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APPENDICES

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1. INTRODUCTION

1.1 PURPOSE OF THIS PLAN

This plan outlines the requirements and responsibilities for the possession and use of controlled substances for authorized research at the University of New Hampshire (UNH) campus. Because select faculty use and/or maintain controlled substances for campus research and analytical purposes, UNH must comply with federal and state laws and regulations regarding their use, storage and disposal, including relevant U.S. Drug and Enforcement Administration (DEA) requirements at Title 21, Part 1300-1308 of the Code of Federal Regulations (C.F.R.). UNH is also subject to New Hampshire Department of Health and Human Services (DHHS), Title XXX, Occupations and Professions, RSA 318-B, Controlled Drug Act.

The DEA has divided the controlled substances into five schedules (Schedules I-V) based on their usefulness in medicine as a drug and their relative abuse potential and likelihood of causing dependence when abused. A complete list of the schedules is published annually on an updated basis in the DEA regulations, 21 C.F.R. § 1308.11-1308.15. A link to the current version of the controlled substances schedules is provided in Appendix J.

1.2 UNIVERSITY POLICY STATEMENT FOR CONTROLLED SUBSTANCES

Individuals who manufacture, distribute, dispense, import, export, conduct research, or perform chemical analysis with a controlled substance are subject to DEA and DHHS regulations. Use of controlled substances in scholarly activity at UNH is restricted to authorized persons working under the direct supervision of a DEA registrant in accordance with the DEA registration and in compliance with all applicable federal, state and university requirements. Failure to comply with this policy may be grounds for employee disciplinary action or research termination.
2. ROLES AND RESPONSIBILITIES

Authorized University employees, including Principal Investigators (PIs) or other supervisors of research where controlled substances are used, bear full responsibility for complying with all applicable regulations and UNH policy regarding controlled substances. In order to ensure compliance, it is important that faculty, research staff, and students understand their responsibilities related to the acquisition, possession, use, storage, and transfer or disposal of controlled substances.

2.1 UNIVERSITY ADMINISTRATION

The University administration has overall responsibility for instituting University policies and programs, establishing systems, and providing resources to help ensure that research activities involving controlled substances are in accordance with all applicable requirements, including DEA regulations. The Provost and Vice President for Academic Affairs will provide senior administrative oversight for this program, and have delegated certain responsibilities to the Senior Vice Provost for Research, Animal Resource Office, Office of Environmental Health and Safety, and the individual Departments, Principal Investigators (PIs), and other affected University employees.

2.2 OFFICE OF THE SENIOR VICE PROVOST FOR RESEARCH

- Oversees the University controlled substances program.
- Provides resources and support to implement and maintain the controlled substances program.

2.3 ANIMAL RESOURCE OFFICE (ARO)

- Maintains the institutional controlled substances registration. [Note: Currently the attending veterinarian in the Animal Resource Office (ARO) is the registrant. A copy of the registration is included as Appendix A.]
- Maintains a list of authorized Principal Investigators (PIs) and authorized users at UNH, based on input from UNH Police and the DEA on the results of background screening for new authorization requests, and from Departments and PIs on changes (e.g., to remove employees from the list of authorized users, etc.).
- Coordinates initial training, and periodic refresher as necessary, for faculty members and other employees authorized to handle or access controlled substances.
- Approves procurement of controlled substances for authorized PIs, in accordance with the registration and applicable regulations.
- Enters and maintains controlled substances data in UNHCEMS, based on procurement and final disposition of controlled substances. Applies the bar code to the controlled substance container upon receipt and lists the assigned UNHCEMS number on the forms provided in Appendices C and D.
- Works with the DEA field office, and UNH EHS as necessary, to ensure the proper disposal/ destruction of controlled substances.
- Coordinates the biennial inventory process.
- Maintains program records.
• Conducts periodic inspections or audits of program implementation in Departments and laboratories.

• Reviews the overall program at least annually and maintains the written plan.

• Coordinates with UNH Police Department in notifying the DEA field office (DEA Manchester, NH DO) upon discovery or report of theft or loss of controlled substances.

• Performs investigation of reported or suspected thefts of controlled substances, working with UNH Police, law enforcement, and other University parties as appropriate.

• Completes and submits a DEA Form 106 if it is determined that theft or significant loss of a controlled substance has occurred.

2.4 PRINCIPAL INVESTIGATORS (PI)

• Maintains a list of laboratory employees authorized to use or otherwise handle controlled substances, and restricts access only to those authorized users.

• Ensures that all applicable Federal, State and University requirements for authorization, acquisition, security, use, handling, storage, transfer or disposal, reporting and recordkeeping are followed for controlled substances maintained by the laboratory.

• Where applicable, obtains research approval from the appropriate UNH committees for animal subjects and/or biological research (e.g., the Institutional Animal Care and Use Committee, Institutional Biosafety Committee) and reports the intention to use controlled substances to external funding sponsors where required upon submission of grant applications.

• Maintains accurate inventory of controlled substances maintained by the laboratory, and submits inventory and controlled substance records to the ARO.

• Contacts the ARO regarding final disposition of controlled substances (e.g., if empty, expired, damaged or otherwise will no longer be used).

• Reports missing or suspected theft of controlled substances immediately upon discovery to UNH Police Department and the ARO.

2.5 AUTHORIZED USER

• Participates in training and authorization prior to handling controlled substances.

• Complies with Federal, State, and University requirements for controlled substances.

• Maintains strict control and inventory of controlled substances.

• Completes all required forms and recordkeeping.

• Immediately reports missing controlled substances to the PI, UNH Police Department and the ARO.

2.6 ENVIRONMENTAL HEALTH AND SAFETY

• Maintains UNHCEMS, which is used for controlled substance inventory records.

• Maintains a master set of Safety Data Sheets (SDSs).
• Provides technical guidance and other assistance related to chemical hazards, laboratory safety and waste management, including periodic laboratory inspections.

2.7 UNH POLICE

• Conducts local inquiries for background screening as part of the authorization process for PIs and employees that handle or otherwise have access to controlled substances. Forwards results to the ARO.

• Reports information on missing or suspected thefts of controlled substances to the ARO, Department chair, and the Senior Vice Provost for Research.

• Conducts and coordinates investigations, and collaborates with the DEA Manchester DO, and/or the DEA NEFD, as appropriate.

• Continuously patrols campus and enforces public safety and security.
3. REGISTRATION

3.1 REGISTRATION

Currently, the ARO maintains the institutional registration of controlled substances (see Appendix A). The DEA Certificate of Registration must be maintained at the registered location and be made readily available at all times. Only those schedules of controlled substances identified on the registration may be used for the designated purposes listed (i.e., the ARO registration is for Schedules 2, 2N, 3, 3N, 4, and 5, and identifies “teaching institution” as the business activity).

3.2 APPLICATION FOR REGISTRATION

If appropriate based on changes in planned controlled substances usage or request from the DEA, UNH may require an individual PI or Department administrator to obtain a DEA registration. To obtain a DEA registration, the authorized PI or Department administrator must apply using DEA Form 224 – New Application for Registration. Applicants should submit the form using DEA’s On-Line forms system (see Appendix E).

A paper copy of the form may be obtained by writing to the address below; however, DEA’s preferred method for new registration submittal is on-line.

Drug Enforcement Administration
Attn: ODR
PO Box 2639
Springfield, VA 22152-2639.

3.3 REGISTRATION RENEWAL

DEA registrations must be renewed every three years. Renewal registrations use DEA Form 224a – Renewal Application for DEA Registration, which is available through DEA’s on-line system (see Appendix E). The ARO (or other registrant if applicable) is responsible for maintaining a current registration and completing the renewal process every three years.

3.4 TERMINATION OF REGISTRATION

To terminate a DEA registration, the registrant must notify the nearest DEA office in writing.

3.5 RESEARCHER - SCHEDULE I

Full time Faculty in research positions can apply for DEA licensure directly from the DEA for research involving Schedule I drugs only. Said researcher will be solely responsible for the purchase, storage, inventory and disposition of these drugs. The storage and usage sites need to be inspected by NH DEA Special Agents and authorized by the Regional Office in Boston, MA prior to obtaining schedule I drugs. Said researcher is subject to periodic inspections by the DEA. Said researcher must also inform the UNH Police of the location of these chemicals and have the drug safes hooked up with an alarm system that directly notifies the UNH Police. The UNH IO will be informed of the researcher and the usage of these
substances. Information on application and requirements for Researcher – Schedule I Only can be found at this link: https://www.deadiversion.usdoj.gov/drugreg/reg_apps/225/225_instruct.htm
4. AUTHORIZATION REQUIREMENTS

Only authorized persons are permitted to utilize or otherwise handle or have access to controlled substances for campus research. The authorization process requires: employee screening, training, and continued good standing with respect to addressing any compliance deficiencies or other action items identified by the University as part of the controlled substances program.

In addition to the authorization for controlled substances, PIs with animal research protocols utilizing controlled substances must maintain approval by the Institutional Animal Care and Use Committee (IACUC), and research protocols involving recombinant DNA, select agents, or other covered biological hazards must be approved by the Institutional Biosafety Committee (IBC), in accordance with applicable University requirements.

4.1 EMPLOYEE SCREENING

Employee screening is a critical component in preventing diversion of controlled substances. The DEA recommends that registrants should not employ as an agent or employee who has access to controlled substances:

1. Any person who has been convicted of a felony offense related to controlled substances;
2. Any person who has been denied a DEA registration;
3. Any person who has had a DEA registration revoked; or
4. Any person who has surrendered a DEA registration for cause.

Therefore, UNH has adopted an employee screening program as part of its authorization process for PIs and other employees who wish to use controlled substances in research, or who will otherwise have access to controlled substances. All PIs and other employees (e.g., technicians, graduate research employees, etc.) intending to handle or otherwise possess a controlled substance for campus research are required to undergo background screening prior to University authorization. Each PI or employee must complete and submit the Employee Authorization Form (Appendix B) to the ARO.

Graduate Students will have a background check performed as part of their acceptance to the Graduate Program. Undergraduate students do not require a background check to work in labs using scheduled substances, but need to be under direct supervision of the Faculty researcher, authorized Laboratory Staff Director/Manager or Graduate Student.

At UNH, routine pre-employment screening is conducted by Human Resources at the time of hire based on the job requirements. Prior to hiring and/or assigning employees to work in or around areas where controlled substances are handled, UNH requires additional employee screening as part of the controlled substances authorization process (see Appendix B). Criminal background checks with local law enforcement authorities and with the DEA will be coordinated by UNH Police and the ARO as part of the UNH employee screening process.

If appropriate, as determined by the ARO, UNH Police, and University Administration, the requirement for employee screening will apply to other University employees who have access to controlled substances [Note: Access to controlled substances includes not only physical access, but also any influence over the handling of controlled substances such as purchases, inventories, etc.].
4.1.1 Inquiries

The DEA recommends that inquiries concerning employees' criminal records be made as follows:

- **Local inquiries** - Inquiries should be made by name, date and place of birth, and other identifying information, to local courts and law enforcement agencies for records of pending charges and convictions. Local practice may require such inquiries to be made in person, rather than by mail, and a copy of an authorization from the employee may be required by certain law enforcement agencies.

- **DEA inquiries** - Inquiries supplying identifying information should also be furnished to DEA Field Division Offices along with written consent from the concerned individual for a check of DEA files for records of convictions. The Regional check will result in a national check being made by the Field Division Office.

UNH Police Department will handle the local inquiries for controlled substances, and the ARO will coordinate with the DEA field office on DEA inquiries. The ARO will forward new authorization requests to UNH Police to complete local inquiries (Appendix B). Upon completion of the local inquiries, UNH Police will provide the employee authorization form to the ARO to complete the DEA inquiries, and to update and maintain the list of authorized PIs and authorized employees.

4.1.2 Employee Questionnaire

As outlined at 21 C.F.R. 1301.9, it is the position of the DEA that obtaining certain information by non-practitioners is vital to fairly assess the likelihood of an employee committing a drug security breach. The DEA indicates that conviction of crimes and unauthorized use of controlled substances are activities that are proper subjects for inquiry, and assumes that the following questions will become a part of an employer's comprehensive employee screening program:

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

These questions have been incorporated into the UNH authorization form for controlled substances (Appendix B). No individual who has been convicted of a felony for any State or Federal law regarding controlled substances will be allowed access to controlled substances.

4.2 TRAINING

To help ensure that all faculty and other employees with access to controlled substances understand the relevant requirements for acquisition, storage, use, handling, and disposal, UNH requires that all authorized persons (registrant, authorized PI, authorized users) receive the information and training as appropriate based on their role in the controlled substances program. Participation in training is required in order to obtain and maintain University authorization to use or maintain controlled substances.

Each PI must participate in initial training in order to procure or maintain controlled substances for his/her laboratory. Courses will be offered periodically, coordinated by the ARO.
Authorized users (researchers working under the direction of an authorized PI) must receive training through such courses or by the PI through a review of training materials provided by the ARO and hands-on training.

All training should be documented using the log provided in Appendix I, or an equivalent form.

4.3 AUTHORIZATION STATUS

A list of authorized persons (PIs and other employees) is maintained by the ARO (Appendix F). An authorized person must be in good standing as far as required training and compliance in order to maintain authorization status. In the event of repeated violations and failure to cooperate in addressing compliance deficiencies, an authorized PI or employee may lose authorization status (i.e., can no longer procure or maintain controlled substances or conduct research utilizing such substances).
5. PROCUREMENT AND RECEIPT

5.1 PURCHASE OF SCHEDULE II THROUGH V CONTROLLED SUBSTANCES

Controlled substances must be purchased under a DEA registration number after approval by the ARO. The PI, or authorized user with PI approval, must complete and submit the UNH Controlled Substances Purchase Request Form (Appendix C) to the ARO. The purchase request form should include the following information:

- Name and quantity of requested controlled substance;
- Names of authorized PI and authorized users;
- Intent of research use;
- Storage location; and
- Any other details relevant to the controlled substances program.

Order requisitions must note the name of the authorized PI requesting the material to allow for proper notification upon receipt by the ARO.

5.1.1 Purchase of Schedule II Controlled Substances

The purchase of schedule II controlled substances requires the submission of DEA Form 222 – U.S. Official Order forms.

All requests for official order forms (DEA Form 222) can be made by registrants who are registered in Schedules I and/or II. Once the online form is submitted, the requestor will receive the maximum number of order form books allowed for his/her business activity. [Note: This requirement applies to Schedule I controlled substances as well; however, UNH does not currently have a registration for Schedule I controlled substances.]

The top and middle portion of the official order form will be forwarded to the supplier and the remaining portion will be kept by the ARO with other controlled substance records. Once the shipment is received, the order form will be annotated to show the date and amount received.

[Note: Records of Schedule II controlled substances must be kept separate from other controlled substances.]

If necessary, the ARO can give power of attorney to another UNH employee who would be able to act in his absence to procure controlled substances. A form to authorize and revoke power of attorney is provided in Appendix K. The power of attorney must be retained in the files, with executed DEA Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records.

5.2 RECEIPT OF CONTROLLED SUBSTANCES

The controlled substance is shipped to the registrant and address as indicated on the DEA registration. Once received by the ARO, the controlled substances must be picked up by the authorized PI or a
designated authorized user and should be opened to verify the contents so any discrepancies can be rectified with the supplier. If discrepancies cannot be readily addressed, the ARO and the DEA should be contacted for assistance.

Receipt of controlled substances must be documented, with a record of the chain of custody including each point where the substance changes hands or is used. Receipt and transfer from the ARO to the PI or authorized user is documented on the form provided in Appendix C. A usage log is then maintained by the PI or authorized user until the controlled substance is consumed or properly disposed of. Receipts of controlled substances must be kept by the responsible PI for the substance life cycle (e.g., until consumed, properly transferred or disposed of), and then returned to the ARO (Appendix D).
6. USE, STORAGE AND SECURITY REQUIREMENTS

6.1 LABELING

Containers of controlled substances must be labeled with the designated symbol for the schedule category it belongs. Controlled substances must not be transferred from their original containers for inventory purposes. Identifying labels must not be removed from the original containers. If the substance is converted or diluted, the new container must be labeled properly.

6.1.1 Symbol

The designated symbols for each schedule of controlled substance is as follows:

- Schedule II - CII or C-II
- Schedule III - CIII or C-III
- Schedule IV - CIV or C-IV
- Schedule V - CV or C-V

6.2 STORAGE

The DEA registrant(s) and each authorized PI and user are required to maintain security for the storage and distribution of controlled substances.

Controlled substances must be stored in a securely locked cabinet of substantial construction, located in areas with limited access (see below for additional details on security).

6.3 SECURITY

Each registrant and authorized PI is responsible for ensuring that effective controls and procedures are provided to guard against theft and diversion of controlled substances (see 21 C.F.R. 1301.71(a)), including the following requirements and guidance:

- Access to controlled substances must be limited to individuals who have current approval as an authorized person (Authorized PI or Authorized User).
- Stocks of Schedule II through V controlled substances must be stored in a securely locked, substantially constructed cabinet.
  - Such a cabinet is interpreted as, at minimum, a structure of wood or metal so constructed as to resist easy entry by simple tools of attack, with internally-mounted hinges, and secured by a deadbolt lock. The cabinet should be permanently constructed or attached to a building structure to prevent physical removal.
  - If a safe is used in lieu of a securely locked, substantially constructed cabinet, the safe is to either be secured so as to prevent removal or be at least 750 lbs.

[Note: If any practitioners are authorized to possess carfentanil, etorphine hydrochloride and/or diprenorphine, these substances must be stored in a safe or steel cabinet equivalent to a U.S. Government Class V security container.]
• Controlled substances must never be left unattended.
• Inventories should be kept to a minimum.
• Key locks or combinations should be changed whenever personnel changes.
• Other appropriate security measures must be implemented where necessary to effectively guard against theft or diversion.

The adequacy of security controls is determined based on consideration of a number of factors including the:

1. Location of the premises and the relationship such location bears on security needs;
2. Type of building and office construction;
3. Type and quantity of controlled substances stored on the premises;
4. Type of storage medium (i.e., safe, vault, steel cabinet);
5. Control of public access to the facility;
6. Adequacy of registrant’s key control and monitoring system (i.e., alarms and detection systems);
7. Extent of supervision over employees with access, and procedures for handling visitors; and
8. Availability of local police protection.

**6.4 BREAKAGE OR SPILLAGE**

Breakage of controlled substances is not considered by the DEA to constitute a "loss" of controlled substances. When there is breakage, damage, spillage, or some other form of destruction, any recoverable controlled substances must be disposed of according to DEA requirements. Damaged goods may be disposed of through shipment to a reverse distributor or by a DEA approved process (see Section 7).

If the breakage or spillage is not recoverable, contact the Animal Resource Office (Rudman Hall, Rm B56, 2-4629). The registrant must document the circumstances of the breakage in the inventory records. Two individuals who witnessed the breakage must sign the inventory records indicating what they witnessed. The submission of a DEA Form 41 is not required for non-recoverable controlled substances.

**6.5 REPORTS OF THEFT, LOSS, OR UNAUTHORIZED USE**

The DEA requires a registrant to notify the DEA field office in their area of any theft, significant loss, or unauthorized use of controlled substances upon its discovery.

At UNH, any unaccountable loss, suspicious theft, or unauthorized use of a controlled substance is to be reported immediately to UNH Police and the ARO, and to the PI.

The ARO will:

1. Notify the DEA upon discovery of any thefts, significant losses, or unauthorized use of controlled substances.
2. Notify the Senior Vice Provost for Research and Department Chair of any theft, significant loss, or unauthorized use of a controlled substance and of the investigation results.
3. Work with UNH Police, other University representatives, and law enforcement as appropriate to investigate each theft, significant loss, or unauthorized use of controlled substances.

4. Complete a DEA Form 106 online at https://www.deadiversion.usdoj.gov/webforms/dtlLogin.jsp, where it is determined that a theft or loss occurred and where the circumstances surrounding the loss are clear (e.g., quantities involved, etc.).

[Note: Only those persons registered with and authorized by DEA to handle controlled substances may utilize and submit DEA Form 106. DEA Form 106 must be filled in online at the DEA Diversion Control Program website (Appendix E).]

Additional guidance for theft or loss includes:

- When details concerning the specific circumstances surrounding the theft or loss are unknown at the time of discovery, the DEA recommends initial notice be provided by faxing a short statement to DEA field office advising of the theft or significant loss.

- If UNH determines that such loss occurred (e.g., by conducting inventories, internal audits, and/or investigations using internal or law enforcement resources, as appropriate), then the DEA Form 106 should be submitted once the circumstances surrounding the theft or significant loss are clear. The DEA Form 106 must document the circumstances of the theft or significant loss and the quantities of controlled substances involved.

- If an investigation takes more than two months to complete, the DEA recommends that registrants provide updates regarding the investigation.

- If, after an investigation of the circumstances surrounding the disappearance of the material, it is determined that no theft or significant loss occurred, no DEA Form 106 need be filed. However, DEA recommends that the registrant advise DEA that a DEA Form 106 is not needed or will not be filed regarding the incident.

- DEA Form 106 is not intended for minor inventory discrepancies.
7. DISPOSAL PROCEDURES

All controlled substances must be accounted for upon their disposal. To dispose of expired, damaged, or unnecessary controlled substances, the PI will contact the ARO who will coordinate with the DEA field office and UNH EHS as necessary for the final disposal of controlled substances in accordance with applicable Federal and State requirements. The ARO will maintain a copy of disposal records for controlled substances for three years after disposal.

The DEA recommends that any registrant seeking to dispose of controlled substances first contact the nearest DEA field office for disposal instructions. The ARO will contact the DEA field office to determine the final disposition of the controlled substance(s), either through a reverse distributor, or in certain cases where approved, by special destruction.

7.1 REVERSE DISTRIBUTOR

Out-of-date, damaged, or otherwise unusable or unwanted controlled substances, including samples, may be transferred to a registrant who is authorized to receive such materials (reverse distributor). DEA Form 222 must be used to transfer Schedule II controlled substances. Schedule III–V compounds may be transferred via invoice. The transfer of Schedules III–V controlled substances must be documented in writing to show the drug name, dosage form, strength, quantity and date transferred, as well as the names, addresses and DEA registration numbers of the parties involved in the transfer of the controlled substances. Records documenting any transfer of controlled substances will be maintained for a period of at least two years.

7.2 SPECIAL DESTRUCTION

For minute quantities or non Schedule II or III drugs, UNH may request special destruction of the materials (i.e., incinerate or otherwise destroy). To request special destruction, the ARO will contact the DEA field office and draft a letter that includes:

1. Name, address of the facility wishing to dispose of the controlled substance
2. Name, address and DEA registration number
3. DEA Form 41 - Registrants Inventory of Drugs Surrendered, listing:
   a. Inventory of drugs to be destroyed;
   b. Name of drug with strength;
   c. Quantity of drug;
   d. Technical name of controlled substance; and
   e. Signature of DEA notification.

The ARO will submit 3 copies of DEA Form 41 to the DEA. The Special Agent in Charge will authorize and instruct the ARO on the manner to dispose of the controlled substance. For special destruction, the date of disposal and the witnesses for destruction (disposal) must be clearly stated on the DEA Form 41. A copy of the completed DEA Form 41 must be returned to the DEA. A copy of DEA Form 41 is available in Appendix E.
8. INVENTORY AND RECORDKEEPING

8.1 BIENNIAL INVENTORY

In addition to maintaining a current record of controlled substances on hand, each registrant shall conduct a new inventory of all controlled substances at least every two years. Inventories should be documented using UNH Controlled Substance Biennial Inventory Form (Appendix H). Each inventory must contain the following information:

- Date inventory was conducted;
- Time of day inventory was conducted;
- Names of controlled substances on hand;
- Quantity of each controlled substance on hand (finished form and number of dosage units); and
- Signature of inspector and registrant.

Each authorized PI is responsible for participating in the biennial inventory process. The inventory will be coordinated by the ARO. Any failure to comply with inventory update requests may result in loss of authorization status.

8.2 RECORDKEEPING

The Controlled Substances Act requires complete and accurate records to be kept of all quantities of controlled substances stored, used, and disposed of. UNH will maintain inventories and records of controlled substances listed in Schedule II separately from all other records. Inventories and records of controlled substances in Schedules III, IV, and V will be maintained separately or in such a form that they are readily retrievable from the ordinary records.

All records related to controlled substances will be maintained for a minimum of two years. Records must be readily available for inspection by the DEA, DHHS, or UNH ARO or UNH Police.

Authorized PIs and users must document all usage and disposal quantities by utilizing the UNH Controlled Substance Usage Log (Appendix D) and through UNHCEMS. Log sheets shall be numbered and kept in the locked safe or cabinet along with the controlled substances.

The following program records will also be maintained:

- Employee authorization records
- Training records
- Executed order forms
- Inventory records
- Disposition records
- Other DEA forms (e.g., reports of theft or loss, disposal, etc.).
9. NON-COMPLIANCE

Non-compliance means using controlled substances in a manner that disregards or violates requirements of the plan, and/or federal and state regulations governing controlled substances. The DEA registrant (currently the ARO) reviews all allegations of non-compliance. Any individual may submit to the ARO a written allegation of non-compliance or complaint related to use of controlled substances at UNH or conducted under the auspices of UNH. The ARO may also initiate a complaint based on information available to the ARO (e.g., deficiencies noted in files, media or scholarly reports of research activity). Non-compliance can include, but is not limited to, the following:

- Unauthorized use of controlled substances;
- Failure to undergo required background screening for handling or accessing controlled substances;
- Failure to obtain required training for the handling or accessing controlled substances;
- Failure to follow requirements for purchasing, labeling, storing, securing, reporting spillage, theft, loss, or unauthorized use, disposing, and inventory and recordkeeping as stipulated in the plan; and
- Inadequate PI supervision of authorized users.

9.1 INITIAL INQUIRY

Whenever a non-compliance allegation or complaint about the use of controlled substances is made against a PI or authorized user, the ARO will conduct an inquiry into the allegation/complaint. Depending on the nature of the allegation/complaint, the ARO may involve UNH Police in the inquiry. The ARO also will send written notice of the allegation to the subject of the allegation/complaint, and request a response. This initial communication must explicitly remind the subject of his/her obligations to maintain the integrity of any records that may subsequently be used in a formal investigation of the allegation/compliant. (Where an allegation/complaint involves theft, significant loss, or unauthorized use of controlled substances, procedures delineated in 6.5 of this plan must be followed as well.) The ARO will review the allegation/complaint, the subject’s response, and any other information necessary to determine whether a full investigation is warranted. At the conclusion of the inquiry, the ARO will report findings to the Senior Vice Provost for Research and the Department Chair (or subject’s supervisor). Findings will address:

- Substance of the allegation or complaint;
- Whether any individuals were put at risk, and/or the need for immediate action to protect individuals’ welfare;
- Whether requirements of the plan were violated;
- Where the allegation or complaint appears founded, whether a formal investigation is warranted; and
- Recommendations, if any, for corrective action.

Recommendations for sanctions, correction, or educational measures will be established by the Senior Vice Provost for Research in consultation with the ARO and UNH Police. The Senior Vice Provost
for Research will also determine whether to refer the matter to another more appropriate process or authority within UNH for resolution (e.g., inquiry/investigation through the UNH Policy on Misconduct in Scholarly Activity), or for formal investigation.

In cases where non-compliance involves use of controlled substances without authorization (i.e., subject is not a PI or an authorized user, according to the plan), the ARO will review a written statement from the subject explaining the reasons why authorization was not sought, and, where applicable, a description of the use of the controlled substance(s). (Where an allegation/complaint involves theft, significant loss, or unauthorized use of controlled substances, procedures delineated in 6.5 of this plan must be followed as well.) The ARO will then make written recommendations to the Senior Vice Provost for Research and Department Chair (or subject’s supervisor) as to the appropriate course of action based on a variety of factors, including whether individuals were put at risk, the need for immediate action to protect individuals’ welfare, and the degree to which requirements of the plan were violated. The Senior Vice Provost for Research shall be the final authority as to the course of action taken by UNH on the matter.

In consultation with the Senior Vice Provost for Research, the ARO will notify the subject of the complaint in writing of the inquiry outcome, including a statement of the reasons for the decision. Depending on the nature of the allegations and the extent of the review required, the inquiry phase is generally completed within thirty working days of receipt of the allegation of non-compliance or complaint. The ARO may extend this time frame if warranted.

9.2  FORMAL INVESTIGATION AND DECISION

For allegations of non-compliance or complaints against a PI or authorized user (as defined in the plan), the Senior Vice Provost for Research, in consultation with the ARO and, if warranted, UNH Police, may decide to conduct a formal investigation when s/he determines that an allegation/complaint appears founded. The investigation normally is conducted by an ad hoc panel consisting of the ARO, the Director of the Office of Environmental Health and Safety (or her/his designee), a UNH Police Department representative, and the Department Chair (or subject’s supervisor). The panel may use any and all materials and reports gathered during the initial inquiry phase, may obtain documents and other records relevant to the investigation, and may interview any persons who may have relevant information. The individual under investigation will be given an opportunity to submit written comments and to appear before the panel on at least one occasion prior to the panel issuing its report. The panel should strive to gather and consider available evidence in a manner that does not incriminate, or cast suspicion on the subject of the allegation/complaint. It should be recognized that damage to the reputation of the subject of an allegation/complaint might result from soliciting information from his/her peers and colleagues, even if complete confidentiality is requested. Thus, the panel should exercise circumspection in conducting its business. Based on its investigation, the panel prepares a report summarizing the information considered and outlining its conclusions and recommended actions. The panel sends the report to the Senior Vice Provost for Research. The investigation phase is expected to be completed within 60 working days, but this may vary depending on the case.

In reaching a decision, the Senior Vice Provost for Research will consider the panel’s report and any comments submitted by the subject of the allegation/complaint. Actions the Senior Vice Provost for Research may take include, but are not limited to, the following:

- Dismissal of the allegation/complaint as unjustified;
- Monitoring of the subject’s future activities that involve controlled substances;
• Restrictions on the subject’s use of controlled substances, such as limiting the type of substance used to a lower schedule;
• Suspension of approval for use of one or more types of controlled substances;
• Termination of approval for one or more types of controlled substances, or
• Referral to other UNH administrators/committees for possible further review and action.

The Senior Vice Provost for Research sends a copy of her/his decision to the subject, the ARO, UNH Police, and the Department Chair (or subject’s supervisor). Where an allegation/complaint involves theft, significant loss, or unauthorized use of controlled substances, additional reporting procedures delineated in 6.5 of this plan must be followed as well. The Senior Vice Provost for Research decides upon and administers any sanctions warranted for non-compliance.

9.3 ACTION PRIOR TO DECISION

At any time during the inquiry or investigation processes, the ARO or UNH Police may determine that it is necessary to suspend the subject’s use of controlled substances. Except in cases of imminent harm to individuals, the ARO or UNH Police will not suspend approval of use of controlled substances until the subject has had an opportunity to respond satisfactorily to the initial allegation/complaint. Notice of suspension or termination is provided. (See 9.8.)

9.4 COORDINATION WITH OTHER INVESTIGATIVE PROCESSES

Some complicated cases require review by other institutional or external authorities. The ARO and/or UNH Police cooperates in the review of allegations of misconduct in scholarly activity, IBC investigations, IACUC investigations, etc. In cases that appear to involve academic misconduct, the ARO may report allegations of such misconduct to the appropriate UNH administrator(s). Where academic misconduct and controlled substances investigations are pending against the same subject, the ARO will coordinate controlled substances activities closely with others to avoid duplication of effort and to minimize competing use of resources.

9.5 CONFIDENTIALITY

All individuals involved in an inquiry and/or investigation of an allegation of non-compliance or complaint must maintain confidentiality of information received during the process. It should be recognized that damage to the reputation of the subject of an allegation/complaint might result from such procedures.

9.6 RETALIATION

The Senior Vice Provost for Research will assist the ARO and/or UNH Police in protecting complainants from retaliatory actions.

9.7 REPORTING THEFT, SIGNIFICANT LOSS, OR UNAUTHORIZED USE

The ARO is required to report theft, significant loss, or unauthorized use of controlled substances according to the procedures delineated in 6.5 of this plan.

9.8 SUSPENSION AND TERMINATION
Repeated or willful violations of federal and/or state laws and the plan regarding use of controlled substances are an extremely serious matter. In such circumstances, the ARO has the authority to suspend or terminate approval of use of controlled substances, or to refuse to authorize further controlled substance use by an individual.

If the ARO determines that an individual has deliberately or continuously violated the requirements of the plan, U.S. Drug and Enforcement Administration (DEA) requirements at Title 21, Part 1300-1308 of the Code of Federal Regulations (C.F.R.), or New Hampshire Department of Health and Human Services (DHHS), Title XXX, Occupations and Professions, RSA 318-B, Controlled Drug Act, the ARO will report the matter promptly to the Senior Vice Provost for Research, with or without a recommendation for specific action. The Senior Vice Provost for Research may then determine appropriate sanctions.

The ARO may temporarily or permanently suspend approval for use of controlled substances at any time. This suspension may not be overridden by the Senior Vice Provost for Research or at any level at UNH. The ARO must report a suspension of approval for use of controlled substances promptly in writing to the Senior Vice Provost for Research, along with the reasons for the suspension.

When the ARO suspends or terminates approval of use of controlled substances for any reason, the following, in addition to the PI or authorized user, are notified in writing within five working days of such suspension or termination:

- Senior Vice Provost for Research,
- PI’s/Authorized User’s Department Chair or Supervisor,
- PI’s/Authorized User’s Dean, Director, or Principal/Academic Administrator,
- Graduate School Dean (if appropriate),
- IBC Chair and/or IACUC Chair, (if appropriate),
- Collaborating PIs (if appropriate),
- DEA (if appropriate), and
- Funding agency (if appropriate).
APPENDIX A:  UNH DEA CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
APPENDIX B:  UNH EMPLOYEE AUTHORIZATION FOR CONTROLLED SUBSTANCES RESEARCH
APPENDIX C: UNH CONTROLLED SUBSTANCES PURCHASE REQUEST FORM
APPENDIX D: UNH CONTROLLED SUBSTANCES USAGE LOG
DEA Forms

DEA Form 224 – New Application for Registration

Paper form may be obtained by writing to:
Drug Enforcement Administration
Attn: ODR
PO Box 2639
Springfield, VA 22152-2639

DEA Form 224a – Renewal Application for DEA Registration
http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms.htm>

DEA Form 222 – U.S. Official Order Forms
<https://www.deadiversion.usdoj.gov/webforms/orderFormsRequest.jsp>

DEA Form 106 – Report of Theft or Loss of Controlled Substances
https://www.deadiversion.usdoj.gov/webforms/dtlLogin.jsp

DEA Form 41 – Registrants Inventory of Drugs Surrendered
http://www.deadiversion.usdoj.gov/21cfr_reports/surrend/index.html>
APPENDIX F: LIST OF AUTHORIZED PIS AND AUTHORIZED USERS/HANDLERS
APPENDIX G: UNH CONTROLLED SUBSTANCES INVENTORY

[Note: The most recent version of the inventory is available through UNHCEMS. A copy (as dated) is provided as an appendix for user convenience.]
APPENDIX H:  UNH CONTROLLED SUBSTANCES BIENNIAL INVENTORY FORM
APPENDIX I: CONTROLLED SUBSTANCES TRAINING LOG
## Controlled Substances Training Log Form

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Instructor – Print Name:

Instructor – Signature:

*Attach training agenda and/or copy of materials to this form for records retention.*
APPENDIX J: CONTROLLED SUBSTANCES – DEA RESOURCES
Controlled Substances – DEA Resources

DEA Controlled Substance Schedules I – V:
<http://www.deadiversion.usdoj.gov/schedules/schedules.htm>

Lists of Scheduling Actions, Controlled Substances and Regulated Chemicals May 2009:

DEA Practitioner’s Manual


Security Outline of the Controlled Substances Act


Conversion factors for controlled substances:

HTML version: <http://www.deadiversion.usdoj.gov/quotas/conv_factor/index.html>
APPENDIX K: CONTROLLED SUBSTANCES – POWER OF ATTORNEY
Power of Attorney for DEA Forms 222 and Electronic Orders

Name of registrant: Address of registrant:

DEA registration number:

I, ____________ (name of person granting power), the undersigned, who am authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act or Controlled Substances Import and Export Act, have made, constituted, and appointed, and by these presents, do make, constitute, and appoint ___________ (name of attorney-in-fact), my true and lawful attorney for me in my name, place, and stead, to execute applications for Forms 222 and to sign orders for Schedule II controlled substances, whether these orders be on Form 222 or electronic, in accordance with 21 U.S.C. 828 and Part 1305 of Title 21 of the Code of Federal Regulations. I hereby ratify and confirm all that said attorney must lawfully do or cause to be done by virtue hereof.

Signature of person granting power:

I, ____________ (name of attorney-in-fact), hereby affirm that I am the person named herein as attorney-in-fact and that the signature affixed hereto is my signature.

Signature of attorney-in-fact:

Witnesses:
1.
2.

Signed and dated on the ____ day of ____, (year), at ____ .

Notice of Revocation

The foregoing power of attorney is hereby revoked by the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act or the Controlled Substances Import and Export Act. Written notice of this revocation has been given to the attorney-in-fact ____ this same day.

Signature of person revoking power:

Witnesses:
1.
2.

Signed and dated on the ____ day of ____, (year), at ____ .

Notes:

- A power of attorney must be executed by the person who signed the most recent application for DEA registration or reregistration; the person to whom the power of attorney is being granted; and two witnesses.
- A power of attorney must be revoked by the person who signed the most recent application for DEA registration or reregistration, and two witnesses.