MANAGEMENT OF DRUGS IN LABORATORY AND ANIMAL-BASED RESEARCH PROCEDURES 2024

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1 Purpose and application

(1) These procedures provide for best practice management of drugs used in laboratory and animal-based research.

(2) These procedures apply to handling drugs in laboratory and animal based research at, or on behalf of, the University for:

(a) all staff, affiliates and students; and

(b) veterinary practitioners that are administering scheduled drugs in accordance with a research project design.

(3) These procedures do not apply to:

(a) the provision of veterinary care; or

(b) laboratory or animal facilities which are:

(i) operated by entities other than the University; and

(ii) not located on University lands.

2 Commencement

These procedures commence on 10 April 2024.

3 Interpretation

(1) Definitions in these procedures may differ from definitions of the same terms in other documents.

(2) In this document:

authorised user	means a person working with scheduled drugs under the supervision of the relevant responsible drugs overseer.
authority holder	means a person authorised by the Director General of NSW Health to possess and use a Schedule 8 or 9 drug listed in an authorisation letter.

Dean	includes, as appropriate: • a Dean of a faculty; • an Executive Dean of a faculty; • a Head of School and Dean of a University school.
drug	means any substance that is used in laboratory or animal-based research at, or on behalf of, the University and is: • included in a Schedule of the Poisons Standard; or • required by the University to be managed under these procedures.
drug register manager	means an authorised user appointed by the responsible drugs overseer to be responsible for drug register upkeep.
end-user declaration	means the declaration required by a supplier to acknowledge receipt of drugs.
faculty	includes, as appropriate, a faculty or a University school.
high risk approver	means, as appropriate, any of: • Head of School; • Head of School and Dean within a faculty; • any other position recorded as a high risk approver in MyLab.
high risk drug	means: • a Schedule 4D, Schedule 8 or Schedule 9 drug; or • any other substance required by the University to be managed as a high risk drug under these procedures.
High Risk Drug Databank	means the University's online system for recording and managing details of high risk drugs. **Note:** See clause 7
loss	includes any method by which drugs are removed or depleted, other than use by an authorised user. This includes: • misplacement • theft • spillage • breakage
MyLab	means the University's online system for obtaining and managing hazardous materials used in research and education. These materials include chemicals, gases, drugs and radioactive and biological materials.
MyLab hub	means a delivery dock managed by MyLab.

Poisons Standard	means: • the Therapeutic Goods (Poisons Standard – February 2024) Instrument 2024; or • any replacement for that instrument. **Note:** This instrument is updated several times each year.
responsible drugs overseer	means a scientifically qualified University staff member responsible for a research project or research group. This person manages and assumes overall responsibility for the scheduled drugs they hold. This may include being an authority holder for Schedule 8 or 9 drugs.
RiskWare	means the University's software application for the recording and management of incidents and hazards.
Schedule # drug	means a drug, or a substance containing a drug, listed in the relevant numbered schedule to the Poisons Standard, except when referring to a Schedule 4D drug.
Schedule 4D drug	means a drug, or a substance containing a drug, listed in Appendix D Prescribed restricted substances, of the *Poisons and Therapeutic Goods Regulation 2008* (NSW) or replacement.
veterinary care	means providing: • advice on research design; or • advice on husbandry or management; or • clinical, surgical, procedural, diagnostic, prophylactic and therapeutic care; for animals involved in research. It includes administering drugs consistently with professional registration responsibilities, where the veterinarian is: • providing care that is not included in the research design; and responding to unexpected health care needs.

4 Governance framework

(1) Every person using or handling chemicals, including drugs, must familiarise themselves with the legislative, regulatory and University requirements which apply to those substances.

(2) The *Poisons and Therapeutic Goods Act 1966* (NSW) and the *Poisons and Therapeutic Goods Regulation 2008* regulate medicines, drugs and poisons in New South Wales.

(a) These instruments provide that only appropriately qualified and authorised people may distribute, prescribe or administer specified substances.

(3) The Poisons Standard, also referred to as the *Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP),* is a Commonwealth legislative instrument which:

(a) classifies medicines and poisons into schedules, which are incorporated by reference into the *Poisons and Therapeutic Goods Act 1966 (NSW);*

(b) contains model provisions about containers and labels;

(c) lists products and substances recommended to be exempt from the standard; and

(d) makes recommendations for controls on drugs and poisons.

5 Scheduled drugs generally

(1) Staff, students and affiliates must comply with the applicable poisons and therapeutic goods legislation, including the *Poisons and Therapeutic Goods Act 1966* (NSW) and *Poisons and Therapeutic Goods Regulation 2008* (NSW).

Note: For further information about Schedules see *NSW Health Legislation* website.

(2) Staff, students and affiliates must follow safe handling procedures as specified in any applicable manufacturer's instructions, safety data sheet or documented safe work procedure.

(3) The responsible drugs overseer, or an authorised user under their direct supervision, may possess and use any Schedule 2, 3, 4 or 4D drug for:

(a) medical or scientific research;

(b) instruction;

(c) quality control; or

(d) analysis.

(4) The responsible drugs overseer, or an authorised user under their direct supervision, may possess and use any Schedule 5 or 6 drug for research and instruction purposes.

Note: Schedule 6 drugs will require a relevant Risk Assessment. For further information see High risk chemicals on the *Chemical Safety* intranet page.

(5) The responsible drugs overseer is responsible for:

(a) complying with all applicable legislative, regulatory and University requirements. This includes requirements for security, storage and record keeping; and

(b) training and supervising authorised users.

(6) An authority holder, or an authorised user under their direct supervision, may possess and use any Schedule 8 or 9 drug:

(a) with the prior authorisation of the Director General of NSW Health; and

Note: Schedule 8 and 9 authorisations are specific to the individual recipient and drug and cannot be transferred.

(b) for:

(i) research;

(ii) instruction; or

(iii) analysis.

(7) The holder of a Schedule 8 or 9 authorisation is responsible for:

(a) complying with all applicable legislative and regulatory requirements. This includes requirements for security, storage, and record keeping;

(b) submitting a list of authorised users to the Director General of NSW Health, and keeping the list up to date by email;

(c) establishing and maintaining records of training delivered and who has completed it; and

(d) recording details of their authorisation, and of associated authorised users, in the High Risk Drug Databank; and

(e) keeping details in the High Risk Drug Databank up to date.

Note: For further information on how to apply for a Schedule 8 or 9 authority and the process for updating authorised user lists, refer to the *Applying for a NSW Authority to Possess or Supply Schedule 8 or 9 substances* guide.

(8) Schedule 10 substances must not be obtained without prior consultation and approval from:

(a) the relevant officer in the University's Health and Safety unit; and

(b) the relevant high risk approver.

(9) Where drugs subject to these procedures require an import or export licence and/or permit under the *Customs (Prohibited Imports) Regulations 1956* and *Customs (Prohibited Exports) Regulations 1958*, researchers must obtain the prior written approval of the Director, Research Integrity and Ethics Administration before applying for and obtaining the relevant licence and/or permit and importing or exporting the drugs.

Note: To check if a drug needs an import or export licence refer to the list of controlled substances published by The Office of Drug Control.

6 High risk drugs

(1) Any person who uses high risk drugs must complete the relevant online training module.

(2) Before using any high risk drug the responsible drugs overseer must:

(a) prepare and record:

(i) the relevant risk assessment; and

(ii) a safe work procedure for managing and handling the drug; and

(b) consult with their Health and Safety partner to review these documents.

Note: Further information is available on the *Chemical Safety* and *Risk Management* intranet pages. A safe work procedure template for a Schedule 8 drug is available on the *Scheduled Drugs Management* intranet page.

7 High Risk Drug Databank

(1) The responsible drugs overseer must create and maintain a record in the High Risk Drug Databank for any high risk drug they hold.

(2) Each entry must include, as appropriate:

(a) a copy of the relevant authority letter from NSW Health;

(b) a copy of the current risk assessment;

(c) a copy of the current safe work procedure;

(d) the identity of the relevant drug register manager;

(e) the identities of all currently authorised users;

(f) the drugs and amounts each authorised user may possess;

(g) the authority start and end dates;

(h) applicable ethics protocol numbers and expiry dates; and

(i) current contact information for the responsible drugs overseer and the drug register manager.

(3) Each authority obtained from NSW Health must have a separate entry.

8 Obtaining drugs

(1) Subject to subclause 8(7), all drugs must be obtained using MyLab.

(2) Only an authority holder or an authorised user listed on an authority from NSW Health may obtain Schedule 8 or Schedule 9 drugs.

(3) Orders for Schedule 8 and Schedule 4D drugs must be approved by the relevant high risk approver.

(4) Orders for Schedule 9 drugs must be approved by both the relevant officer in the University's Health and Safety unit and the relevant high risk approver.

(5) Orders for Schedule 4D, Schedule 8 and Schedule 9 drugs must provide a link to the relevant record in the High Risk Drug Databank.

(6) Drugs may only be received through, or by, a MyLab hub.

(a) If a supplier will not deliver to a MyLab hub, the "hub bypass" request process in MyLab must be used to arrange delivery.

(b) All drug orders must be collected or received within five business days of delivery.

(c) Only the responsible drugs overseer or authorised users recorded in the relevant High Risk Drug Databank may collect or receive an order for Schedule 4D, Schedule 8 or Schedule 9 drugs.

(d) Any person receiving an order of Schedule 8 or Schedule 9 drugs must complete and sign the end-user declaration at the time of receipt.

(7) Any drug (including samples or collaborative aliquots) not obtained through MyLab must be recorded in the MyLab inventory within two business days of receipt.

(a) Zero cost high risk items must be pre-approved in MyLab by both the relevant officer in the University's Health and Safety Unit, and the relevant high risk approver.

Note: For instructions on how to buy scheduled drugs, refer to the guides for ordering scheduled drugs or requesting approval for zero cost drugs.

9 Storing drugs

(1) Any person authorised to possess drugs is responsible for:

(a) understanding the legislative, regulatory and University requirements for their storage; and

(b) storing them consistently with these requirements.

(2) All drugs must be stored consistently with the manufacturer's instructions, including instructions about temperature control and expiry dates.

(3) Except as provided in subclause 9(4), high risk drugs, including refrigerable items, must be stored securely in a separate room or container. This must be:

(a) physically attached to the structure of the premises;

(b) kept securely locked when not in use;

(c) only used to store drugs and no other goods except for related documents;

(d) accessed only by authorised users using a key or code which is safely stored; and

(e) within a secure laboratory or animal facility.

Note: For room temperature drugs the recommended storage method is a safe attached to the premises.

(4) Schedule 4D drugs may be stored in a manner inconsistent with subclause 9(3) with the prior written approval of the Director, Research Integrity and Ethics Administration.

(5) All other drugs must be stored in a locked area to which access is restricted, such as a secure laboratory or animal facility. The storage area must minimise visibility and access for other staff and students.

Note: For further information, refer to the *Storage of scheduled drugs* guide.

10 Transporting drugs

(1) Only the holder of the authorisation, the responsible drugs overseer or an authorised user may transport, or arrange transport, of drugs.

(2) All drugs must be transported securely and safely.

(3) The primary container must be sealed and packed inside a secondary container that is suitable to contain spills or breakages.

(4) The secondary container should be sealed. It should not indicate that it contains drugs.

(5) Where required, the containers must have an appropriate temperature management system.

Note: For further information, see the *Safety Health and Wellbeing Chemical Safety Standards 2020* and the *Transport of scheduled drugs* guide.

11 Disposing of drugs

(1) All drugs must be destroyed or disposed of safely once they are no longer required.

(2) Expired drugs:

(a) must not be used on animals; and

(b) should be destroyed as soon as practicable after the expiry date.

(3) For Schedule 8 or 9 drugs, the relevant authority holder or an authorised user must arrange for the drugs to be destroyed in the presence of a police officer, unless expressly exempted from this requirement by the Director General of NSW Health.

(4) For Schedule 4D, 8 or 9 drugs, destruction must:

(a) be co-ordinated through the Research Integrity and Ethics Administration team; or

(b) follow a documented process approved by the Director, Research Integrity and Ethics Administration and organised by:

(i) a responsible drugs overseer; or

(ii) a disposal service approved by the Director, Research Integrity and Ethics Administration.

(5) For Schedule 2, 3 or 4 drugs, the responsible drugs overseer or an authorised user must arrange for destruction through the University of Sydney Hazardous Waste program.

Note: For further information, see the *Disposal and destruction process for scheduled drugs* guide.

12 Record keeping, including drug registers

(1) All drug holdings must be recorded in an appropriate and permanent manner.

(2) Individuals responsible for any drug holdings must be able to account for all usage and able to produce appropriate evidence.

(3) A person authorised to possess high risk drugs must maintain a drug register which records all usage of that drug.

(4) Drug registers must be kept manually, in hard copy format. They must have:

(a) clear identification of the responsible person;

(b) pages that cannot be removed or replaced (i.e. bound book);

(c) pages that are consecutively numbered; and

(d) a separate page for each formulation (e.g. liquid, solid) and each concentration including dilutions.

Note: Drug registers, in large and small versions, may be purchased from a MyLab hub.

(5) A separate drug register must be kept at each place a high risk drug is stored.

(6) Drug registers must be retained for at least two years after the date of the last entry.

(7) Any person who receives, removes or uses a high risk drug must record this in the drug register.

(a) All entries must:

(i) be made on the day of the event;

(ii) state the date;

(iii) be written in permanent ink in English;

(iv) be legible, complete and accurate; and

(v) include the name and signature of the person making the entry.

(b) Entries for drugs received must also record:

(i) the date of receipt;

(ii) the quantity received;

(iii) the name and address of the supplier or manufacturer; and

(iv) the remaining total balance of the drug holding.

(c) Entries for drugs used or removed must also record:

(i) the quantity used or removed;

(ii) the purpose for which it was used or removed, including animal details and ethics protocol numbers where appropriate; and

(iii) the remaining total balance of the drug holding.

Note: If there is a discrepancy in the remaining balance, follow the inventory discrepancy reporting process outlined in the *Record keeping in drug registers for scheduled drug use in animal and laboratory research* guide. See also clause 14.

(8) Any person who observes that a drug register has been lost or destroyed must:

(a) inform each of the following as soon as possible:

(i) the Director, Pharmaceutical Regulatory Unit at NSW Health;

Note: Emails should be sent to MOH-PharmaceuticalServices@health.nsw.gov.au with attention to the Director Pharmaceutical Regulatory Unit.

(ii) if within a faculty, the relevant Head of School and the relevant Dean;

(iii) the Director, Research Integrity and Ethics Administration; and

(b) record the event in RiskWare within 24 hours.

(9) The person responsible for a lost or destroyed drug register must immediately:

(a) buy a new register; and

(b) undertake a complete inventory of all relevant drugs.

Note: For further information, see the *Record keeping in drug registers for scheduled drug use in animal and laboratory research* guide.

13 Inventory control

(1) The authorised holder or the drug register manager must complete a full inventory of all high risk drugs for which they are responsible in March and September each year.

(2) An inventory must:

(a) accurately record the balance of all drugs held at the date of the inventory; and

(b) be completed directly below the last entry for each drug form and concentration, including dilutions.

Note: If there is a discrepancy in the remaining balance, follow the inventory discrepancy reporting process outlined in the *Record keeping in drug registers for scheduled drug use in animal and laboratory research* guide. See also clause 14.

(3) When responsibility for managing a high risk drug register is reallocated for a period of one month or longer, a full inventory should be completed.

(4) Either of the Research Integrity and Ethics Administration or Health and Safety units may require review of high risk drug holdings at any time. Such a review:

(a) will be undertaken jointly by the requiring unit and the authorised holder or drug register manager; and

(b) may involve either or both of personal inspection or a self-review survey of authority holders, responsible drugs overseers and authorised users.

(5) All responsible drugs overseers must participate in reviews if requested.

Note: For further information, refer to the *Record keeping in drug registers for scheduled drug use in animal and laboratory research* guide.

14 Drug loss or theft

(1) For high risk drugs, the responsible drugs overseer or relevant drug register manager must immediately:

(a) report any loss or theft of a high risk drug in writing to:

(i) if within a faculty, the relevant Head of School and relevant Dean;

(ii) the Director, Research Integrity and Ethics Administration; and

(iii) NSW Health;

and

(b) record the event within 24 hours in each of:

(i) the relevant drug register; and

(ii) RiskWare.

(2) Any drug loss suspected to be due to theft must also be reported to the Office of General Counsel.

(3) For all other drugs, the responsible drugs overseer must:

(a) immediately report any theft or misplacement in writing to:

(i) if within a faculty, the relevant Head of School and relevant Dean; and

(ii) the Director, Research Integrity and Ethics Administration;

(b) record in Riskware within 24 hours:

(i) any theft or misplacement;

(ii) any loss due to breakage or spills; and

(iii) any actual or potential adverse events.

Note: For further information see the *Reporting loss or theft of scheduled drugs* guide.

NOTES

Management of Drugs in Laboratory and Animal-Based Research Procedures 2024

Date adopted:	10 April 2024
Document owner:	Pro Vice-Chancellor (Research)
Review date:	10 April 2027
Related documents:	
	Customs (Prohibited Exports) Regulations 1958
	Customs (Prohibited Imports) Regulations 1956
	Poisons and Therapeutic Goods Act 1966 (NSW)
	Poisons and Therapeutic Goods Regulations 2008 (NSW)
	Therapeutic Goods (Poisons Standard - February 2024) Instrument 2024
	Recordkeeping Policy 2017
	Work Health and Safety Policy 2016

AMENDMENT HISTORY

Provision	Amendment	Commencing