Signature) Signature (As Written on the	Environmental Health and Safe	ety	
(Print or Type) (Legal Signature) (As Written on the	<u>-</u>	-	
Administered/Dispensed Recor			(As Written on the
			Administered/Dispensed Record
<u> </u>	rant Signature:		

Appendix E - Carnegie Mellon University Controlled Substance Physical Inventory

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1. Initial inventory must be zero (0).

DEA Number:_____

- 2. Record all controlled substances obtained for research prior to application.
- 3. Subsequent inventories must be taken at least annually and all controlled substances in storage must be recorded.

Date:_____

Name of Controlled Substance	Quantity on Hand	Name of Controlled Substance	Quantit on Hand
(Strength and Size)		(Strength and Size)	

Appendix F - Carnegie Mellon University Record of DEA Form 222 Use

Beginning Form Number:	
Ending Form Number:	

INSTRUCTIONS FOR COMPLETION

Order Form Number: From the block titled "No. of this Order Form" (e.g. 910966683).

Name of Supplier: Name of Company or Person Form was submitted to.

Date Form Submitted: Date entered on DEA 222 Form.

Name of Item: List all products ordered on each DEA 222 Form. Use a separate line for each

product.

Amount Ordered: Enter amount listed in No. of Packages block on DEA 222 Form. **Amount Received:** Enter Amount and Date Received. If product is received in two shipments, a separate line is required for each shipment.

Note: This record does not relieve you of the responsibility of retaining copy 3 of the DEA Form 222 in your records. Copy 3 of the DEA Form 222 must be annotated to reflect the amount of merchandise received and the date received. The purpose of this record is to maintain accountability of all DEA Form 222's.

Order Form Number	To: Name Supplier	Date Form Submitted	Name of Item (List All Products)	Amount Ordered	Amount Received	Date Received

Appendix G - Section 1308.11 Schedule I.

- (a) **Schedule I** shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the DEA Controlled Substances Code Number set forth opposite it.
- **Opiates**. Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation (for purposes of paragraph_ (b)(34) only, the term isomer includes the optical and geometric isomers):

(1) Acetyl-alpha-methylfentanyl (N-[1-(1-methyl-2-phenethyl)-4-piperidinyl]-N-phenylacetamide)	9815
(2) Acetylmethadol	9601
(3) Allylprodine	9602
(4) Alphacetylmethadol (except levo-alphacetylmethadol also known as levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM)	9603
(5) Alphameprodine	9604
(6) Alphamethadol	9605
(7) Alpha-methylfentanyl (N-[1-(alpha-methyl-beta-phenyl)ethyl-4-piperidyl] propionanilide; 1-(1-methyl-2phenylethyl)-4-(N-propanilido) piperidine)	9814
(8) Alpha-methylthiofentanyl (N-[1-methyl-2-(2-thienyl)ethyl-4- piperidinyl]-N-phenylpropanamide)	9832
(9) Benzethidine	9606
(10) Betacetylmethadol	9607
(11) Beta-hydroxyfentanyl (N-[1-(2-hydroxy-2-phenethyl)-4- piperidinyl]-N-phenylpropanamide)	9830
(12) Beta-hydroxy-3-methylfentanyl (other name: N-[1-(2-hydroxy-2- phenethyl)-3-methyl-4-piperidinyl]-Nphenylpropanamide	9831
(13) Betameprodine	9608
(14) Betamethadol	9609
(15) Betaprodine	9611
(16) Clonitazene	9612
(17) Dextromoramide	9613
(18) Diampromide	9615
(19) Diethylthiambutene	9616
(20) Difenoxin	9168
(21) Dimenoxadol	9617
(22) Dimepheptanol	9618
(23) Dimethylthiambutene	9619
(24) Dioxaphetyl butyrate	9621

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(25) Dipipanone	9622
(26) Ethylmethylthiambutene	9623
(27) Etonitazene	9624
(28) Etoxeridine	9625
(29) Furethidine	9626
(30) Hydroxypethidine	9627
(31) Ketobemidone	9628
(32) Levomoramide	9629
(33) Levophenacylmorphan	9631
(34) 3-Methylfentanyl (N-[3-methyl-1-(2-phenylethyl)-4-piperidyl]-N-phenylpropanamide)	9813
(35) 3-methylthiofentanyl (N-[(3-methyl-1-(2-thienyl)ethyl-4-piperidinyl]-N-phenylpropanamide)	9833
(36) Morpheridine	9632
(37) MPPP (1-methyl-4-phenyl-4-propionoxypiperidine)	9661
(38) Noracymethadol	9633
(39) Norlevorphanol	9634
(40) Normethadone	9635
(41) Norpipanone	9636
(42) Para-fluorofentanyl (N-(4-fluorophenyl)-N-[1-(2-phenethyl)-4-piperidinyl] propanamide	9812
(43) PEPAP (1-(-2-phenethyl)-4-phenyl-4-acetoxypiperidine	9663
(44) Phenadoxone	9637
(45) Phenampromide	9638
(46) Phenomorphan	9647
(47) Phenoperidine	9641
(48) Piritramide	9642
(49) Proheptazine	9643
(50) Properidine	9644
(51) Propiram	9649
(52) Racemoramide	9645
(53) Thiofentanyl (N-phenyl-N-[1-(2-thienyl)ethyl-4-piperidinyl]-propanamide	9835
(54) Tilidine	9750
(55) Trimeperidine	9646

(c) **Opium derivatives**. Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, 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:

(1) Acetorphine	9319
(2) Acetyldihydrocodeine	9051
(3) Benzylmorphine	9052

(4) Codeine methylbromide	9070
(5) Codeine-N-Oxide	9053
(6) Cyprenorphine	9054
(7) Desomorphine	9055
(8) Dihydromorphine	9145
(9) Drotebanol	9335
(10) Etorphine (except hydrochloride salt)	9056
(11) Heroin	9200
(12) Hydromorphinol	9301
(13) Methyldesorphine	9302
(14) Methyldihydromorphine	9304
(15) Morphine methylbromide	9305
(16) Morphine methylsulfonate	9306
(17) Morphine-N-Oxide	9307
(18) Myrophine	9308
(19) Nicocodeine	9309
(20) Nicomorphine	9312
(21) Normorphine	9313
(22) Pholcodine	9314
(23) Thebacon	9315

(d) **Hallucinogenic substances**. 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 paragraph only, the term "isomer" includes the optical, position and geometric isomers):

(1) Alpha-ethyltryptamine	7249
Some trade or other names: etryptamine; Monase; alpha-ethyl-1H-indole-3-ethanamine; 3-(2-aminobutyl) indole; alpha-ET; and AET.	
(2) 4-bromo-2,5-dimethoxy-amphetamine	7391
Some trade or other names: 4-bromo-2,5-dimethoxyalpha-methylphenethylamine; 4-br	omo-2,5-DMA
(3) 4-Bromo-2,5-dimethoxyphenethylamine	7392
Some trade or other names: 2-(4-bromo-2,5-dimethoxyphenyl)-1-aminoethane; alpha-desmethyl DOB; 2C-B, Nexus.	
(4) 2,5-dimethoxyamphetamine	7396
Some trade or other names: 2,5-dimethoxy-alpha-methylphenethylamine; 2,5-DMA	
(5) 2,5-dimethoxy-4-ethylamphet-amine	7399
Some trade or other names: DOET	
(6) 2,5-dimethoxy-4-(n)-propylthiopenenthylamine (2C-T-7), its optical isomers, salts and salts of isomers	7348
(7) 4-methoxyamphetamine	7411

Some trade or other names: 4-methoxy-alpha-methylphenethylamine; paramethoxyar	mphetamine, PMA
(8) 5-methoxy-3,4-mdthylenedioxy-amphetamine	7401
(9) 4-methyl-2,5-dimethoxy-amphetamine	7395
Some trade and other names: 4-methyl-2,5-dimethoxy-alpha-methylphenethylamine;	"DOM"; and "STP"
(10) 3,4-methylenedioxy amphetamine	7400
(11) 3,4-methylenedioxymethamphetamine (MDMA)	7405
(12) 3,4-methylenedioxy-N-ethylamphetamine (also known as N-ethyl-alpha-methyl-3,4(methylenedioxy)phenethylamine, N-ethyl MDA, MDE, MDEA	7404
(13) N-hydroxy-3,4-methylenedioxyamphetamine (also known as N-hydroxy-alphamethyl-	
3,4(methylenedioxy)phenethylamine, and N-hydroxy MDA	7402
(14) 3,4,5-trimethoxy amphetamine	7390
(15) Alpha-methyltryptamine (other name: AMT)	7432
(16) Bufotenine	7433
Some trade and other names: 3-(beta-Dimethylaminoethyl)-5-hydroxyindole; 3-(2-dimethylolo); N, N-dimethylserotonin; 5-hydroxy-N,N-dimethyltryptamine; mappine	ethylaminoethyl)-5-
(17) Diethyltryptamine	7434
Some trade and other names: N,N-Diethyltryptamine; DET	·
(18) Dimethyltryptamine	7435
Some trade or other names: DMT	·
(19) 5-methoxy-N,N-diisopropyltryptamine (5-MeO-DIPT), its isomers, salts and salts of isomers	7439
(20) Ibogaine	7260
Some trade and other names: 7-Ethyl-6,6 beta;,7,8,9,10,12,13-octahydro-2-methoxy-6,9 2':1,2] azepino [5,4-b] indole; Tabernanthe iboga	9-methano-5H-pyrido [1'
(21) Lysergic acid diethylamide	7315
(22) Marihuana	7360
(23) Mescaline	7381
(24) Parahexyl7374; some trade or other names: 3-Hexyl-1-hydroxy-7,8,9,10-tetrahydro6,6,9-trimethyl-6H-dibenzo[b,d]pyran; Synhexyl.	
(25) Peyote	7415
Meaning all parts of the plant presently classified botanically as Lophophora whether growing or not, the seeds thereof, any extract from any part of such compound, manufacture, salts, derivative, mixture, or preparation of such pla extracts (Interprets 21 USC 812(c), Schedule I(c) (12))	plant, and every
(26) N-ethyl-3-piperidyl benzilate	7482
(27) N-methyl-3-piperidyl benzilate	7484
(28) Psilocybin	7437
(29) Psilocyn	7438
(30) Tetrahydrocannabinols	7370
(So, Islanda Godina God	1,3,3

Meaning tetrahydrocannabinols naturally contained in a plant of the genus Cannabis (cannabis plant), as well as synthetic equivalents of the substances contained in the cannabis plant, or in the resinous extractives of such plant, and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity to those substances contained in the plant, such as the following:

- -1 cis or trans tetrahydrocannabinol, and their optical isomers
- -6 cis or trans tetrahydrocannabinol, and their optical isomers
- -3,4 cis or trans tetrahydrocannabinol, and its optical isomers

(Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered.)

structures, regardless of flumerical designation of atomic positions covered.)	
(31) Ethylamine analog of phencyclidine	7455
Some trade or other names: N-ethyl-1-phenylcyclohexylamine, (1-phenylcyclohexyl)ethylamine, N-(1phenylcyclohexyl)ethylamine, cyclohexamine, PCE	
(32) Pyrrolidine analog of phencyclidine	7458
Some trade or other names: 1-(1-phenylcyclohexyl)-pyrrolidine, PCPy, PHP	
(33) Thiophene analog of phencyclidine	7470
Some trade or other names: 1-[1-(2-thienyl)-cyclohexyl]-piperidine, 2-thienylanalog of phencyclidine, TPCP, TC	
(34) 1-[1-(2-thienyl)cyclohexyl]pyrrolidine	7473
Some other names: TCPy	

(e) **Depressants**. 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:

(1) gamma-hydroxybutyric acid (some other names include GHB; gamma-hydroxybutyrate;	
4-hydroxybutyrate; 4-hydroxybutanoic acid; sodium oxybate; sodium oxybutyrate)	2010
(2) Mecloqualone	2572
(3) Methaqualone	2565

(f) **Stimulants**. 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:

(1) Aminorex (Some other names: aminoxaphen; 2-amino-5-phenyl-2- oxazoline; or 4,5dihydro-5-phenly-2-oxazolamine)	1585
(2) N-benzylpiperazine (some other names: BZP; 1-benzylpiperazine), its optical isomers, salts and salts of isomers	7493
(3) Cathinone	1235
Some trade or other names: 2-amino-1-phenyl-1-propanone, alpha-aminopropiophenone, 2-aminopropiophenone, and norephedrone	
(4) Fenethylline	1503

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(5) Methcathinone (Some other names: 2-(methylamino)-propiophenone; alpha(methylamino)propiophenone; 2-(methylamino)-1-phenylpropan-1-one; alpha-Nmethylaminopropiophenone; monomethylpropion; ephedrone; N-methylcathinone; methylcathinone; AL-464; AL-422; AL-463 and UR1432), its salts, optical isomers and	
salts of optical isomers	1237
(6) (+/-)cis-4-methylaminorex ((+/-)cis-4,5-dihydro-4-methyl-5-phenyl-2-oxazolamine)	1590
(7) N-ethylamphetamine	1475
(8) N,N-dimethylamphetamine (also known as N,N-alpha-trimethyl-benzeneethanamine; N,Nalpha-trimethylphenethylamine)	1480

(g) **Temporary listing of substances subject to emergency scheduling**. Any material, compound, mixture or preparation which contains any quantity of the following substances:

(1) N-[1-benzyl-4-piperidyl]-N-phenylpropanamide (benzylfentanyl), its optical isomers, salts and salts of isomers	9818
(2) N-[1-(2-thienyl)methyl-4-piperidyl]-N-phenylpropanamide (thenylfentanyl), its optical isolers, salts and salts of isomers	9834

Appendix H - Section 1308.12 Schedule II.

- (a) **Schedule II** shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the Controlled Substances Code Number set forth opposite it.
- (b) **Substances, vegetable origin or chemical synthesis**. Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:
 - (1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate excluding apomorphine, thebaine-derived butorphanol, dextrorphan, nalbuphine, nalmefene, naloxone, and naltrexone, and their respective salts, but including the following:

- (2) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in <u>paragraph (b) (1)</u> of this section, except that these substances shall not include the isoquinoline alkaloids of opium.
- (3) Opium poppy and poppy straw.
- (4) Coca leaves (9040) and any salt, compound, derivative or preparation of coca leaves (including cocaine (9041) and ecgonine (9180) and their salts, isomers, derivatives and salts of isomers and

- derivatives), and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine.
- (5) 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), 9670.
- (c) **Opiates**. Unless specifically excepted or unless in another schedule any of the following opiates, including its isomers, esters, ethers, salts and salts of isomers, esters and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation, dextrorphan and levopropoxyphene excepted:

(1) Alfentanil	9737
(2) Alphaprodine	9010
(3) Anileridine	9020
(4) Bezitramide	9800
(5) Bulk dextropropoxyphene (non-dosage forms)	9273
(6) Carfentanil	9743
(7) Dihydrocodeine	9120
(8) Diphenoxylate	9170
(9) Fentanyl	9801
(10) Isomethadone	9226
(11) Levo-alphacetylmethadol	9648
[Some other names: levo-alpha-acetylmethadol, levomethadyl acetate, LAAM]	
(12) Levomethorphan	9210
(13) Levorphanol	9220
(14) Metazocine	9240
(15) Methadone	9250
(16) Methadone-Intermediate, 4-cyano-2-dimethylamino-4,4-diphenyl butane	9254
(17) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid	9802
(18) Pethidine (meperidine)	9230
(19) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine	9232
(20) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate	9233
(21) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid	9234
(22) Phenazocine	9715
(23) Piminodine	9730
(24) Racemethorphan	9732

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(25) Racemorphan	9733
(26) Remifentanil	9739
(27) Sufentanil	9740

(d) **Stimulants**. 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:

(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers	1100
(2) Methamphetamine, its salts, isomers, and salts of its isomers	1105
(3) Phenmetrazine and its salts	1631
(4) Methylphenidate	1724
(5) Lisdexamfetamine, its salts, isomers, and salts of its isomers	1205

(e) **Depressants**. 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:

(1) Amobarbital	2125
(2) Glutethimide	2550
(3) Pentobarbital	2270
(4) Phencyclidine	7471
(5) Secobarbital	2315

(f) Hallucinogenic substances.

(1) Nabilone	7379
[Another name for nabilone: (+/-)-trans-3-(1,1-dimethylheptyl)-6,6a,7,8,10,10a-hexahydro-1-hydroxy-6, 6-dimethyl-9H-dibenzo[b,d]pyran-9-one]	

(i) Phenylacetone	8501	
Some trade or other names: phenyl-2-propanone; P2P; benzyl methyl ketone; methyl benzyl ketone;		

Immediate precursors to phencyclidine (PCP):

(i) 1-phenylcyclohexylamine	7460
(ii) 1-piperidinocyclohexanecarbonitrile (PCC)	8603

- (g) **Immediate precursors**. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances:
 - (1) Immediate precursor to amphetamine and methamphetamine:

Appendix I - Section 1308.13 Schedule III.

- (a) Schedule III shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the DEA Controlled Substances Code Number set forth opposite it.
- (b) **Stimulants**. 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:

(1) Those compounds, mixtures, or preparations in dosage unit form containing any stimulant substances listed in schedule II which compounds, mixtures, or preparations were listed on August 25, 1971, as excepted compounds under Sec. 1308.32, and any other drug of the quantitative composition shown in that list for those drugs or which is the same except that it contains a lesser quantity of	
controlled substances	1405
(2) Benzphetamine	1228
(3) Chlorphentermine	1645
(4) Clortermine	1647
(5) Phendimetrazine	1615

- (c) **Depressants**. 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:
 - (1) Any compound, mixture or preparation containing:
 - (i) Amobarbital 2126
 - (ii) Secobarbital 2316
 - (iii) Pentobarbital 2271

or any salt thereof and one or more other active medicinal ingredients which are not listed in any schedule.

- (2) Any suppository dosage form containing:
 - (i) Amobarbital 2126
 - (ii) Secobarbital 2316
 - (iii) Pentobarbital 2271

or any salt of any of these drugs and approved by the Food and Drug Administration for marketing only as a suppository.

(3) Any substance which contains any quantity of a derivative of barbituric acid or any salt thereof	2100
(4) Chlorhexadol	2510
(5) 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	2012
(6) Ketamine, its salts, isomers, and salts of isomers	7285
[Some other names for ketamine: (±)-2-(2-chlorophenyl)-2-(methylamino)-cyclohexar	none]
(7) Lysergic acid	7300
(8) Lysergic acid amide	7310
(9) Methyprylon	2575
(10) Sulfondiethylmethane	2600
(11) Sulfonethylmethane	2605
(12) Sulfonmethane	2610
(13) Tiletamine and zolazepam or any salt thereof	7295
	•

Some trade or other names for a tiletamine-zolazepam combination product: Telazol Some trade or other names for tiletamine: 2-(ethylamino)-2-(2-thienyl)-cyclohexanone Some trade or other names for zolazepam: 4-(2-fluorophenyl)-6,8-dihydro-1,3,8-trimethylpyrazolo-[3,4-e] [1,4]diazepin-7(1H)-one, flupyrazapon

- (d) Nalorphine 9400.
- (e) Narcotic Drugs. 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 calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:

>	9803
(ii) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts	9804
(iii) Not more than 300 milligrams of dihydrocodeinone (hydrocodone) per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium	9805
(iv) Not more than 300 milligrams of dihydrocodeinone (hydrocodone) per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts	9806
(v) Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts	9807

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(vi) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts	9808
(vii) 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	9809
(viii) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts	9810

(2) Any material, compound, mixture, or preparation containing any of the following narcotic drugs or their salts, as set forth below:

(i) Buprenorphine	9064	
(ii) [Reserved]		

(f) **Anabolic steroids**. 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:

(1) Anabolic Steroids	4000

(g) Hallucinogenic substances.

(1) Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule	
in a U.S. Food and Drug Administration approved product	7369

[Some other names for dronabinol: (6a*R-trans*)-6a,7,8,10a-tetrahydro-6,6,9-trimethyl-3-pentyl-6*H*-dibenzo [*b,d*]pyran-1-ol] or (-)-delta-9-(*trans*)-tetrahydrocannabinol]

Appendix J - Section 1308.14 Schedule IV.

- (a) Schedule IV shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the DEA Controlled Substances Code Number set forth opposite it.
- (b) **Narcotic drugs**. 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:

(1) Not more than 1 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit	9167
(2) Dextropropoxyphene (alpha-(+)-4-dimethylamino-1,2-diphenyl-3-methyl-2propionoxybutane)	9278

(c) **Depressants**. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, 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:

(1) Alprazolam	2882
(2) Barbital	2145
(3) Bromazepam	2748
(4) Camazepam	2749
(5) Chloral betaine	2460
(6) Chloral hydrate	2465
(7) Chlordiazepoxide	2744
(8) Clobazam	2751
(9) Clonazepam	2737
(10) Clorazepate	2768
(11) Clotiazepam	2752
(12) Cloxazolam	2753
(13) Delorazepam	2754
(14) Diazepam	2765
(15) Dichloraphenazone	2467
(16) Estazolam	2756
(17) Ethchlorvynol	2540
(18) Ethinamate	2545

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(19) Ethyl loflazepate	2758
(20) Fludiazepam	2759
(21) Flunitrazepam	2763
(22) Flurazepam	2767
(23) Halazepam	2762
(24) Haloxazolam	2771
(25) Ketazolam	2772
(26) Loprazolam	2773
(27) Lorazepam	2885
(28) Lormetazepam	2774
(29) Mebutamate	2800
(30) Medazepam	2836
(31) Meprobamate	2820
(32) Methohexital	2264
(33) Methylphenobarbital (mephobarbital)	2250
(34) Midazolam	2884
(35) Nimetazepam	2837
(36) Nitrazepam	2834
(37) Nordiazepam	2838
(38) Oxazepam	2835
(39) Oxazolam	2839
(40) Paraldehyde	2585
(41) Petrichloral	2591
(42) Phenobarbital	2285
(43) Pinazepam	2883
(44) Prazepam	2764
(45) Quazepam	2881
(46) Temazepam	2925
(47) Tetrazepam	2886
(48) Triazolam	2887
(49) Zaleplon	2781
(50) Zolpidem	2783
(51) Zopiclone	2784

(d) **Fenfluramine**. Any material, compound, mixture, or preparation which contains any quantity of the following substances, 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:

(1) Fenfluramine 1670

(e) **Stimulants**. 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:

(1) Cathine ((+)-norpseudoephedrine)	1230
(2) Diethylpropion	1610
(3) Fencamfamin	1760
(4) Fenproporex	1575
(5) Mazindol	1605
(6) Mefenorex	1580
(7) Modafinil	1680
(8) Pemoline (including organometallic complexes and chelates thereof)	1530
(9) Phentermine	1640
(10) Pipradrol	1750
(11) Sibutramine	1675
(12) SPA ((-)-1-dimethylamino- 1,2-diphenylethane)	1635
(12) SPA ((-)-1-dimethylamino- 1,2-diphenylethane)	1635

(f) **Other substances**. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances, including its salts:

(1) Pentazocine	9709
(2) Butorphanol (including its optical isomers)	9720

Appendix K - Section 1308.15 Schedule V.

- (a) Schedule V shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section.
- (b) Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs and their salts, as set forth below: (1) [Reserved]
- (c) Narcotic drugs containing non-narcotic active medicinal ingredients. Any 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, which shall include one or more non-narcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by narcotic drugs alone:
- (1) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams.
- (2) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams.
- (3) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.
- (4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.
- (5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.
- (6) Not more than 0.5 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.
- (d) **Stimulants**. Unless specifically exempted or excluded 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:

(1) Pyrovalerone	1485
(2) [Reserved]	

- (e) **Depressants**. Unless specifically exempted or excluded 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:
- (1) Pregabalin [(S)-3-(aminomethyl)-5-methylhexanoic acid] 2782
- (2) [Reserved]

Appendix L - Controlled Substances Questionnaire

Please fill out this form and return to:
Andrew Lawson
311 Mellon Institute
Mail Drop 90

Name_	
Campu	us Phone Number Room/Lab Number
1.	Do you use controlled substances in your work at Carnegie Mellon University? (Yes or No) (If No, stop here) a. If so, do you have a DEA number? (Yes or No) b. What is your DEA number(s)?
	c. When are you due for renewal? Month Year d. Which controlled substances are used?
	e. What schedule(s) are they in? (Check all that apply) IIIIIIIV
	f. What are they used for? (Research, Analysis, Animal Use)
2.	How are the controlled substances stored?
3.	Do you keep records of receipt and use/dispense of the controlled substances? (Yes or No)
	a. If so, what information is kept?
4.	Do you have any employees working with controlled substances? (Yes or No)
5.	If so, have they been screened and filled out an appropriate questionnaire? (Yes or No)
6.	Has there been any loss or theft of a controlled substance? (Yes or No)
7.	How do you dispose of the controlled substance? (Check all that apply)
	Use all substance
	Return to Manufacturer
	Through EHS

Department:_____

Supervisor: _____

Appendix M - Employee Questionnaire for Employees Who will Have Access to Substances Regulated by the Drug Enforcement Agency

sub Mel the	The Drug Enforcement Agency (DEA) requires that any person who will have account substances regulated under Title 21 CFR Section 1300.01 as a result of employ Mellon University undergo an employee screening process. This screening prothe following question be answered by such persons. The responses to this question the strictest of confidence.	ment at Carnegie cess requires that
1)	Within the past five years, have you been convicted of a felony, or within the of any misdemeanor or are you presently formally charged with committing offense? (Do not include any traffic violations, juvenile offenses or military except by general court-martial.) If the answer is yes, furnish details of conflocation, date and sentence. Yes No	ng a criminal convictions,
2)	2) In the past three years, have you ever knowingly used any narcotics, amph barbiturates, other than those prescribed to you by a physician? If the answer details. Yes No	
Nar	Name (Signature): (print):	
Nar	Name PI/Supervisor (Signature):(print):	
Dat	Date:	