NIH POLICY MANUAL

1345 - HANDLING AND SAFEGUARDING OF CONTROLLED SUBSTANCES FOR NONHUMAN USE

Issuing Office: ORS/DIRS/VRP 435-2780
Release Date: July 11, 2000

---

1. **Explanation of Material Transmitted:** This Chapter describes NIH policies and procedures for handling and safeguarding controlled substances for nonhuman use, from acquisition through disposal. This is the first issuance by ORS since the recent reorganization. It incorporates the functions and responsibilities of the Office of Research Services, Division of Intramural Research Services, Veterinary Resources Program (VRP)Pharmacy.

2. **Filing Instructions:**

   Remove: NIH Manual 1345 dated 01/10/97

   Insert: NIH Manual 1345 dated 07/11/00

3. **Distribution:** Electronic Mailing. If paper copies are needed, please contact the Veterinary Resources Program at 435-2780.

PLEASE NOTE: For information on:

- **content of this chapter**, contact the issuing office listed above.
- **On-line information, enter this URL: http://www3.od.nih.gov/oma/manualchapters/**
- **To sign up for e-mail notification of future changes, please go to the NIH Manual Chapters LISTSERV Web page.**

HANDLING AND SAFEGUARDING OF CONTROLLED SUBSTANCES FOR NONHUMAN USE

Table of Contents

Illustration 1, Controlled Substances Overall Process. . . iii

Illustration 2, Titles of Individuals Involved in Safeguarding Controlled Substances. iv

A. Purpose. 1

B. Policy 1

C. Scope. 1

D. Exceptions 1

E. Definitions. 1

F. Responsibilities 3

1. NIH Controlled Substance Officer. 3

2. IC Scientific Director 3

3. IC Controlled Substance Program Coordinator. . . . 4

4. Controlled Substance Custodian. 5

5. IC Principal Administrative Officer for Intramural Research 6

6. ORS/DIRS/VRP Purchasing Office. 7

G. Procedures 7

1. Acquiring Controlled Substances for Nonhuman Use 7

2. Purchase Order/Contract Placement By ORS/DIRS . . 7

3. Delivery and Receipt. 8

HANDLING AND SAFEGUARDING OF CONTROLLED SUBSTANCES FOR NONHUMAN USE

4. Use and Security of Controlled Substances, and DEA Regulated Chemicals 8

a. Controlled Substances. 8

b. DEA Regulated Chemicals. 13

5. Physical Inventory and Reporting 13

a. Biennial Inventory 13

b. Twelve Month Inventory 14

6. Surplus and Disposal 14

H. Records Retention and Disposal 14

I. Management Controls. 15

APPENDICES

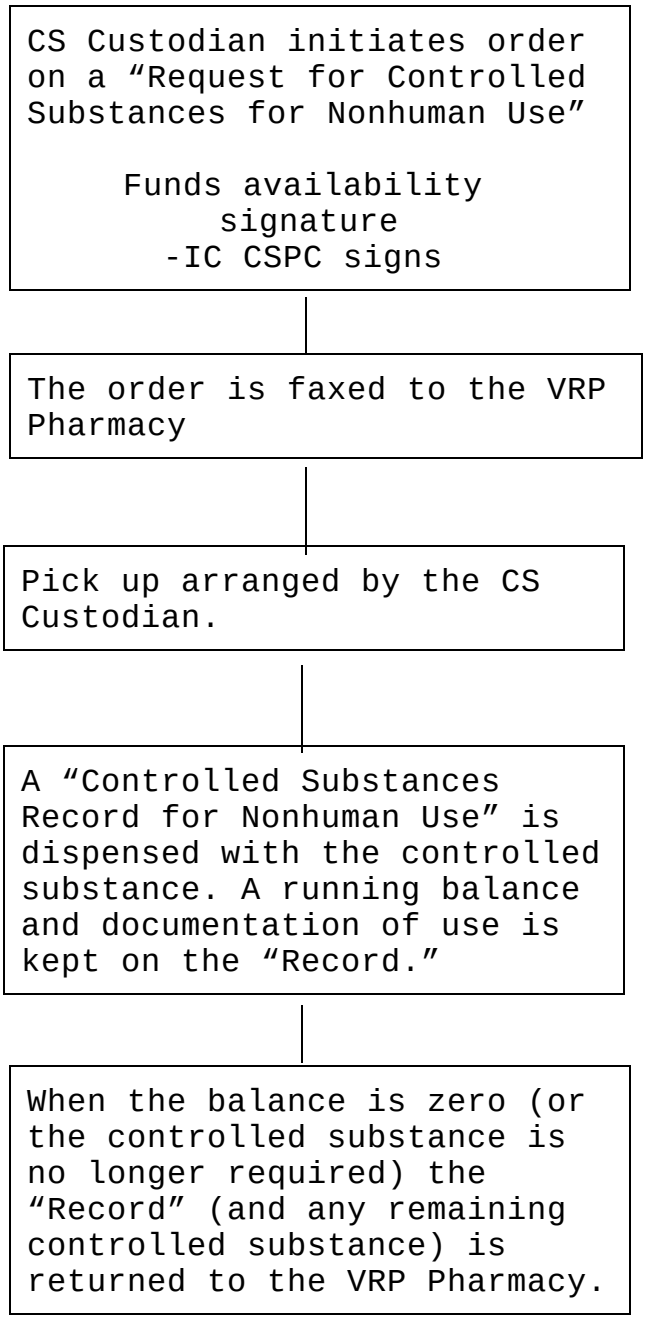
1. Form NIH 2765-1, “Request for Controlled Substances for Nonhuman Use”

2. Form NIH 2765-2, “Controlled Substance Record for Nonhuman Use”

3. Form NIH 2765-3, “Intra-Institute Controlled Substance Transfer Notification”

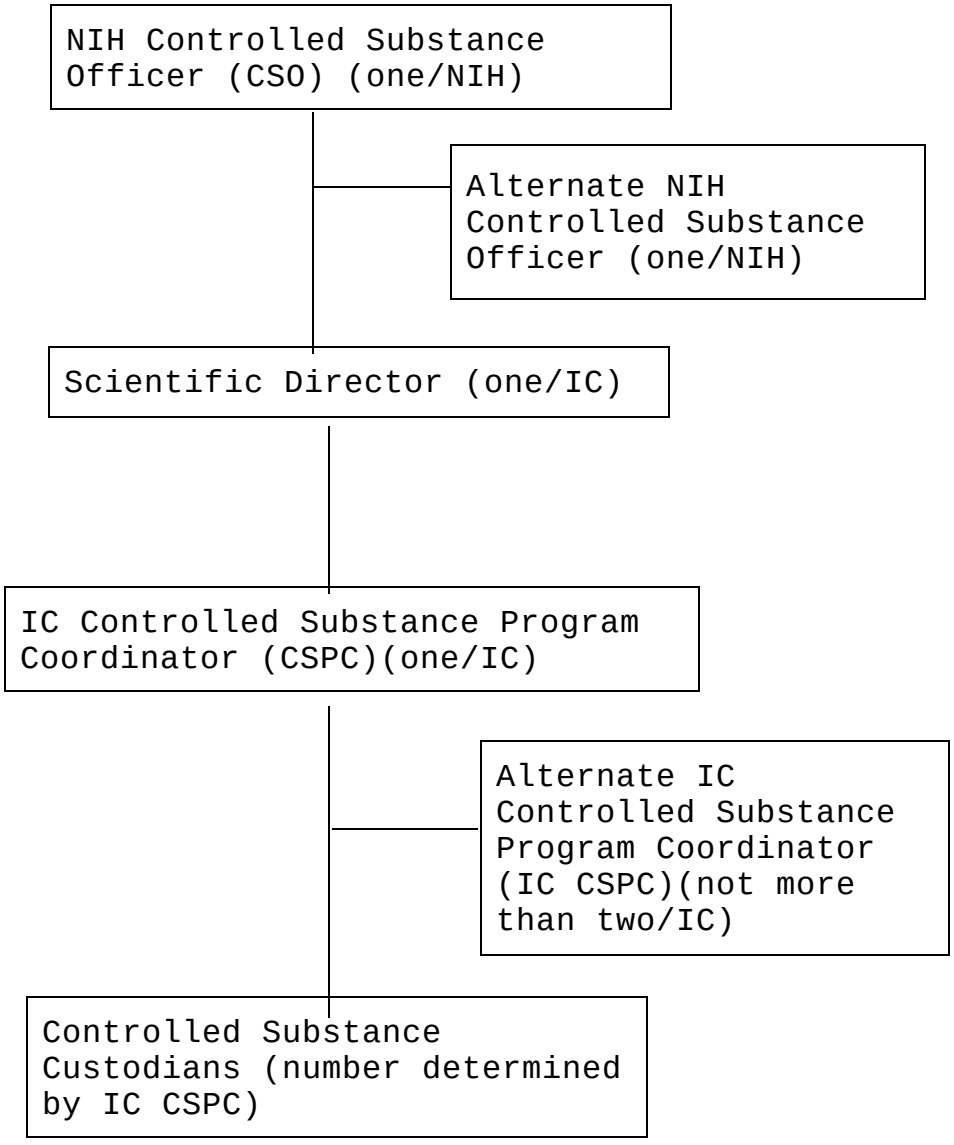
HANDLING AND SAFEGUARDING OF CONTROLLED SUBSTANCES FOR NONHUMAN USE

Controlled Substances Overall Process



HANDLING AND SAFEGUARDING OF CONTROLLED SUBSTANCES FOR NONHUMAN USE

Titles of Individuals Involved in Safeguarding Controlled Substances



HANDLING AND SAFEGUARDING OF CONTROLLED SUBSTANCES FOR NONHUMAN USE

A. Purpose: This policy describes policies and procedures for handling and safeguarding controlled substances for nonhuman use (i.e., those to be administered to animals or used for *in vitro* research) at the National Institutes of Health (NIH) Intramural Research Program, from acquisition through disposal, as required by the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended.

B. Policy: It is the policy of the NIH that controlled substances will be used solely for research and patient care, and that adequate controls will be established to prevent unauthorized use. Except as noted below under "Exceptions," the ORS/DIRS/VRP (VRP)Pharmacy is the only organization authorized to acquire Controlled Substances and Drug Enforcement Agency (DEA) Regulated Chemicals for nonhuman use for the Institutes and Centers (IC's). All controlled substances, including vendor samples and those supplied by other ICs, shall come through the VRP Pharmacy.

C. Scope: All Intramural NIH personnel and organizations involved in the nonhuman use of controlled substances and DEA regulated chemicals are subject to the provisions of this policy.

D. Exceptions: The NIEHS in Research Triangle Park, NC, NIA/IRP and NIDA/IRP in Baltimore, MD, NIAID/RML in Hamilton, MT, NIDDK in Phoenix, AZ, and NCI/FCRDC in Frederick, MD, are authorized to procure controlled substances and DEA regulated chemicals for nonhuman use under research licenses granted to those organizations by the DEA. The above organizations shall develop internal policies and procedures governing controlled substances which are consistent with the policies and procedures contained herein.

E. Definitions:

HANDLING AND SAFEGUARDING OF CONTROLLED SUBSTANCES FOR NONHUMAN USE

1. **Controlled Substances** are 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 Substances Act of 1970, as amended (21 U.S.C. 812 et seq.). Controlled Substances are those items listed in 21 U.S.C. 812 and 21 C.F.R. Part 1308.11-1308.15.

2. **DEA Regulated Chemicals** are chemical precursors, reagents and solvents required for the manufacture of controlled substances, which appear on List I and List II in 21 C.F.R. Part 1310.02.

3. **NIH Controlled Substance Officer (NIH CSO**)(or designee) is a permanent government employee, appointed by the Associate Director for Research Services, ORS to administer the NIH controlled substance program for nonhuman use overseen by the VRP Pharmacy. (See NIH Manual 1130, Property: Personal #4B “Controlled Substances.”)

4. **Alternate NIH Controlled Substance Officer** is a senior level permanent government employee who is designated in writing by the Associate Director for Research Services, ORS. The Alternate performs the duties of the NIH CSO in the absence of the NIH CSO.

5. **IC Controlled Substance Program Coordinator (IC CSPC)** is a senior level permanent government employee who is designated in writing by the IC's Scientific Director to oversee the IC’s controlled substance program.

6. **Alternate IC Controlled Substance Program Coordinator** is a senior level permanent government employee who is designated in writing by the IC Scientific Director. The Alternate performs the duties of the IC CSPC in the absence of the IC CSPC. There may be no more than two Alternates in each IC.

7. **Controlled Substance Custodian (CS Custodian**) is a permanent government employee designated in writing by the IC CSPC to be responsible for the oversight and use of controlled substances in his/her area of responsibility (e.g., Investigator, Physician, Veterinarian, Facility Manager, Technician).

8. **Controlled Substance Lock Box Number** is a number assigned by the NIH CSO to a specific CS Custodian for a specific lock box location. The assigned number will be affixed to the inside of the controlled substance lock box or safe.

F. Responsibilities:

1. NIH Controlled Substance Officer (and Alternate NIH CSO in the absence of the NIH CSO) is responsible for:

   a. Ensuring NIH's compliance with all DEA requirements (21 C.F.R. Part 1300 to end), i.e., acquisition, receipt, delivery, security, reporting (inventory) and disposal of controlled substances for nonhuman use.

   b. Ensuring renewal of the DEA registration certificate every September, obtaining preprinted DEA Forms 222 and securing them in a lock box, coordinating the biennial inventory and maintaining a separate file for controlled substance orders.

   c. Maintaining a database of all controlled substances issued to CS Custodians. The data base will contain a record for each substance dispensed. The record will include the name of the substance, quantity dispensed, lock box number and CS Custodian responsible. The data base will also contain the inventory of

substances in the VRP Pharmacy and will include a record for each item received.

d. Conducting the training course “Acquiring and Safeguarding Controlled Substances, Nonhuman Use” for the IC CSPC’s and alternates.

2. IC Scientific Director is responsible for:

a. Ensuring the IC's compliance with this policy.

b. The appointment of an IC CSPC and not more than two Alternates, and providing that information in writing to the NIH CSO.

c. Ensuring that the IC CSPC and Alternate(s) attend the ORS/DIRS training seminar "Acquiring and Safeguarding Controlled Substances, Nonhuman Use" and receive a copy of the most recent version of this policy.

3. IC Controlled Substance Program Coordinator (and Alternate(s) in the absence of the IC CSPC) is responsible for:

a. Attending the training course entitled "Acquiring and Safeguarding Controlled Substances, Nonhuman Use.” Providing training to the CS Custodians in their IC.

b. Appointing the IC’s CS Custodians by submitting a completed lock box registration/CS Custodian signature card to the NIH CSO. By signing the signature card, the IC CSPC validates that the CS Custodian has completed the mandatory training and that appropriate lock box(s)/security cabinet(s) or safe(s) are available in each CS Custodian’s area of responsibility to secure all controlled

substances and DEA regulated chemicals.

c. Approving requests submitted by the IC's CS Custodians for acquiring controlled substances or DEA regulated chemicals. The IC CSPC reviews the request and justification of need to ensure its authenticity. The IC CSPC may require documentation of need, which can include, but is not limited to, a copy of the Animal Study Proposal, a brief outline of the study in which the controlled substances are used, a copy of the research protocol and/or a progress report.

d. Serving as signature authority for the IC's CS Custodians in their absence.

e. Conducting a physical inventory of controlled substances stored by each CS Custodian in the IC every 12 months.

f. Conducting and/or assisting the NIH CSO in periodic and biennial physical inventory of controlled substances in their IC.

4. Controlled Substance Custodian is responsible for:

a. Completing applicable controlled substance handling training required by their IC CSPC prior to ordering controlled substances.

b. Initiating requests for acquiring controlled substances and DEA regulated chemicals used within his/her area of responsibility.

c. Maintaining up-to-date records for all controlled substances used within his/her area of responsibility. The disposition of all substances issued to his/her lock box shall be tracked on the "Controlled Substance Record for

Nonhuman Use" provided by the VRP Pharmacy with each controlled substance received.

d. Ensuring that all controlled substances and DEA regulated chemicals used within his/her area of responsibility are kept secured in a lock box or double locked steel cabinet which has been previously registered with both the IC CSPC and NIH CSO.

e. Ensuring that all individuals utilizing controlled substances and DEA chemicals within his/her area of responsibility have been trained in the appropriate handling, record keeping and security procedures prior to being granted access to these substances.

f. Conducting periodic physical inventories of controlled substances within his/her area of responsibility to ensure that all records accurately reflect the current balance of each item. Physical inventories shall be conducted a minimum of every 3 months. In high volume areas more frequent physical inventories may be necessary.

g. The following additional responsibilities are required of all Custodians ordering controlled substances designated by the DEA as Schedule 1:

(1) The CS Custodian or investigator must apply to the DEA for a Schedule 1 Researcher Registration.

(2) Once the DEA has issued a Schedule 1 Researcher Registration to the CS Custodian or investigator, it is the CS Custodian's responsibility to submit a copy of the completed application form (listing the

controlled substance(s) the registrant is permitted to procure), along with a copy of the Researcher Registration provided by DEA, to the NIH CSO prior to the procurement of a Schedule 1 substance.

(3) All Schedule 1 substances are subsequently ordered as outlined below and in Section G., Items 1-3. Once the Custodian takes possession of a Schedule 1 controlled substance, his/her DEA Registration must be maintained as current until the substance is used up or properly destroyed and documented.

5. IC Principal Administrative Officer for Intramural Research is responsible for providing an up-to-date list of individuals who can certify funds availability for controlled substance purchases.

6. ORS/DIRS/VRP Purchasing Office is responsible for the acquisition of controlled substances and DEA regulated chemicals for nonhuman use, in support of the NIH Intramural Research Program, in accordance with DEA and acquisition regulations, policies and procedures.

G. Procedures:

1. Acquiring Controlled Substances for Nonhuman Use:

Utilizing Form NIH 2765-1 (Appendix 1), “Request for Controlled Substances for Nonhuman Use” Online form: http://forms.cit.nih.gov/ListPDF.html, CS Custodians initiate requests for the acquisition of controlled substances and DEA regulated chemicals used within their area of authority. Custodians shall review the completed form for accuracy and obtain funding and approval signatures prior to submission to the IC

CSPC. Note: If the item(s)under procurement are not stocked by the ORS/DIRS/VRP Pharmacy, possible sources must be included in the appropriate areas of the form.

If the item requested is a DEA Schedule 1 substance, the CS Custodian or an investigator in his/her area of responsibility, must hold a DEA Schedule 1 registration for the substance being procured (see Section F.4.g). When procuring Schedule 1 substances, the "Request for Controlled Substances for Nonhuman Use" sent to the VRP Pharmacy must be accompanied by a completed DEA Form 222.

2. Purchase Order/Contract Placement By ORS/DIRS:

The VRP shall designate, in writing, Purchasing Agents and Contracting Officers responsible for the placement of orders and approval of contracts for all DEA regulated chemicals and controlled substances. Only these individuals will be authorized to place and approve such orders and contracts.

3. Delivery and Receipt:

Officials who order controlled substances may not also receive delivery of those controlled substances.
With the exception of DEA Schedule 1 substances, the VRP Pharmacy is the only location for receipt of controlled substances and DEA regulated chemicals from outside vendors.

The CS Custodian will arrange for pick up of the ordered substances from the VRP Pharmacy. The CS Custodian or, in his/her absence, the IC CSPC, will sign for and receive all controlled substances and DEA regulated chemicals. The CS Custodian must

present an NIH identification card and record its number when signing his/her name. The VRP Pharmacy will issue a "Controlled Substance Record for Nonhuman Use," Form NIH 2765-2 -- Online form: http://forms.cit.nih.gov/ListPDF.html, with each controlled substance.

DEA Schedule 1 controlled substances will be delivered directly to the address printed on the DEA registration form. The CS Custodian shall notify the VRP Pharmacy/NIH CSO immediately, via fax of the receiving information to 301-480-0088, upon receipt of a Schedule 1 controlled substance. Subsequently, arrangements will be made by the VRP Pharmacy/NIH CSO for the Custodian to obtain a "Controlled Substance Record for Nonhuman Use" to record the disposition of the controlled substance.

4. Use and Security of Controlled Substances and DEA Regulated Chemicals:

   a. Controlled Substances

      (1) Physical Security of Inventory. Each CS Custodian is responsible for the proper use and security of controlled substances in his/her area of responsibility. The CS Custodian shall ensure that all controlled substances are maintained in the appropriately numbered and registered lock box(s) and/or safe(s) assigned to him/her. The CS Custodian is responsible for control of the combination and/or key(s) for their safe(s) or lock box(s). Random, unannounced visits by the NIH CSO, IC CSPC or their designees will be conducted to monitor compliance with these security requirements.

HANDLING AND SAFEGUARDING OF CONTROLLED SUBSTANCES FOR NONHUMAN USE

(2) Record-Keeping Requirements. A notebook containing the "Controlled Substance Record for Nonhuman Use" issued with each controlled substance, must be locked up in the same room where the controlled substances are stored. The forms must be accessible for review and recording at all times. When recording the use of a controlled substance, a line entry is made on the form, using one line per procedure or animal treated. Entries on the "Controlled Substance Record for Nonhuman Use" shall be made by the individual withdrawing the drug from the lock box or safe at the time the item is withdrawn Each line entry will include the date, name of Principal Investigator or Veterinarian (as required by the DEA) authorizing the administration, the signature of the individual removing the drug from the lock box or safe, the quantity withdrawn, the balance remaining/current balance, and the purpose for administration. Units of measure must remain constant on an individual CS Record and accurately reflect the amount of controlled substance in stock (ex. mg, ml, tablet count, or gm).

There are three different formats for documenting the "purpose": 1) For an animal with an individual chart and ID#, record the animal ID#, species and the reason why the controlled substance was administered; 2) For an animal without an individual chart or ID#, record the species, the Animal Study Proposal (ASP or protocol number and the reason why the controlled substance is being administered; [When a group of animals of the same

species without individual charts or identification numbers are treated at the same time, with the same dose, for the same purpose, a one-line entry can be made for the entire group.] and; 3)when no animal is involved, describe the *in vitro* use of the substance.

(3) Accidental Destruction, Damage or Contamination. When a controlled substance is accidentally destroyed, damaged, or contaminated, a line entry is made on the "NIH Controlled Substances Record for Nonhuman Use." Each line entry shall include the date, description of circumstances, signatures of two individuals witnessing the destruction of the substance, quantity involved and current balance. When a dose is withdrawn from the lock box and recorded on the Controlled Substance Record and only partially administered to an animal, the excess remaining should be destroyed and logged as such, in either the animal's permanent medical record or on the Controlled ubstance Record. The entry should be witnessed and initialed by both parties.

(4) Bulk Powdered Controlled Substances. The following procedure shall be used to keep an accurate inventory of bulk powdered controlled substances. In general, these substances are provided in jars with removable and replaceable lids.

(a) Inventory. Following removal of the tamper proof seal and prior to opening the jar, determine the total weight of

the jar, lid and contents. On the first line of the "Controlled Substances Record for Nonhuman Use," make an entry that states: a) the date; b) the total weight of jar, lid and contents in mg; c) the signature of person making the entry; and d) in the balance column record the weight of the controlled substance contained in the full jar as stated on the manufacturer's label.

(b) When technically possible, the following is the recommended way to dispense powdered controlled substances:

- Prior to opening the jar, weigh the jar, lid and contents and verify the weight with that previously recorded on the Controlled Substances Record;

- Remove the lid from the jar and place the jar containing the powder on an electronic balance and tare the balance;

- Remove the powder until the electronic balance indicates that the required amount has been removed;

- Make a line entry on the Controlled Substance Record as described above [Section G. Item 4.a. (2) of this policy], entering the "quantity withdrawn";

- Replace the lid and verify the weight of the jar, lid, and contents,

which should be minus the amount removed.

(C) Reconstitution. When a vial of a powdered drug is reconstituted, record the following information on the "NIH Controlled Substances Record for Nonhuman Use": the date reconstituted, final concentration of solution that was made, name of individual who made the solution, and the final volume of solution in ml's.

(5) Transfer of Controlled Substances. Transfer of controlled substances from one CS Custodian to another is only permitted within the same IC and must be arranged through the IC CSPC. All items transferred must be accompanied by the item's original "NIH Controlled Substances Record for Nonhuman Use." Following transfer of an item, the IC CSPC must submit a completed Form NIH 2765-3, "Intra-Institute Controlled Substance Transfer Notification" --Online form: http://forms.cit.nih.gov/ListPDF.html (Appendix 3), to the VRP Pharmacy/NIH CSO the day of the transfer or the next business day if transfer occurs on a weekend or holiday. Transfers between ICs are not permitted without the authorization of the NIH CSO. Items listed as DEA Schedule 1 cannot be transferred.

(6) Project Completion and Records Retention. Upon completion of each "Controlled Substances Record for Nonhuman Use," the balance of the controlled substance remaining should be zero. Prior to

returning the completed form to the VRP Pharmacy, the CS Custodian shall retain a photocopy for his/her records. Copies shall be filed by drug and are required to be kept for a period of two years by the CS Custodian. If at anytime all entry lines are filled in on a given Controlled Substance Record and there is still a quantity of the drug remaining, the Custodian shall use a copy of a blank back page of a form NIH 2765-2. If the CS Custodian does not have a blank back page contact the VRP Pharmacy for a continuation page. Staple the first page and the continuation page together.

b. DEA Regulated Chemicals

The CS Custodian must ensure proper security of DEA regulated chemicals to prevent theft of these chemicals. Logging each use and keeping running balances are not required for these items. No Controlled Substance Records will be issued to the CS Custodian when they sign for and receive DEA regulated chemicals. A “Request for Controlled Substances for Nonhuman Use,” with proper authorizing signatures is required for the acquisition of DEA regulated chemicals.

5. Physical Inventory and Reporting:

a. Biennial Inventory. The DEA requires registrants to conduct a physical inventory of all controlled substances every other year. The NIH CSO will send out a memo notifying each IC CSPC when the biennial inventory is to be conducted. Attached to that memo will be a list of outstanding NIH Controlled Substances Records for each CS Custodian in the IC. The list will

contain the control numbers on the Records and the corresponding controlled substances issued to each CS Custodian and not yet returned to the VRP Pharmacy. A physical inventory will be taken by comparing the list from the NIH CSO with the contents of the controlled substances lock box and the balance on the Controlled Substances Records in the CS Custodian's notebook. Record the current balance on the same line as the corresponding control number and the controlled substance description on the list obtained from the NIH CSO. The Controlled Substances Physical Inventory List will reflect all controlled substances in stock at the time the inventory is taken. If there are items in stock that are not on the list received from the NIH CSO, then the IC CSPC should add them to the list. The CS Custodian and the IC CSPC (or designee) will sign and date the bottom of the inventory list. The IC CSPC will compile the IC's response to the biennial inventory, forward the original to the NIH CSO and keep a copy in his/her file for 2 years.

b. Twelve Month Inventory. When the IC CSPC decides to conduct a 12-month inventory, as mentioned previously under Section F. Item 3.e, he/she will contact the NIH CSO to obtain printouts of all the outstanding Controlled Substances Records for their IC's CS Custodians. The lists will be used to conduct the physical inventory in the same manner as the biennial inventory. If there are no discrepancies found, then the 12-month inventory records should be filed with the biennial inventory records and kept for two years. If any discrepancies are noted, such as missing numbered CS Record pages that are listed on the inventory form or any differences between the balance on the CS Record

and the amount in the lock box, they should be reported to the NIH CSO immediately.

6. Surplus and Disposal:

Controlled substances must be transferred to the VRP Pharmacy when the CS Custodian no longer requires them. Contact the VRP Pharmacy to arrange the transfer of the controlled substance and the corresponding "Controlled Substances Record for Nonhuman Use." The NIH CSO is responsible for the disposal of expired or no longer required controlled substance. Quantities of DEA regulated chemicals below the threshold levels (see 21 CFR Part 1310.02) can be disposed of through NIH's chemical waste contractor.

H. 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 NIH Manual 1743, "Keeping and Destroying Records," Appendix 1, "NIH Records Control Schedule," Item 3000-H and/or 2600-C. See manual for specific instructions.

NIH E-mail messages. NIH E-mail messages (messages, including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. Contact your IC Records Officer for additional information.

All E-mail messages are considered Government property and, if requested for a legitimate Government purpose, must be provided to the requester. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of the Inspector General may request access to or copies of the E-mail messages.

Request for Controlled Substances for Nonhuman Use

1. Controlled Substance Custodian's Name *(print)*			2. Controlled Substance Custodian Requester *(signature and date)*		
3. Phone No.	4. Fax No.	5. Date needed	6. Organization *(IC)*	7. CAN	8. CC
9. Building/Room -			10. Lock Box No.		
11. Name of Lab/Branch Approving Official *(print)*			12. Lab/Branch Approval *(signature and date)*		
13. IC Controlled Substance Program Coordinator *(print)*			14. IC Controlled Substance Program Coordinator *(signature and date)*		
15. Funds Authorization, Name and Title *(print)*			16. Funds Authorization Approval *(signature and date)*		

Description *(Generic name, strength, size, form)*	Quantity	Units/ Control Page	Control Number *(Pharmacy use only)*

18. Justification *(Purpose of use of the controlled substances, required for restricted commodity)*

For items not routinely stocked by the VRP Pharmacy, provide the following information on a suggested source:

19. Potential Source		20. Company Phone Number	
21. Catalog Number	22. Price	23. Company Clerk's Name	
24. Issued By		25. NIH ID No.	26. Date
27. Received By		28. NIH ID No.	29. Date

NIH Manual 1345, Appendix 2 - Form NIH 2765-2.

Controlled Substance Record for Nonhuman Use

Control No.

Lock Box No.

Generic Name

Strength

Form

Size

Initial Quantity Issued

For Powders: *Date Reconstituted*

Concentration and final volume

Reconstituted By

Date	Purpose/Animal ID/Protocol	Authorized By *(vet or PI)*	Removed from Safe/Cabinet By *(signature)*	Quantity Removed	Current Balance

NIH 2765-2 (Rev. 8/00)

INSTRUCTIONS FOR CS CUSTODIAN: This form is to accompany the above-identified controlled substance until the substance is completely utilized or returned to the VRP Pharmacy. Following completion, return the original form to the VRP Pharmacy while retaining a copy for your records. All substances are ***non-transferable*** unless authorized in advance by your IC CSPC.

Intra-Institute Controlled Substance Transfer Notification

In accordance with NIH Manual Issuance 1345, controlled substances can be transferred within an IC from one CS Custodian to another. Transfer of a controlled substance requires that the CS Custodian surrendering the drug complete and submit a copy of this form to the NIH Controlled Substance Officer (fax 480-0088). Telephone the VRP Pharmacy at 435-2780 to confirm the receipt of the fax. The original shall be kept by the surrendering CS Custodian as documentation of the transfer. At the time of transfer, the surrendering Custodian shall make a line entry on the "Controlled Substance Record for Nonhuman Use" (Form NIH 2765-2) accompanying the drug that states: (a) his/her signature; (b) the date of transfer; (c) the lock box number to which the drug is being transferred; and (d) the current balance (which equals the "Quantity Transferred" on this form). The line entry is then signed by the CS Custodian receiving the controlled substance.

Name of IC

Transferred from: *(Lock box number)*	**Transferred to:** *(Lock box number)*

Description of controlled substance transfer:

Generic name

Strength	Form	Size
Quantity transferred	Control number	Date and time transferred

Transfer **approved by**: (*Printed name of IC CSPC*)	IC CSPC's signature and date
Controlled substance **surrendered by**: (*Printed name of CS Custodian*)	CS Custodian's signature and date
Controlled substance **received by**: (*Printed name of CS Custodian*)	CS Custodian's signature and date

NIH 2765-3 (Rev. 8/00)

E-mail messages must also be provided to Congressional committees if requested and are subject to Freedom of Information Act requests. Since most E-mail systems have back-up files that are retained for significant periods of time, E-mail messages and attachments are likely to be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

I. MANAGEMENT CONTROLS: The purpose of this manual issuance is to establish the NIH policy and describe the system for handling and safeguarding controlled substances for nonhuman use on the NIH enclave and other locations where the NIH has such privileges that are administered by the NIH.

1. Office Responsible for Reviewing Management Controls Relative to this Chapter (Issuing Office): Through this manual issuance, the Office of Research Services (ORS), Division of Intramural Research Services (DIRS), Veterinary Resources Program (VRP), is responsible for the method used to ensure that management controls are implemented and working.

2. Frequency of Review: Ongoing review.

3. Method of Review: The VRP will maintain oversight and ensure effective implementation and compliance with this policy through review of a myriad of resources, e.g., complaints received from NIH ICs, biennial physical inventory, random unannounced checks of the IC-controlled lock boxes by the NIH CSO or designee, and other issues that may arise and require tracking.

4. Review reports are sent to: Associate Director for Research Services, ORS and Deputy Director for Management, NIH. Issues of special concern will be

brought immediately to the attention of the Associate Director for Research Services.

Request for Controlled Substances for Nonhuman Use

1. Controlled Substance Custodian's Name *(print)*			2. Controlled Substance Custodian Requester *(signature and date)*		
3. Phone No.	4. Fax No.	5. Date needed	6. Organization *(IC)*	7. CAN	8. CC
9. Building/Room -			10. Lock Box No.		
11. Name of Lab/Branch Approving Official *(print)*			12. Lab/Branch Approval *(signature and date)*		
13. IC Controlled Substance Program Coordinator *(print)*			14. IC Controlled Substance Program Coordinator *(signature and date)*		
15. Funds Authorization, Name and Title *(print)*			16. Funds Authorization Approval *(signature and date)*		

Description *(Generic name, strength, size, form)*	Quantity	Units/ Control Page	Control Number *(Pharmacy use only)*

18. Justification *(Purpose of use of the controlled substances, required for restricted commodity)*

For items not routinely stocked by the VRP Pharmacy, provide the following information on a suggested source:

19. Potential Source		20. Company Phone Number	
21. Catalog Number	22. Price	23. Company Clerk's Name	
24. Issued By		25. NIH ID No.	26. Date
27. Received By		28. NIH ID No.	29. Date

NIH Manual 1345, Appendix 2 - Form NIH 2765-2.

Controlled Substance Record for Nonhuman Use

Control No.

Lock Box No.

Generic Name

Strength

Form

Size

Initial Quantity Issued

For Powders: *Date Reconstituted*

Concentration and final volume

Reconstituted By

Date	Purpose/Animal ID/Protocol	Authorized By *(vet or PI)*	Removed from Safe/Cabinet By *(signature)*	Quantity Removed	Current Balance

NIH 2765-2 (Rev. 8/00)

INSTRUCTIONS FOR CS CUSTODIAN: This form is to accompany the above-identified controlled substance until the substance is completely utilized or returned to the VRP Pharmacy. Following completion, return the original form to the VRP Pharmacy while retaining a copy for your records. All substances are ***non-transferable*** unless authorized in advance by your IC CSPC.

Intra-Institute Controlled Substance Transfer Notification

In accordance with NIH Manual Issuance 1345, controlled substances can be transferred within an IC from one CS Custodian to another. Transfer of a controlled substance requires that the CS Custodian surrendering the drug complete and submit a copy of this form to the NIH Controlled Substance Officer (fax 480-0088). Telephone the VRP Pharmacy at 435-2780 to confirm the receipt of the fax. The original shall be kept by the surrendering CS Custodian as documentation of the transfer. At the time of transfer, the surrendering Custodian shall make a line entry on the "Controlled Substance Record for Nonhuman Use" (Form NIH 2765-2) accompanying the drug that states: (a) his/her signature; (b) the date of transfer; (c) the lock box number to which the drug is being transferred; and (d) the current balance (which equals the "Quantity Transferred" on this form). The line entry is then signed by the CS Custodian receiving the controlled substance.

Name of IC

Transferred from: *(Lock box number)*	**Transferred to:** *(Lock box number)*

Description of controlled substance transfer:

Generic name

Strength	Form	Size
Quantity transferred	Control number	Date and time transferred

Transfer **approved by**: (*Printed name of IC CSPC*)	IC CSPC's signature and date
Controlled substance **surrendered by**: (*Printed name of CS Custodian*)	CS Custodian's signature and date
Controlled substance **received by**: (*Printed name of CS Custodian*)	CS Custodian's signature and date

NIH 2765-3 (Rev. 8/00)