

Policy for the Use of Controlled Substances in Laboratory and Animal Research

Introduction and Purpose

Certain drugs and chemical precursors fall under the jurisdiction of the Missouri Bureau of Narcotics and Dangerous Drugs (BNDD) and the US Department of Justice (DOJ) Drug Enforcement Administration (DEA). These drugs and chemicals are known as Controlled Substances and must be purchased, maintained, used and disposed in accordance with extensive federal and state regulations. It is the policy of Washington University in St. Louis to comply with all federal and state laws and regulations pertaining to the use of Controlled Substances. This policy provides an overview of responsibilities that must be met when using Controlled Substances in laboratory and animal research. For detailed procedures regarding these responsibilities, see [Procedures for the Use of Controlled Substances in Laboratory Animal Research](#) for the Danforth Campus and Medical School.

Scope

This policy applies to all Washington University in St. Louis investigators who use Controlled Substances in laboratory and/or animal research. This policy applies to all materials listed on Schedules I-V, as described in 21 CFR § 1300.01 and 19 CSR 30-1. The DEA has a [complete list of Controlled Substances](#). **This policy does not apply to the use of Controlled Substances in clinical patient care or clinical human subjects research.**

Certain portions of this policy apply to WUSTL investigators who obtain Controlled Substances from a Division of Comparative Medicine (DCM) or Danforth Animal Facility (DAF) stockroom, for use in Institutional Animal Care and Use Committee (IACUC) approved animal research. Both Washington University campuses, Danforth and Medical School, maintain federal (DEA) and state (MO-BNDD) registrations to obtain controlled substances on behalf of all investigators using controlled substances for the purpose of IACUC-approved animal research projects.

Certain portions of this policy apply to Washington University in St. Louis investigators who obtain Controlled Substances directly from an outside commercial vendor or governmental agency, for use in laboratory research not involving animals, or for approved animal research where investigators purchase Controlled Substances directly from commercial vendors or receive them from governmental agencies.

Applicable Regulations

[Missouri Department of Health and Human Services, 19 CSR 30-Chapter 1](#)
[U.S. Drug Enforcement Agency, Title 21 CFR Section 1300](#)

Responsibilities

Principal Investigator (PI)

PIs conducting laboratory or animal research with Controlled Substances are responsible for:

1. Completing the appropriate training: IACUC Animal Use Regulations training module and/or Environmental Health & Safety (EH&S) Laboratory Safety Training;
2. Ensuring all employees proposed to have access to Controlled Substances successfully pass a DEA NADDIS and National Crime Information Center (NCIC) background check before having access to Controlled Substances;
3. Providing appropriate security and storage of all Controlled Substances;
4. Restricting access to Controlled Substances to only lab staff needing such access and maintaining an accurate list of approved controlled substances users. This list is to be kept with the Controlled Substances paperwork and must be accessible to inspectors at all times;
5. Meeting all inventory requirements (to be maintained and accessible to inspectors at all times in accordance with the [forms matrix](#));
6. Properly disposing or returning any unwanted or expired Controlled Substances; and
7. Notifying the Institutional Animal Care and Use Committee (IACUC) (for use in animal research) or EH&S (for all other uses) of the location of the Controlled Substances use and storage location changes.

PIs who obtain Controlled Substances directly from an outside commercial vendor or governmental agency using his or her individual registration have the following additional responsibilities:

1. Obtaining and maintaining as current, Controlled Substances Researcher Registrations from both the BNDD and DEA prior to obtaining any Controlled Substances; and
2. Providing copies of current BNDD and DEA Controlled Substances Researcher Registrations to EH&S prior to obtaining any Controlled Substances.

Lab Staff Responsibilities – as delegated by the PI

Staff conducting laboratory or animal research with Controlled Substances are responsible for:

1. Submitting and successfully passing of DEA NADDIS and National Crime Information Center (NCIC) background checks before having access to Controlled Substances;
2. Ensuring appropriate security and storage of all Controlled Substances;
3. Helping to maintain an accurate list of approved controlled substances users for each protocol. This list is to be kept with the Controlled Substances paperwork and must be accessible to inspectors at all times;

4. Limiting access to Controlled Substances to only approved users;
5. Meeting all inventory requirements (to be maintained and accessible to inspectors at all times in accordance with the [forms matrix](#)); and
6. Properly disposing or returning any unwanted or expired Controlled Substances.

Environmental Health & Safety (EH&S)

EH&S is responsible for performing annual inspections of all PI use locations (regardless of whether PIs obtain Controlled Substances from DCM, DAF, or from outside vendors under their own registration) to ensure that all security and record keeping requirements are met as appropriate. EH&S will maintain a central database of DEA and BNDD researcher registration numbers for PIs with individual registrations. EH&S will assist PIs in locating registered reverse distributors for disposal of Controlled Substances.

Institutional Animal Care and Use Committee (IACUC)

The IACUC is responsible for reviewing and approving all proposed uses of Controlled Substances in animal research. The IACUC will verify that personnel listed with access to controlled substances have successfully completed the appropriate training and background checks. The IACUC or its designees are also responsible for inspecting all animal use locations on a semi-annual basis. During these inspections, the IACUC will verify that use of Controlled Substances is consistent with the approved IACUC protocol and that no Controlled Substances used in animal research are expired.

Quality Assurance / Quality Improvement (QA/QI) Program

Compliance oversight of the animal care and use program at WUSTL is a function of the IACUC, with delegated authority for laboratory inspections to the QA/QI staff. As part of the inspection process, the QA/QI staff is responsible for the following as it relates to Controlled Substance use:

1. Educating the PIs/staff on the responsibilities that must be met when using Controlled Substances in animal research;
2. Verifying Controlled Substances in use are consistent with IACUC approved protocol(s);
3. Verifying that no Controlled Substances are expired;
4. Ensuring proper security of Controlled Substances; and
5. Reviewing all records pertaining to acquisition, use and final disposition of Controlled Substances for completeness.

Division of Comparative Medicine (DCM)

DCM only handles the acquisition and disposal of Controlled Substances obtained through the Washington University Medical School registration. DCM is responsible for purchasing Controlled Substances for use at the Medical School campus in Institutional Animal Care and Use Committee (IACUC) approved protocols. DCM will provide secure storage and record keeping at the stockroom location on the Medical School campus and will document all

movement of Controlled Substances from the stockroom to approved PI use locations. For Controlled Substances obtained through the Washington University Medical School registration, DCM will properly dispose of expired or unwanted Controlled Substances returned to the stockroom. DCM will also coordinate the required annual physical inventory verification for areas where DCM materials are in use.

Danforth Animal Facility (DAF)

DAF only handles the acquisition and disposal of Controlled Substances obtained through the Washington University Danforth Campus registration. DAF is responsible for purchasing Controlled Substances for use at the Danforth campus in Institutional Animal Care and Use Committee (IACUC) approved protocols. DAF will provide secure storage and record keeping at the stockroom location on the Danforth campus and will document all movement of Controlled Substances from the stockroom to approved PI use locations. For Controlled Substances obtained through the Washington University Danforth Campus registration, DAF will properly dispose of any expired or unwanted Controlled Substances returned to the stockroom. DAF will coordinate the required annual physical inventory verification for areas where DAF materials are in use.

Human Resources (HR)

HR is responsible for performing the DEA NADDIS and NCIC background checks on all employees who will need access to Controlled Substances and ensuring that these checks meet DEA and BNDD requirements.

Sanctions

Failure to comply with this policy, including deficiencies on IACUC or EH&S laboratory inspections, may result in university sanctions. For detailed sanctions see the [Procedures for the Use of Controlled Substances in Laboratory Animal Research](#) for the Danforth Campus and Medical School. Failure to comply with federal and state laws and regulations may also result in DEA or BNDD sanctions.

Approval

Approved July 8, 2010 by the Executive Committee on Research

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