San Diego State University
Environmental Health and Safety

PROGRAM FOR THE USE OF CONTROLLED SUBSTANCES OR PRECURSOR/LIST CHEMICALS IN RESEARCH

SUMMARY

A number of substances or chemicals regulated by the U.S. Drug Enforcement Administration (DEA) and the CA Bureau of Narcotics (BNE) are used in research at SDSU. These substances or chemicals are also known as "controlled substances", "list chemicals", and "precursor chemicals". Their acquisition, possession, use, and disposal are governed by regulations that require procedures be developed, implemented and enforced to ensure safety and prevent abuse. A written guide that includes such procedures has been established at SDSU. This guide also describes responsibilities by individuals or groups working with controlled substances and precursor/list chemicals under the auspices of San Diego State University (SDSU). SDSU currently maintains an institutional DEA registration governing the use of these regulated substances or chemicals for research. Environmental Health and Safety Department (EHS) serves as Program Administrator overseeing the acquisition, possession, use, and disposal of these regulated substances or chemicals.

The key elements of the Controlled Substances and Precursor/List Chemicals Program include:

- Proper DEA registration.
- An institutional application and approval process.
- Controls on the ordering, receipt, use, storage, disposition, and disposal of these substances.
- Provisions for inventory, audits and inspections.

Major responsibilities are assigned to various departments and individuals.

- The Department of Environmental Health & Safety is responsible for administering SDSU's Controlled Substances and Precursor/List Chemicals Program. Other major responsibilities are assigned in the written procedure.

- Principal Investigators and Department Chairs must ensure that research activities under their direction are in compliance with Federal and State regulations as well as SDSU policies and procedures pertaining to the acquisition, possession, use, disposition and disposal of the controlled substances and precursor/list chemicals.

- Procurement Departments (both SDSU and Research Foundation) are responsible for proper handling of Controlled Substance and Precursor/List Chemicals purchases.

- The Pharmacists at Student Health Services are responsible for properly receiving and notifying EHS of the arrival of these controlled substances and precursor/list chemicals.

- The Department of Public Safety is responsible for investigation and enforcement actions pertaining to the illegal use or possession of controlled substances and precursor/list chemicals.

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A. OVERVIEW AND PURPOSE

Federal and State regulations require that procedures be established to ensure safe and authorized use of controlled substances or precursor/list chemicals at any place of business, research or manufacturing where they are used. The purpose of this program guide is to set forth these procedures for research activities by persons or groups working under the auspices of San Diego State University DEA Registration.

B. DEFINITIONS AND ACRONYMS

1. Definitions

Controlled Substances - Drugs and certain other chemicals, both narcotic and non-narcotic, which come under the jurisdiction of Federal and State laws regulating their manufacture, sale, distribution, use and disposal.

EHS Controlled Substance or Precursor/List Chemical Purchase Request – An EHS form filled out by purchasers of controlled drugs or precursor/list chemical that is separate from and in addition to the Purchase Requisition Form sent to Procurement Departments. The EHS Controlled Substances or Precursor/List Purchase Request Form is to be sent to EH&S, while the corresponding Purchase Order Request is sent to Procurement (copy sent to EHS).

Form 222 - A form issued by the Drug Enforcement Administration that must be filled out in order to purchase or transfer controlled substances schedule II. The dispenser or vendor sends a copy of the form to the Federal Drug Enforcement Administration.

Registration Certificate - A document issued to individuals or businesses by the Drug Enforcement Administration, permitting manufacture, research, medical and other uses and handling of controlled substances.

Schedule - Any of five groups or classes of controlled substances, divided as such by their relative potential for abuse, status of accepted medical use and the degree of physical or psychological dependence that may be caused by abuse of the material.

2. Acronyms

DEA - The Drug Enforcement Administration of the United States Department of Justice

CSUA – Controlled Substance Use Authorization

PLCUA – Precursor/List Chemical Use Authorization

CSDR - Controlled Substances Dispense Record

EH&S - Department of Environmental Health & Safety at San Diego State University

C. RESPONSIBILITIES

1. The EH&S Department of the University is responsible for:

   (a) Developing, revising and training the requirements described in this program document.

   (b) Obtaining and renewing DEA Controlled Substance Registration Certificates.

   (c) Issuing use authorizations and purchase.

   (d) Auditing the records and procedures of research investigators using the substances and chemicals under the SDSU DEA Registration Certificates.

2. Principal investigators, faculty and department heads are responsible for:

   (a) Compliance Federal and State regulations and SDSU policies and procedures pertaining to the use of controlled substances and precursor/list chemicals.

   (b) Selection and training of auxiliary staff who will order, receive, store, use, maintain records and surrender controlled substances and precursor/list chemicals.

   (c) Maintaining strict control over inventory and security for the controlled substances and precursor/list chemicals.

   (d) Contacting EH&S with questions concerning use of the controlled substances and precursor/list chemicals or if portions of the controlled substances or precursor/list chemicals are missing.

3. The Pharmacist at Student Health Services is responsible for receiving and notifying EHS of the arrival of controlled substances and precursor chemicals.

4. Procurement Departments (both SDSU and Research Foundation) are responsible for processing Purchase Order Requests and EHS PURCHASE REQUESTS in accordance with this procedure.

D. AUTHORITY AND REGULATORY COMPLIANCE

The SDSU's program for regulation and administration of controlled substances distinguishes between patient-care (e.g. Student Health Services) and research application. EH&S has been delegated the responsibility for coordination of acquisition, distribution, use and disposal of controlled substances and precursor/list chemicals used in research at SDSU. The use of controlled substances in patient-care applications is not within the auspices of this program document. Pharmacists and physicians supporting Student Health Services will operate under their own DEA Registration Numbers and will maintain their own purchase, recordkeeping, disposal and other regulated practices.

Compliance with Federal and State laws and SDSU policies and procedures is expected by all individuals and groups associated with SDSU. These regulations include the following:

1. Code of Federal Regulations: Title 21, Chapter II (Parts 1300 to end) - These regulations implement the Controlled Substances Act of 1970, the Diversion Control Amendments of 1984, 1985, 1986 and subsequent amendments.

2. Health and Safety Code: Division 10: California Uniform Controlled Substances Act.

3. Federal Chemical Diversion and Trafficking Act of 1988.

All records regarding the use of controlled substances and precursor/list chemicals are subject to review by the SDSU Controlled Substance Program Manager or officials and investigators from the U.S. Drug Enforcement Agency and California Bureau of Narcotic Enforcement.

This procedure is not to be construed as a summary of all regulations that may be pertinent to handling of controlled substances and precursor/list chemicals. Individuals who bear responsibility in this area are encouraged to read for themselves the Federal and State regulations that govern use of the materials and to be aware of the fines and penalties associated with their misuse.

E. CONTROLLED SUBSTANCE SCHEDULES AND DRUG CODES

Drugs and other substances that are considered controlled substances under the Controlled Substances Act (CSA) are divided into five schedules. An updated and complete list of the schedules is published annually in **Title 21 Code of Federal Regulations (C.F.R.) §§ 1308.11 through 1308.15**. Substances are placed in their respective schedules based on whether they have a currently accepted medical use in treatment in the United States, their relative abuse potential, and likelihood of causing dependence when abused. Substances within each schedule are also divided into narcotic and non-narcotic categories. Some examples of the drugs in each schedule are listed below.

The following characteristics apply to the schedules indicated:

1. Schedule I

   (a) The drug or substance has a high potential for abuse.

   (b) The drug or substances has no currently accepted medical use in treatment in the United States.

   (c) There is a lack of accepted safety for use of the drug or substance under medical supervision.

   (d) Some examples of substances listed in Schedule I are: heroin, lysergic acid diethylamide (LSD), marijuana (cannabis), peyote, methaqualone, and 3,4-methylenedioxymethamphetamine (“Ecstasy”).

2. Schedule II

   (a) The drug or substance has a high potential for abuse.

(b) The drug or substance has a currently accepted medical use in treatment in the United States or a currently accepted use with severe restrictions.

(c) Abuse of the drug or substance may lead to severe psychological or physical dependence.

(d) Examples of Schedule II narcotics include: hydromorphone (Dilaudid®), methadone (Dolophine®), meperidine (Demerol®), oxycodone (OxyContin®, Percocet®), and fentanyl (Sublimaze®, Duragesic®). Other Schedule II narcotics include: morphine, opium, and codeine.

Examples of Schedule II stimulants include: amphetamine (Dexedrine®, Adderall®), methamphetamine (Desoxyn®), and methylphenidate (Ritalin®).

Other Schedule II substances include: amobarbital, glutethimide, and pentobarbital.

3. Schedule III

(a) The drug or substance has a potential for abuse less than the drugs or other substances in Schedules I and II.

(b) The drug or substance has a currently accepted medical use in treatment in the United States.

(c) Abuse of the drug or substance may lead to moderate or low physical dependence or high psychological dependence.

(d) Examples of Schedule III narcotics include: combination products containing less than 15 milligrams of hydrocodone per dosage unit (Vicodin®), products containing not more than 90 milligrams of codeine per dosage unit (Tylenol with Codeine®), and buprenorphine (Suboxone®).

Examples of Schedule III non-narcotics include: benzphetamine (Didrex®), phendimetrazine, ketamine, and anabolic steroids such as Depo®-Testosterone.

4. Schedule IV

(a) The drug or substance has a low potential for abuse relative to the drugs or other substances in Schedule III.

(b) The drug or substance has a currently accepted medical use in treatment in the United States.

(c) Abuse of the drug or substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule III.

(d) Examples of Schedule IV substances include: alprazolam (Xanax®), carisoprodol (Soma®), clonazepam (Klonopin®), clorazepate (Tranxene®), diazepam (Valium®),

lorazepam (Ativan®), midazolam (Versed®), temazepam (Restoril®), and triazolam (Halcion®).

5. Schedule V

(a) The drug or other substance has a low potential for abuse relative to the drugs or other substances in Schedule IV.

(b) The drug or other substance has a currently accepted medical use in treatment in the United States.

(c) Abuse of the drug or substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule IV.

(d) Substances in this schedule consist primarily of preparations containing limited quantities of certain narcotics.

(e) Examples of Schedule V substances include: cough preparations containing not more than 200 milligrams of codeine per 100 milliliters or per 100 grams (Robitussin AC®, Phenergan with Codeine®), and ezogabine.

For current listing of Schedule I through V Controlled Substances, List I and II Regulated Chemicals, go to http://www.deadiversion.usdoj.gov/schedules/index.html#list . The schedule number and identity of substances that are controlled change periodically. Contact EH&S for questions regarding the current listing.

F. LIST CHEMICALS AND DRUG CODES

G. PRECURSOR CHEMICALS

H. AUTHORIZATION, ACQUISITION, AND USE PROCEDURES

The following section describes how controlled drugs are to be ordered, received and handled by persons associated with SDSU. Individual subsections are devoted to use-authorization, ordering, receiving, storage and security, disposal and record keeping procedures.

1. USE AUTHORIZATION PROCEDURES

Persons who desire to use controlled substances, precursor or list chemicals at SDSU must first complete and submit a USE AUTHORIZATION APPLICATION FORM to EH&S for review and approval. The approval authorizes the applicant and all listed individuals to use drugs Scheduled II to V for research. For example, a researcher may obtain an authorization to use Schedule II drugs for experimentation on pre-natal effects of drug exposure in rats.

Once the application is reviewed, signed and approved by EHS, it remains valid subject to the following conditions:

(a) There are no changes in protocol #, procedures or the types of drugs used. A USE AUTHORIZATION UPDATE must be filed with EH&S to document this. Also, the UPDATE form must be submitted to EH&S whenever a change in personnel who have access to the drug occurs.

(b) There are no egregious violations to the use of controlled substances, precursor, or list chemicals.

A copy of the initial USE AUTHORIZATION APPLICATION FORM is found in Appendix 2. A copy of the AUTHORIZATION UPDATE form is found in Appendix 3.

2. ORDERING PROCEDURES

Controlled substances are usually ordered from a vendor licensed to sell the drugs.

(a) To order controlled substances <u>from a licensed vendor.</u>

(1) Complete a USE AUTHORIZATION APPLICATION FORM to EH&S. See Section F.1 above.

(2) Complete and submit an EHS PURCHASE REQUEST to EH&S. A copy of this form is found in Appendix 4.

(3) Submit a Purchase Order Request to the Foundation or University Procurement Department, whichever department handles the finances for your research or instruction. This is the usual Purchase Order Request form used for all other campus purchases, and is <u>in addition to</u> the EHS PURCHASE REQUEST which is sent to EH&S.

(4) After your USE AUTHORIZATION APPLICATION FORM and EHS PURCHASE REQUEST form is approved by EH&S, a signed copy of the EHS PURCHASE REQUEST FORM will be sent to the SDSU or Foundation Procurement Department, along with a filled-out DEA Form 222 (for schedule II) and a copy of the DEA Registration Certificate for the drug will be purchased and used.

<u>NOTE:</u> Procurement Departments are not to process Purchase Request forms until a signed PURCHASE REQUEST form has been received from EH&S, along with the DEA 222 form (for schedule II) and a copy of the DEA Registration Certificate.

(b) While waiting to receive the ordered drugs, all individuals listed on the USE AUTHORIZATION APPLICATION must read and sign a copy of the ACKNOWLEDGEMENT SHEET and SCREENING SHEET (Appendix 5). Signed ACKNOWLEDGEMENT SHEET and SCREENING SHEET must be sent to EHS.

(c) Procurement Departments shall clearly indicate on all controlled substance purchase orders that the drugs are ONLY to be delivered to the SDSU Student Health Services Pharmacy.

3. RECEIVING PROCEDURES

(a) Drugs are to be delivered only to the Student Health Services Pharmacy at the main campus. They may NOT be received by the SDSU or Foundation Receiving Departments, by individual

researchers or by the Procurement Department. The only individuals who are authorized to receive controlled substances is the Pharmacists at Student Health Services.

(b) When a drug is received, the drug is to be immediately stored in the Student Health Services Pharmacy. The Pharmacist should then notify EH&S of the drug's arrival.

(c) The signee on the Controlled Substance Registration Certificate, the Program Coordinator of the Controlled Substance and its designee at EH&S are the only individuals who can pick-up the controlled substance from Student Health Services Pharmacy. EH&S will record the date, time, name of controlled substance, amount of controlled substance received, number of containers received and the vendor supplying the controlled substance on the packing slip or invoice and CUSTODY CONTROL SHEET (Appendix 6). EH&S will record the number of individual packages or containers received and date received of the schedule II drug on SDSU's copy of the FORM 222. EH&S will hold the controlled substance in a secured storage.

(d) EH&S will notify the principal investigator who ordered the drug that it has arrived. The faculty member or principal investigator may pick up the drug, or send one of the authorized persons listed on the USE AUTHORIZATION APPLICATION form. They must sign the CUSTODY CONTROL SHEET in the presence of an EH&S authorized representative. The signature and a signed picture ID will be verified by an EH&S authorized representative against the EH&S copy of the USE AUTHORIZATION APPLICATION. The only acceptable identifications are a valid driver's license or SDSU I.D. card.

(e) For security reasons it may be desirable to have an escort (or Public Safety representative) accompany the individual who is carrying the controlled substance to its place of storage.

4. STORAGE AND SECURITY PROCEDURES

(a) Controlled substances are to be stored according to requirements for stability and sterility printed on the label (e.g. packaging integrity and refrigeration).

(b) The drugs must be kept ONLY in a fixed and stationary, secure and substantially constructed locked cabinet, vault or other containment furniture. Access to the drugs is to be limited to individuals whose names are listed on the USE AUTHORIZATION APPLICATION and approved USE AUTHORIZATION UPDATES.

(c) If practical, these containment structures should be located in a room or office that is not accessible to the general public or students.

(d) Safe combinations should be changed whenever personnel changes occur.

(e) Flip-off tops and other types of seals affixed to controlled substance containers are not to be removed prior to use, to assure the integrity of the container.

(f) ANY significant unaccountable loss of drugs, or loss apparently due to theft or misuse, is to be reported to Public Safety and EH&S immediately upon discovery. (See Section F.5, Disposition of Controlled Substances, for further information on this subject.)

(g) Only Controlled Substance Dispense Record can be stored with the controlled substances in the secured storage. Non-controlled substances i.e. non-controlled pharmaceuticals or other miscellaneous items cannot be stored in the secured storage with controlled substances.

(h) EH&S may conduct an inspection of proposed controlled substance storage locations or containment furniture prior to issuing a USE AUTHORIZATION CERTIFICATE to an applicant. The storage site is also subject to periodic inspection by EH&S.

5. DISPOSITION OF CONTROLLED SUBSTANCES

(a) Controlled drugs are not to be loaned or shared with any other researcher, laboratory or class. They are only to be used by the persons listed on the USE AUTHORIZATION APPLICATION and USE AUTHORIZATION UPDATES, for the specific use indicated on the form.

(b) Any significant loss of drugs or discrepancies in recordkeeping are to be reported to EH&S immediately upon their discovery. If theft or misuse is suspected, Public Safety must be notified immediately. "Significant" losses are not precisely defined here, but it should be noted that it is better to report suspected losses up front than to have the discrepancy identified during a biennial inventory or DEA inspection.

(c) Based on the details and amount involved in reported losses, EH&S may need to file a DEA Form 106 (loss Form) or submit an incident report. The University (through Public Safety and EH&S) also reserves the right to impound drugs and records pertinent to an investigation into inventory or recordkeeping discrepancies.

(d) All expired substances or those left over at the end of the research or instructional activity for which they were required, are to be returned to EH&S for proper disposal. A copy of the INVENTORY OF CONTROLLED SUBSTANCE SURRENDERED (Appendix 7) must be completed and submitted to EHS. In the event the principal investigator or instructor is no longer formally affiliated with SDSU, the controlled substances shall also be returned to EH&S.

6. RECORD KEEPING PROCEDURES

a) Individual researchers or faculty must adequately document all controlled substance usage, waste, and damaged material. Each time a quantity of a drug is taken from stock, an entry is to be made in the CONTROLLED SUBSTANCE DISPENSE RECORD (CSDR). A copy of this record is found in Appendix 8. This sheet supplied by EH&S contains spaces to note the date, quantity used, quantity wasted, and the signature of the individual authorized to handle the controlled substance.

b) Any time supplies are wasted, this information must be documented on the CSDR. A second authorized person (listed on the USE AUTHORIZATION APPLICATION or USE AUTHORIZATION UPDATE) must verify witnessing the wastage by signing their name in the CSDR. "Wasting" of supplies may only occur if small quantities of the substance removed from the original container have become contaminated or have otherwise become unusable. "Disposal" of controlled substances applies to generally larger quantities of unused drugs that have expired or are no longer required or authorized. See Section F.5 (d) for disposal requirements.

c) An accurate perpetual balance for each controlled substance container is to be maintained at all times on the CONTROLLED SUBSTANCE DISPENSE RECORD.

d) If there is not enough space on the original CSDR to account for all dispensing of a given substance, additional copies are to be properly completed and attached to the original CSDR. CSDR for each drug are to be returned to EH&S after research has been completed (whether or not unused portions of the substances remain), or when all the supply of the drug has been used. The total number of sheets is to be indicated at the bottom of all CSDR forms. Empty containers of controlled substances are also to be returned to EH&S.

e) Separate, more detailed laboratory records may be used to record other information pertinent to administration of the drugs, such as the observed effects caused by the drug, other related procedures, etc. The CSDR may serve as a useful experimental record, but remember that only copies of the CSDR will be kept by the researcher, since the original is to be forwarded to EH&S at the end of the authorized use for the drug.

I. INVENTORY

Federal regulations require an inventory of all controlled substances be performed at least once every two years. At SDSU, a stricter schedule i.e. monthly, quarterly or annually is established based on frequency of dispense to generate and obtain a more current and accurate biennial inventory. This inventory is conducted to verify the perpetual balances maintained on the CSDR for individual drugs. The performance of these inventories will be witnessed by EH&S.

The following procedures are to be followed by researchers and EHS when conducting the biennial inventory:

1) The only persons authorized to conduct the inventory are Principal Investigators, co-investigators, and faculty members and those listed on the USE AUTHORIZATION APPLICATION. Other individuals are not authorized to carry out the inventory.

2) An CONTROLLED SUBSTANCE INVENTORY RECORD (Appendix 9) shall be used to record the information from the inventory. For each substance in stock, the inventory agent must list the name and dose form of the drug, the total quantity of the substance in metric units or the total number in finished dose form, and the date the drug was purchased by the researcher or faculty member. The total amount of each substance shown as the perpetual balance on its CSDR form is to be listed next to the inventoried amount. If there are any discrepancies, these must be explained on the reverse side of the CONTROLLED SUBSTANCE INVENTORY RECORD.

3) EHS will maintain an inventory record of surrendered controlled substances on hand so that an accountability audit could be conducted and a biennial inventory could be obtained and generated.

J. PRECURSOR and LIST I and LIST II CHEMICALS

The Federal Chemical Diversion and Trafficking Act of 1988 was enacted to control the manufacture, distribution, export and import of certain chemicals used in the manufacture of controlled substances.

EH&S will routinely monitor purchasing data to verify that threshold quantities of precursor and essential chemicals are not exceeded. Procurement departments (University and Foundation) shall make pertinent data available for analysis by EH&S.

K. INSPECTIONS

1. Records and inventories of controlled substances used under EH&S Registration Certificate are subject to unannounced and announced inspection and audit by the Controlled Substance Program Manager or its designee. Inspection and audit schedule i.e. monthly, quarterly or annually is established based on frequency of dispense to ensure: 1) complete and accurate records and inventory for accountability, 2) maintenance of secured storage and 3) non-pharmaceutical or expired drugs are not used in animal research unless conditional use has been approved by the IACUC. All records and drugs must be immediately available for review. Representatives of state and federal agencies may also wish to inspect your operations.

2. At the time of inspection, the following items are subject to evaluation:

    a) Proper storage and security arrangements

    b) Accuracy and completeness of your CONTROLLED SUBSTANCE DISPENSE RECORDS

    c) Ensuring that workers handling controlled substances are only those listed on the USE AUTHORIZATION APPLICATION and approved USE AUTHORIZATION UPDATES.

    d) Deficiencies found during previous inspections have been corrected

    e) Procedures for use and disposal of the drugs in compliance with state and federal regulations

3. Department or individual researchers are encouraged to perform periodic self-evaluation surveys.

4. The CONTROLLED SUBSTANCE INSPECTION FORM is found in Appendix 10.

L. INQUIRIES

Questions or comments regarding these procedures should be addressed to:

Controlled Substance Program Coordinator
Department of Environmental Health and Safety
San Diego State University
5500 Campanile Drive
San Diego, CA 92182-1243
(619) 594-2865