

C-20 DEA Controlled Substance Program

I. Purpose

This chapter contains policies and procedures for handling and safeguarding controlled substances to be administered to animals or used for in vitro research at NCI-Frederick.

II. Background

In the performance of scientific research, it is the policy of the NCI-Frederick to use U.S. Drug Enforcement Agency (DEA) Controlled Substances controlled by the U.S. Department of Justice, Drug Enforcement Administration. NCI-Frederick holds the Environment Health and Safety Department (EHS) of the OTS Contractor and the off-site facility program director or his or her alternate accountable for the receipt, storage, and dispensing of controlled substances.

III. Policy

The policy applies to all Contractor and Government employees who work at NCI-Frederick Frederick and off-site facilities.

IV. Definitions

Audit: A Systematic check or assessment, especially of the efficiency or effectiveness of an organization or a process, typically carried out by an independent assessor.

Inventory: The merchandise or stock that a store or company has on hand.

Controlled Substance: Drugs and other materials by whatever name (common or unusual name, chemical name, or brand name) designated and categorized under one of five schedules by the Controlled Substance Act of 1970, as amended. Controlled substances are those items listed in 21 CFR Part 1308.11-1308.15.

http://www.deadiversion.usdoj.gov/21cfr/cfr/1308/1308_11.htm

Controlled drug substances Schedules:

Schedule I - High abuse potential, no accepted medical use in US, e.g., Acetorphine.

Schedule II - High abuse potential, potentially leading to severe psychological or physical dependence; schedule II agents have acceptable medical uses, e.g., narcotics.

Schedule III - High abuse potential, moderate to low physical dependence, and high psychological dependence potential, with

acceptable medical uses, which may be narcotic, e.g., nalorphine, paregoric, or nonnarcotic, e.g., aprobarbital.

Schedule IV - Minimal abuse potential, limited physical or psychological dependence potential, nonnarcotic, e.g., barbital.

Schedule V - Very low abuse/dependence potential, e.g., opium, some codeine preparations.

Controlled Substance Coordinator: EHS staff member that reviews the purchase request (PR) and written justification to determine whether the materials and quantities requested are appropriate. Upon approvals from the Program Area Drug Control Officer, Program Director, Laboratory of Animal Sciences Program (LASP) Coordinator and EHS on form CG-4 (approval routing form <http://web.ncifcrf.gov/Cad/Media/Documents/Cg4.pdf>), the Controlled Substance Coordinator will then forward to the Purchasing Department for acquisition.

DEA Regulated Chemicals: Chemical precursors, reagents and solvents required for the manufacture of controlled substances, which appear on List I and List II in 21 CFR Part 1310.02.

http://www.deadiversion.usdoj.gov/chem_prog/34chems.htm

Drug Control Officer: The staff member that initiates the request to purchase the controlled substance.

Environment Health and Safety (EHS): Authorizes procurement of Controlled Substances.

Logistics Support Department (LSD): Receives material and contacts EHS for delivery to the Program Director or Authorized Representative.

Program Director or Authorized Representative: Reviews the purchase request (PR) and written justification and confirms the need for the required item and the quantity requested.

Purchasing Department: Process the purchase request and orders the material.

V. Responsibilities

Contracts and Acquisitions Directorate: Maintains all requisite procurement authorizations with applicable federal and state regulatory agencies.

EHS Directorate:

1. Performs the initial review and approval of a program to receive and use controlled substances. Once approved, EHS issues a DEA logbook and documents this approval into the DEA Controlled Substance Logbook Spreadsheet.

2. Verifies that storage location and security obligations meet minimum requirements.
3. Performs an audit of each controlled substance logbook on a quarterly basis.
4. Any deficiencies shall be reported to the Controlled Substance Coordinator and the Director of EHS. This notification must be made immediately after a suspected infraction of DEA regulations or the Frederick National Laboratory for Cancer Research (NCI-Frederick) policy becomes known, whether through the performance of quarterly audits or other mechanisms such as employee allegations, suspicious procurement records, etc. The Controlled Substance Coordinator and the Director of EHS assess the collected information and determine whether this incident should be elevated this to the next level.

The Controlled Substance Coordinator and the Director of EHS will notify the OTS Contractor senior management, the NCI-Frederick Contracting Officer, and NCI-Frederick Project Officer. This group determines whether the DEA and/or other law enforcement officials should be informed of the potential infraction. This team also decides whether the respective HR departments should be notified.

If the alleged infraction merits reporting to the DEA or law enforcement, then the Director of EHS shall notify OTS Contractor Office of Legal Counsel and the Government.

5. Provide assistance to laboratory personnel in inventory control procedures, secure storage, and proper disposal of controlled substances; and
6. Provide the LSD with a list of investigators and alternates who are authorized to receive controlled substances.

Logistics Support Department:

1. Ensure that the receipt, storage, and issue of accountable materials at the NCI-Frederick Receiving Department are in compliance with federal and state regulations;
2. Completes form 544-92 (Controlled Substance Delivery Form) and contacts EHS to retrieve and deliver the controlled substance to the authorized investigators or designated alternates on-site; and
3. Maintain records of controlled substances dispensed to investigators from Environment Health and Safety (EHS).

NCI-Frederick Contractor and Government Investigators:

1. Ensure that the receipt, storage, and issue of accountable materials are in compliance with federal and state regulations;

2. Review, confirm, and communicate requirements for controlled substance use in laboratories for which they are responsible; and
3. Authorize the requisition and monitor the receipt, storage, inventory, dispensing, use, and disposal of controlled substances.

Off-site Program Directors:

1. Ensure that the receipt, storage, and issue of accountable materials at the off-site Receiving Department are in compliance with federal and state regulations; and
2. Maintain records of controlled substances dispensed to authorized investigators/users.

VI. Procedure

1. Permits to procure Controlled Substances on the NCI-Frederick campus and at off-site facilities are secured by EHS.
2. EHS shall be responsible for providing Drug Control Officers and alternates with DEA Controlled Substances Logbooks and with proper procedures for ordering, receiving, recording, securely storing, dispensing, and disposition of controlled substances.
3. EHS shall audit the Controlled Substance Logbooks every three (3) months.
4. EHS shall serve as the office of record for Controlled Substance Delivery Forms 544-92, audit dates, audit reports, list of Drug Control Officers and alternates, location of controlled substances, and closed and completed logbooks for two years.
5. EHS shall confirm proper transfer of responsibility when Drug Control Officers and alternates terminate employment.
6. EHS staff will assist in the disposal of excess controlled substances in accordance with regulations of the Drug Enforcement Administration, U.S. Department of Justice. Form 544-92 will be completed by EHS to document the material from cradle to grave.
7. EHS maintains a list of Drug Control Officers and alternates which is provided to Purchasing, and Warehouse and Inventory Control, no less than semi-annually.

VII. Records Retention and Disposal

All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of OTS Contractor Administrative Handbook Policy SG-18: "Records Retention".

VIII. References

U.S. Department of Justice, Drug Enforcement Administration, Office of Diversion Control:

<http://www.deadiversion.usdoj.gov/schedules/index.html>.

NIH Policy Manual:

<http://www.deadiversion.usdoj.gov/schedules/index.html>.

EHS BioSafety webpage:

<http://www.deadiversion.usdoj.gov/schedules/index.html>

Attachment 1
CONTROLLED SUBSTANCE DELIVERY FORM 544-92

The following information must be filled out completely. Each Drug Control Officer is accountable for the material which he/she receives. Only those persons listed on the Controlled Substance Log Book Holders list are authorized to sign for and receive controlled substances. Controlled Substance Logs are subject to review by Safety personnel at any time.

FULL NAME OR BRAND NAME OF SUBSTANCE _____

DRUG CONTROL OFFICER _____

LOCATION (BLDG., ROOM NO.) _____ EXT _____

DESIGNATED ALTERNATE FOR DRUG CONTROL OFFICER _____

LOCATION (BLDG., ROOM NO.) _____ EXT _____

PURCHASE ORDER NO. _____

VENDOR _____

STRENGTH (IF APPLICABLE) _____ FORM _____

DATE RECEIVED _____ QTY RECEIVED _____

WAREHOUSE RECEIVING CLERK'S SIGNATURE

EHS SIGNATURE _____

EHS EMPLOYEE NAME (PRINTED) _____

DRUG CONTROL OFFICER'S OR ALTERNATE'S SIGNATURE _____

DRUG CONTROL OFFICER'S OR ALTERNATE'S NAME (PRINTED)

LOG BOOK NUMBER _____