Wake Forest University

Guidelines: Use of Controlled Substances in Research

Wake Forest University Office of Environmental Health and Safety

8/23/2013

Table of Contents

I. Important Message to Principal Investigators Holding Controlled Substances Registrations

The information contained in this document is provided to support faculty and staff if they are using or intend to use controlled substances in research activities. The principal investigator (the registered user) retains full responsibility for compliance with state and federal regulations as conveyed by the U.S. Drug Enforcement Administration (DEA) and the North Carolina Department of Health and Human Services, Drug Control Unit (NC-DCU).

Biomedical research, testing, and teaching programs often require that controlled substances be administered to produce anesthesia, analgesia, tranquilization, sedation or hypnosis or to study the actions of particular drug regimens. Controlled substances can also be illegally diverted and misused. Accordingly, state and federal drug enforcement entities require individuals using controlled substances to hold a state registration and federal registration, and abide by the regulations and policies which pertain to the licensing, storage, distribution, and use of these chemical agents. Registration for use of controlled substances is an individual action; there are no federal or state regulatory provisions requiring institutional management. Even so, Wake Forest protects the well-being of research animals and the integrity of its researchers: faculty and staff. T his set of procedures provides assistance to individuals holding controlled substance registrations. An audit process will be coordinated by Environmental Health and Safety, the IACUC and the Animal Resources Program under the auspices of the Office of Research.

II. Principal Guidance

North Carolina Controlled Substances Act

U.S. Drug Enforcement Administration: Title 21 Code of Federal Regulations

WFU Controlled Substances in Research Policy

Prior to obtaining or using controlled substances, researchers at Wake Forest must register with the US DEA and the NC DHHS. Researchers must also notify the Environmental Health and Safety office using the "Notice of Intent" form.

Each registrant must:

- Follow pertinent regulations
- Maintain continuous registration

- Abide by the conditions of the registration: activities and use of the permitted controlled substances.
- Maintain all required records in a consistent and clear manner.
- Control and safeguard the controlled substance inventory.

III. Key Definitions

- Authorized User: A staff or scientific faculty member authorized to use controlled substances under the authority of a Unit / Individual Registrant (registration holder).
- Controlled Substance: Any substance listed in the Controlled Substances Act, Code of Federal or Substance Regulations (21 CFR, part 1300 to end), or in the North Carolina Controlled Substances Act, Chapters 26 and 29.
- Controlled Substance File: The file (or folder) where transactions of controlled substances (e.g. receipt, use, disposal) are recorded.
- Disposal: The approved method of discarding controlled substances which are outdated, redundant, contaminated, wasted, or no longer needed.
- Disposition Records: An accurate, continuous, and current record used to track the acquisition, use and disposal of controlled substances. Disposition Records must be maintained for 3 years.
- Drug Enforcement Administration (DEA): The unit within the United States Department of Justice that establishes and enforces the regulations for the handling and the use of controlled substances.
- Institutional Animal Care and Use Committee (IACUC): The Wake Forest School of Medicine Institutional Animal Care and Use Committee. The unit within Wake Forest which serves to assist, train, and provide auditing for individuals having/using controlled substances in animal research, testing, or teaching
- Location: The physical location of the controlled substance cabinet.
- North Carolina Department of Health and Human Services (NCDHHS): Authorized by North Carolina statute, NCDHHS is the agency that requires annual application for registration of persons engaging in animal-based research, teaching or educational projects involving the use, study, or testing of controlled substances. Renewal of NCDHHS licensure is required by October of each year (annual registration renewals).
- Public Vendor: Any registered company or pharmaceutical provider who has a controlled substance registration for selling controlled substances.
- RCS: The abbreviation for Research, Controlled Substance.
- Registration: The formal process of obtaining authority from the Federal DEA and/or North Carolina Department of Health and Human Services (NCDHHS) for the use of controlled substances.
- Registrant: The individual that holds NCDHHS registration and Federal DEA registration for

controlled substances, and is responsible for ordering, storing, using, and disposing of controlled substances. This individual is obligated to ensure compliance of all activities and personnel associated with controlled substances use under their registration. Registrants and their Authorized Users are the only ones who can use controlled substances from the registrant's controlled substance cabinet. Registrants may appoint a subordinate to manage the records; however, the registrant retains the obligation for recordkeeping, storage, and use of controlled substances. Deficiencies or discrepancies in recordkeeping are the responsibility of the registrant. Registrants must be listed as approved personnel on all Wake Forest IACUC protocols for which their registration is being used.

- Unit: A Unit is a department, division, institute, center, or investigator 's laboratory personnel who are working under a single registrant.

IV. Purpose of this Manual: What to Do & How to Do It

If you intend to use controlled substances in your research, this manual will provide clear and concise guidance. The main requirements, the big issues, are listed below:

A. Notify Environmental Health and Safety if you intend to use Controlled Substances.

B. Register with the state of North Carolina and the US Drug Enforcement Agency

   These registrations establish an accountable relationship between the individual (principal investigator) and the regulatory agencies.

C. Provide a secure location for controlled substances.

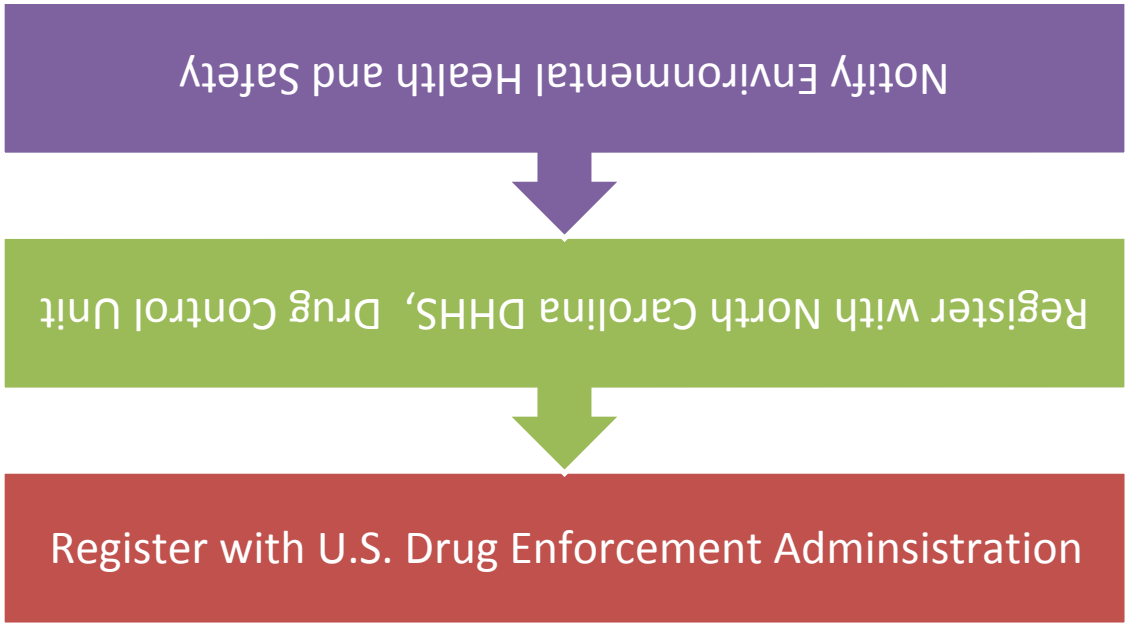
D. Allow only trusted individuals access and use of controlled substances.

E. Be able to track the life cycle of all controlled substances; from ordering to receipt to use to disposal. You must be able to establish (in writing) how each drug was used and by whom and for what purpose.

F. Report any and all suspicious activity: loss, theft or misuse of controlled substances.

V. Notification and Registration: The Process

The Big Picture



The Details

A. Wake Forest University Reynolda Campus Notification

- Before initially obtaining, using or storing controlled substances investigators must complete a *"Notice of Intent to Use Controlled Substances in Research"* form and submit to Environmental Health and Safety

- Researchers should send notification to Environmental Health and Safety when no longer using or registered to use controlled substances.

B. Registration with the North Carolina Department of Health and Human Services, Drug Control Unit

- Complete NCDHHS form 225. Obtain form by contacting: Ms. Joi Baker (919.733.1765). Submit form to the address provided on the form.

- The state license fee is due at the time of submission.
- Registration application fees are processed by Ms. Evelyn Johnson (919.334.1271). A copy of the NCDHHS form 225 is required at the time of payment. Fee is $125 for an initial application.
- Annual renewal fee is $125, due in October.

Info and Advice

An agent of the NCDHHS will contact the controlled substance registrant and schedule an onsite inspection of the proposed storage or holding area.

The NCDHHS application, inspection and licensure process may take several months to complete. Start early.

Contact the NCDHHS:
Department of Health and Human Services
Controller's Office-Accounts Receivable
2025 Mail Service Center
Raleigh, North Carolina 27699-2025
(919) 733-1765

A copy of the approved registration must be available for review.

C. Federal Registration: US DEA

- The North Carolina approved registration must be in your possession prior to submission of a federal application. The DEA will not process a federal registration until NCDHHS has issued a state controlled substance registration number.
- Complete the Federal form 225. The DEA preferred option is online submission. DEA online forms.
- Initial application fee is $184.
- Annual renewal fee is $184, due on the anniversary of your initial approval.

Info and Advice

The US DEA requires a physical site inspection for all Schedule I substances.

Inspections for Schedules II-V are optional, at the discretion of US DEA.

A copy of NCDHHS registration must be available for review.

A researcher using controlled substances at separate locations must maintain separate registrations for each location.

Questions? DEA website

Hard copy form 225 may be submitted to:
Drug Enforcement Administration
Registration Section/ODR
P.O. Box 2639
Springfield, VA 22152-2639

D. Terminating Registrations

If a registrant is leaving the institution or is no longer using RCS, then applicable registrations must be terminated.

VI. Physical Security of Controlled Substances

The security of controlled substances is the responsibility of the registrant. Regardless of schedule, all controlled substances must be:

- kept under a minimum of two locks
- in a substantially constructed cabinet or safe
- accessible only to authorized persons

A. Storage Options:

Preferred method: A locked controlled substance container inside a locked cabinet.

Alternative methods: A locked cabinet in a locked room. The room must always be locked when it is not occupied by the registrant or an authorized user. Locks may be combination or cipher locks or key locks.

Schedule I and II substances have the highest security requirements. They must be stored in an approved safe, steel cabinet or vault.

Addition physical security information: 21 CFR Section 1301.72 Physical security controls for non-practitioners...

Advice and Tips	Storage cabinets must be heavy enough to be effectively immovable or built into or permanently affixed to the building.

Portable storage containers or units are not acceptable for securing controlled substances.

Schedule I controlled substances (and Schedule VI in North Carolina) must be physically separated from other scheduled substances.

If key locks are used:

- The two locks must be keyed differently
- The two keys must not be stored together, e.g. not on the same key ring.
- Both keys must be safeguarded and not accessible to unauthorized personnel.
-
- Refrigerators used for storage must be lockable. If a non locking refrigerator is used, a lock box should be installed securely to hold RCS.
-

B. Security Requirements for Those Who Have Access to Controlled Substances

Authorized Users are individuals who are approved to use specific controlled substances under the sanction of the registrant. It is the responsibility of the registrant to screen these employees prior to granting authorization. The Employee Security Questionnaire asks each potential authorized user to answer the following questions:

- 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 three years, have you knowingly used narcotics, amphetamines, or barbiturates other than those prescribed to you by a physician?
- Have you had an application for registration with the DEA denied, revoked, or surrendered for cause?

Registrants must maintain the completed questionnaires for authorized personnel in asecure place.

Complementary	Limit rigorously the number of individuals who have access to controlled substances

Information	under your registration. The registrant is liable for the activities of all authorized users with access to controlled substances. It is recommended that authorized users of Schedule I and II substances complete the Employee Security Questionnaire annually.

VII. Ordering Controlled Substances

When the state and federal registration process is complete and registration numbers issued, the registrant may initiate orders for any approved substance and amount.

Schedule I and II controlled substances must be ordered using an Official Order Form DEA 222. To obtain through online request, go to: DEA Order Request

- Schedule I controlled substances may be procured through federally approved Schedule I vendors (222 form required).
- Schedule II controlled substances are available through NCBH Department of Pharmacy or a registered public vendor (222 form required).
- Schedule III – V controlled substances are available through NCBH Department of Pharmacy or a registered public vendor.

Ordering pathways at WFU Reynolda Campus:

- University Procurement Services
- NCBH Department of Pharmacy
- National Institutes of Health (NIH) sources

VIII. Managing Controlled Substances: Process and Procedures

Vigilant onsite management of controlled substances is required at all laboratory levels, from ordering to receipt to use to disposal. The ability to track the life of a controlled substance must be demonstrated consistently in the laboratory setting.

The above diagram presents the components of a management system for controlled substances:

1. **Personnel and Physical Security:** ***Limited and reliable*** authorized users and control of access to controlled substances.

2. **Receipt of controlled substances**: Each order is ***verified and recorded*** by the registrant or an authorized user.

3. **Recordkeeping:** A written system which provides an ***accurate, continuous and current*** record to track the acquisition, use and disposal of controlled substances.

4. **Disposal:** Practice of ***properly disposing*** of waste, unneeded and expired controlled substances.

5. Audit and Assessment: An ongoing ***auditing program*** which provides corrective and beneficial review of the laboratory controlled substance process.

Receiving of Controlled Substances

- Either the Registrant or an Authorized User may receive controlled substances.
    - The receiving individual must:
        - Verify the contents of the order received. Sign and date.
        - Resolve discrepancies immediately. Contact the vendor/seller to correct document errors, etc. A copy of the DEA Form 222 may be used to document initial quantities.
        - Sign and date the original receiving documents. Maintain these documents for three years.
    - The use of a purchase log is highly recommended. Appendix provides an example of a Purchase Log Form.
- **Transfer of a controlled substance between Wake Forest University registrants is not permitted unless indicated in the terms of the registration.**
    - Schedule I controlled substances **may not** be transferred within the institution.
    - Schedule II controlled substances may be transferred to another research (registrant). The requesting registrant must complete a DEA Form 222 and provide a copy to the source or providing registrant.
    - Schedule III – V controlled substances may be transferred between registrants. It is advisable to use DEA Form 222 to provide documentation of a legal transfer.

Recording the Use (Dispensing of Controlled Substances)

An accurate, continuous and current record of controlled substances is mandatory under state and federal regulations. While specific forms are not mandated, it is prudent to use a form which will provide a clear audit trail of controlled substance usage.

A written record may include:

- Name of the substance
- Source of the substance
- Date of expiration of the substance
- Date of receipt
- Unique identification number for the bottle
- Starting quantity of controlled substance
- Date of use
- Protocol (or project) for which it is being used
- Animal (or group of animals) for which it is being used
- Person dispensing the medication from storage
- Person administering the medication to the animal(s)
- Quantity (cc/ml/grams) of agent dispensed, administered and wasted.
- Quantity remaining in the vial/bottle/box

Inventory of Controlled Substances

It is recommended that controlled substances be inventoried every quarter even though the regulatory requirement stipulates every two years.

In addition to balance log records, initial and ongoing inventory records are required for all schedules of controlled substances. Schedule I substances must be completed on a separate record from other schedules. The inventory should include the name of each substance, each finished for of the substance (solid, tincture, inhalant, etc.), the number of units or volume of each finished form and number of containers of each finished form. Damaged, defective, expired, or impure substances awaiting disposal must be included in the inventory (until they are official disposed). Refer to the DEA Diversion web site for further information: DEA Inventory Requirements

Labeling of Controlled Substances

Each bottle (or box) of controlled substances must be individually identified by a unique (not re-used) number.

a. Original packaging showing the product information should be used when possible. Controlled substances containers (vials, ampoules, or boxes) may be removed from the original packaging if the interior container(s) has been labeled to include: the name of the controlled substances, the lot number (or unique identifier), the date opened, the final concentration, the amount per container, and the expiration date (either as per the manufacturer recommendations or the most recent expiration date of the combined substances if mixed).

b. If syringes are filled and stored in the controlled substance cabinet; or if controlled substances are compounded, diluted or combined, each container/syringe must be labeled and tracked. The label must include the following:

- the name of the controlled substances,
- the lot number (or tracking number) of the product,
- the date opened,
- the final concentration,
- the amount per container, and
- the expiration date (either as per the manufacturer's recommendations or the most recent expiration date of the combined substances).

Complementary Information

Schedule I substances require a bound book rather than a loose leaf notebook.

A bound book is suggested for all controlled substance use, but only required for Schedule I.

There are a variety of acceptable ways to track usage. The main point is that it seem sensible to Wake Forest, state and federal auditors.

- Accurate
- Continuous
- Current

IX. Loss, Theft, or Misuse of Controlled Substances

Diversion of a controlled substance is the technical term for loss, theft or misuse. Controlled substance regulations exist primarily to prevent illegal use. Particularly at the federal level, any discovery of controlled substance loss is taken very seriously. The worst action is no action.

Losses should be reported within 3 business days to:

- Wake Forest University Police for Reynolda Campus
- WFU Environmental Health and Safety
- Federal DEA

Manage losses by:

- Validating substance tracking documentation (logs)
- Contacting the DEA Office of Diversion Control in Greensboro (336 547 4219). The DEA staff will advise whether you need to complete a copy of the DEA For 106: Report of Theft or Loss of Controlled Substances: DEA Form 106
- Report to EH&S ehs@wakehealth.edu
- Reporting losses to NCDHHS is not required.

How can theft or misuse of controlled substances occur in your lab?

- Poor recordkeeping.
- Failure to limit access. Too many persons with physical access to controlled substances.
- Poor key control.
- Witness not used during disposal of controlled drugs.
- Unlabeled bottles and syringes.

Signs that drug diversion may be occurring?

- Abnormal increase in drug use by the lab or unit
- Reports of excessive wastage.
- A controlled drug seems less effective or experiment results are abnormal.
- Evidence of altered records.

Employees seeking to work unsupervised, after hours.

- Signatures requested for blank order forms.

X. Disposal of Controlled Substances

Controlled substances which are disposed must be accounted for in writing. Substances which are expired, unused, or contaminated must be stored under lock and key until officially disposed. In many cases disposal the NC-DCU special agent must be present onsite to witness the destruction/disposal.

Disposal Requiring NC-DCU Notification

- Disposing of Schedule I (or VI) substances in any quantity.
- Disposing of Schedule II – V substances including:
    - Expired chemicals
    - Multi-does vials that are not consumed completely
    - Unused or unwanted substances

Both the state agent and the registrant are required to sign the disposal document (DEA Form 41). If the registrant is not available (left the institution), contact the NC-DCU at 919 733-1765 for guidance.

Fax a copy of the DEA Form 41 to the DEA Office of Diversion Control in Greensboro (fax 336 547-4209). Keep a copy for at least three years.

Disposal of Schedule II – V Controlled Substances without NC-DCU Notification

Allowable conditions:

- Unused part of an injection
- Small residue in original container
- Contaminated dose such as unused in syringe or when controlled substances are reconstituted for use, but short shelf life prevents use of the residue.

Disposal still requires documentation and a witness signature. For pure substances not combined with other waste types, the registrant can dispose through the sanitary sewer in most cases. Contact EH&S if you have questions, wfuehs@wfu.edu.

Breakage and Spillage

When there is breakage, damage, spillage or some other form of accidental destruction of a controlled substance any recoverable amount must be disposed of according DEA and NC DCU requirements.

The portion of the breakage/spillage that is not recoverable must be recorded and explained (circumstances) in use and inventory records. Two individuals who witnessed the event(s) must attest by signature what they observed. A DEA Form 41 is not required in these non-recoverable situations.

XI. Import and Export

An Import/Export Declaration for List I and List II Chemicals, DEA Form 486, must be completed by each regulated person for each regulated import, export, or international transaction. This form may be found on-line at **http://www.deadiversion.usdoj.gov/21cfr_reports/chemicals/index.html**.

Information regarding this subject may be found at 21 U.S.C. §§ 957 and 971 and 21 C.F.R. §§ 1313.05, 1313.08, and 1313.12 - 1313.17. Note that a minimum 15-day advance notification is required prior to importation.

The importer of a List I or List II chemical must provide the following types of information on the DEA Form 486 or DEA Form 486A.

1. Contact information for the United States chemical importer, and contact information for the broker or forwarding agent (if any);
2. The name and description of each listed chemical as it appears on the label or container, the name of each listed chemical as described by the DEA in 21 C.F.R. § 1310.02, the size or weight of the container, the number of containers, the net weight of each listed chemical given in kilograms or parts thereof, and the gross weight of the shipment given in kilograms or parts thereof;
3. The proposed import date, the foreign port of exportation, and the first U.S. Customs port of entry;
4. Contact information of the consigner in the foreign country of exportation; and
5. Contact information of the person(s) to whom the importer intends to transfer the listed chemical and the quantity to be transferred to each transferee.

It is unlawful to import into the United States ephedrine, pseudoephedrine, and phenylpropanolamine except such amounts as the DEA finds to be necessary to provide for medical, scientific, or other legitimate purposes. An Import Declaration for Ephedrine, Pseudoephedrine, and Phenylpropanolamine, DEA Form 486A, must be completed by each DEA-registered importer for each import. The DEA Form 486A and the instructions for completing and distributing it can be found online at **http://www.deadiversion.usdoj.gov/21cfr_reports/chemicals/index.html**.

Information regarding exports may be found at 21 U.S.C. §§ 960 and 971 and 21 C.F.R. §§ 1313.05 and 1313.21 - 1313.27.

It is unlawful to export any listed chemical, knowing or having reasonable cause to believe the export is in violation of the laws of the country to which the chemical is exported or the chemical will be used to manufacture a controlled substance in violation of the Controlled Substances Act or the laws of the

country to which the chemical is exported.

The exporter of a List I or List II chemical must provide the following types of information on the DEA Form 486.

1. Contact information for the United States chemical exporter and contact information for the export broker, if any;
2. The name of each listed chemical as described by the DEA in 21 C.F.R. § 1310.02, the size or weight of container, the number of containers, the net weight of each listed chemical given in kilograms or parts thereof, and the gross weight of the shipment given in kilograms or parts thereof;
3. The proposed export date, the U.S. Customs port of exportation, and the foreign port of entry;
4. Contact information of the consignee(s) in the country where the chemical shipment is destined, and contact information of any intermediate consignee(s).

XII. Auditing

Audits by the Registrant

Recommended: Quarterly.
Required: Every two years.

Institutional Audits

Annually.

Federal or State Audits

Subject to specific jurisdictional requirements.

XIII. Education and Assistance

In addition to the contents of this manual, Environmental Health and Safety and the IACUC have collaborated to develop an online training module through the Wake Forest University School of Medicine which explains the proper management and use of controlled substances at Wake Forest University. Additionally, onsite assistance will be provided upon request by contacting wfuehs@wfu.edu .

Appendix I

Laboratory Records

WAKE FOREST UNIVERSITY

CONTROLLED SUBSTANCE SEMI-ANNUAL INVENTORY FORM

CONTROLLED SUBSTANCE	SUBSTANCE SCHEDULE NUMBER	TOTAL INVENTORY QUANTITY* (including concentration for solutions)	REASON FOR SUBSTANCE BEING MAINTAINED

*Total quantity of the substance to the nearest metric unit weight/volume of the total number of units (for Schedule II, perform an exact count or measure of quantity).

Principal Investigator / Senior Staff (Print/Signature):	Department/Buidling/Room Number:
Phone:	E-Mail:
Inventory Date:	Inventory recorded by (Print/Signature):

WAKE FOREST UNIVERSITY

AUTHORIZED USERS SIGNATURE LOG

Signature of all persons designated by the Principal Investigator as Authorized Users for thie Location are required.

Principal Investigator Name: _____

Location: _____

Date Signed	Key / Combination (Yes/No or Both)	Name (Print)	Title	Signature	Initials (as used in research records)	Date Departed

I certify that Ihave designated the persons listed above as Authorized Users for this location. Person is no longer an Authorized User when a "Date Departed" is entered.

Principal Investigator / Senior Staff (Print/Signature): _____ Date: _____

WAKE FOREST UNIVERSITY

RECORD OF CONTROLLED SUBSTANCE (SCHEDULE II-V) ADMINISTERED/DISPENSED (USAGE LOG)

Unique Bottle ID# (assigned by laboratory upon receipt):_____

Drug Name: _____ Concentration (mg/ml): _____ Bottle Size (mls): _____

Date	IACUC Protocol# (if applicable)	Project Name or Animal Species (or Group)/ID#	Initials of Dispensor	Amount Administered or Dispensed	Initials of Person Administering	Amount Wasted	Initials of Witness

WAKE FOREST UNIVERSITY

CONTROLLED SUBSTANCE RECEIPT LOG (LIQUID)

DEA Number: _____ Registrant Name:_____

Date of Receipt	Drug Name	Drug Concentration (mg/ml)	Bottle Volume (total mg)	Quantity (Number of Bottles)	Assigned Unique ID Number(s)	Vendor	Purchase Order Number	Initials of Person Receiving

WAKE FOREST UNIVERSITY

CONTROLLED SUBSTANCE RECEIPT LOG (POWDER)

DEA Number: _____ Registrant Name:_____

Date of Receipt	Drug Name	Drug Concentration (mg/ml)	Bottle Volume (total mg)	Quantity (Number of Bottles)	Assigned Unique ID Number(s)	Vendor	Purchase Order Number	Initials of Person Receiving

WAKE FOREST UNIVERSITY

Controlled Substance Discrepancy Report

Type of Discrepancy

_____ Loss or other discrepancies of controlled drugs

_____ Discrepancy discovered during semi annual inventory (IACUC Facilities Inspection)

_____ Broken safety tab

_____ Apparent break-in

Name of Individual Completing Report: _____

Description of Discrepancy (Include date discovered, location, individual involved, etc.)
Note: For liquid drugs, 0.15 ml/dose drawn discrepancy permitted for residual quantities in syring hub.

_____

_____

_____

_____

_____

_____

_____

Signature: _____ Date: _____

Witness: _____

Registrant Name: _____ Signature: _____

Copies: ☐ Environmental Health and Safety
☐ **WFU POLICE**

WAKE FOREST UNIVERSITY

CONTROLLED SUBSTANCE AUDIT CHECKLIST

PRINCIPAL INVESTIGATOR: _____

AUDITOR: _____

DATE: _____

CATEGORY	S/NS/NS*	COMMENTS
Administration		
Copy of Guidelines available		
SOP available		
NC and USDEA registrations current		
Copy of registration available		
Physical Security		
All CS kept under minimum of two locks		
Locks keyed differently		
Keys not kept together		
Locks in good condition		
Substantially constructed cabinet or safe in use		
Schedule I and II stored in approved safe, steel cabinet or vault		
Schedule I and VI physically seperated from other scheduled substances		
Accessible only to authorized personnel		
Personnel Security		
Background checks completed on authorized personnel		
Registrants completed questionnaires for authorized personnel maintained in secure location		
Personnel trained in CS protocolcs		
Access limited to PI and designated personnel		
Means of access to CS limited to authorized personnel by means of locks, keys, etc.		
Ordering		
Ordering protocol follows Guideline, Section VIII		
Receipt records maintained and recorded		
Inventory Control		
Written record in place		
Record up-to-date		
Form matches data required in Guidelines		
Inventory review quarterly		
Schedule I kept in bound book		
Labeling		
Container labeled		
Distinct ID# / container		
Expiration date present		
Use Area		
Area security established (alarm, key, etc.)		
Contamination Control		
No uncontained substances observed		
General housekeeping maintained		
Personnel exposure control		
Fume hood(s) functioning		
PPE available		
Discrepancies		
Discrpancies? (Yes/No)		
Discrepancy protocol in Guidance followed		
Disposal		
Disposal accounted for in writing		
Disposal document DEA Form 41 used		
Non-notification disposal follows protocol in Guidelines		
Import / Export		
CS Imported (Yes/No)		
CS Exported (Yes/No)		
DEA Form 486 completed and on file		

*S/NS/NA - Satisfactory/Non-Satisfactory/Not-Applicable