Scheduled Drugs and Poisons Management Procedure

Section 1 - Purpose and Context

(1) This document sets out the University's procedural requirements for the management of Scheduled Drugs and Poisons (substances) which are used at the University for research and teaching activities and are regulated in a manner consistent with legislative requirements in order to eliminate or control potential health, safety and security risks.

(2) The Poisons and Therapeutic Goods Act 1966 (NSW) and Poisons and Therapeutic Goods Regulation 2008 (NSW) (the Regulation) provide for the establishment of a Poisons List, which groups drugs and poisons into 'Schedules', according to the restrictions to be placed on their supply in order to protect public health and safety.

(3) The Poisons List, as determined by the NSW Ministry of Health, consists of eight Schedules which align closely with the Standard for the Uniform Scheduling of Medicines and Poisons.

Scope

(4) This procedure applies to all University research and teaching activities that involve the use of Scheduled drugs and poisons as designated in the Poisons List by the NSW Ministry of Health. For more information refer to the:

a. NSW Health Pharmaceuticals Services publication: Poisons List 2013 (alphabetical including NSW variations)
b. NSW Health Pharmaceuticals Services publication: Schedule 4 Appendix D Drugs (Prescribed Restricted Substances)
c. NSW Health Pharmaceuticals Services publication: Schedule 8 Drugs (Drugs of Addiction).

(5) This procedure details required practice in relation to the regulation of Scheduled drugs and poisons including: authorisation to possess and use; storage; use and disposal; record-keeping; security and reporting; and information, training and supervision.

Section 2 - Definitions

(6) For the purpose of this procedure, the following definitions and acronyms apply unless otherwise stated:

a. authorised personnel - refers to the person who has written authority from Pharmaceutical Services of NSW Ministry of Health to possess and use Schedule 8 drugs of addiction for the purpose of research, analysis or instruction at the University.
b. competent person - is defined in Work Health and Safety Regulation 2017 as:

> "a person who has acquired through training, qualification or experience the knowledge and skills to carry out that task."

a. approved personnel - refers to the person who has authority from the Dean of School or Director, Research

Institute to manage the possession, use, storage and disposal of Schedule 2, 3, 4 and/or 7 substances on behalf of the School or Research Institute.

b. Schedule 4 (S4) - refers to prescribed restricted substances as per the schedule maintained by Pharmaceutical Services (PS). The PS web site must be consulted for the current list of scheduled drugs.
c. Schedule 8 (S8) - refers to drugs of addiction as per the schedule maintained by PS. The PS web site must be consulted for the current list of scheduled drugs.
d. Poison - refers to any substance specified in Schedule 1 (S1), Schedule 2 (S2), Schedule 3(S3), Schedule 5 (S5), Schedule 6 (S6), or Schedule 7 (S7) of the Poisons List.
e. A scientifically qualified person is defined in the Regulation as:
    i. a medical practitioner, dentist, veterinary practitioner or pharmacist, or
    ii. a person who holds a degree or diploma approved for the time being by the Director-General of Health, or
    iii. a person approved for the time being by the Director-General of Health.
f. Prescribed restricted substances - see Schedule 4 (S4) above.
g. Drugs of addiction - see Schedule 8 (S8) above.

Section 3 - Policy Reference

(7) Refer to the Health Safety and Wellbeing Procedures - Alcohol and Drug Control.

Section 4 - Procedure

Part A - All Poisons, Restricted Substances and Drugs of Addiction

Authorisation to Possess and Use

(8) Where poisons, restricted substances and drugs of addiction are to be used in animals or in materials of biological origin or in humans, staff must seek approval from the relevant Ethics and/or Biosafety and Radiation Safety Committee.

Storage

(9) All poisons, restricted substances and drugs of addiction must, at a minimum, be kept:

a. in a restricted area to which the public does not have access, and kept apart from food intended for consumption by humans or animals;
b. so that, if the container breaks or leaks, they cannot contaminate any food intended for consumption by humans or animals.

(10) Further restrictions for Schedule 4 and 8 substances are found in Part C and Part D respectively.

Use and Disposal

(11) Poisons, restricted substances and drugs of addiction must only be used and disposed of in a manner not likely to constitute a risk to the public. Further requirements for the disposal of Schedule 8 substances are found in Part D.

Part B - S2, S3 and S7 Poisons

Authorisation to Possess and Use

(12) A scientifically qualified person in charge of a laboratory or department, or a person acting under the direct personal supervision of such as person, is authorised to possess and use any Schedule 2 or 3 substance required for the conduct of medical or scientific research or instruction or the conduct of quality control or analysis.

(13) Certain Schedule 7 substances may be supplied and used by a person in charge of an institution or facility for scientific research, instruction, analysis or study of that Schedule 7 substance.

Part C - Restricted Substances (S4)

Authorisation to Possess and Use

(14) Possession and use of restricted substances (S4) is restricted to competent and approved personnel as designated by the Dean of School or Director, Research Institute. The Regulation allows a scientifically qualified person in charge of a laboratory or department, or a person acting under the direct personal supervision of such as person, to possess and use any Schedule 4 substance required for the conduct of medical or scientific research or instruction or the conduct of quality control or analysis.

Secure Storage and Transport of Restricted Substances

(15) Approved Personnel must ensure that restricted substances are stored apart from all other goods in a separate room, safe, cupboard or other receptacle securely attached to a part of the premises. The storage area or receptacle must be kept securely locked when not in immediate use.

(16) Restricted substances must always be transported in a secure manner and with the intent to maximise security.

(17) For transport outside the building where the restricted substance(s) is usually stored, a lockable, metal container must be used, and only approved personnel may have access to the key. The transport container must:

a. not indicate it contains restricted substances;
b. be designed in a way to prevent breakage of any enclosed bottles; and
c. be kept out of direct sunlight and away from sources of heat.

(18) During road transport, the container holding restricted substances must not be visible from outside the vehicle. The vehicle transporting the restricted substances must:

a. remain locked whenever stationary, with the keys remaining in the possession of the driver; and
b. not be left unattended while the engine is running.

Pentobarbitone sodium

(19) Authority to obtain or use pentobarbitone sodium must be obtained from NSW Health Pharmaceutical Services using the form Application for Authority to Obtain and Use Pentobarbitone Sodium for the Humane Euthanasia of Animals.

(20) An authorised person who uses pentobarbitone sodium (to the extent that it is an S4 restricted substance and not an S8 drug of addiction) for the destruction of animals must:

a. store pentobarbitone sodium separately from all other goods in a safe, cupboard or other receptacle that is securely attached to a part of the premises and kept locked except when in immediate use;

b. keep a separate register of all pentobarbitone sodium obtained or used.

(21) On the day on which an authorised person obtains or uses any pentobarbitone sodium, the authorised person must enter the following details (as relevant to the transaction) in the register:

a. the quantity obtained or used;
b. the name and address of the person from whom it was obtained;
c. the number and species of animals for which it was used;
d. the total quantity held by the authorised person after the entry is made;

(22) Each entry must be dated and signed by the authorised person.

Use and Disposal

(23) Restricted substances must only be used and disposed of in a manner not likely to constitute a risk to the public.

Security and Reporting of Loss/Theft

(24) Any loss or theft of a prescribed restricted substance, regardless of the amount, must be immediately reported by the Dean of School/Director, Research Institute, or their nominee, for immediate notification to:

a. University Security for reporting to the Police; and
b. Director-General, NSW Ministry of Health, initially by telephoning Pharmaceutical Services, followed by submission of the notification form Notification of Loss or Theft of Accountable Drugs. Where more than three different preparations have been lost or stolen, a Supplementary Page: Notification of Loss or Theft of Accountable Drugs must also be completed and submitted. These forms must be completed and submitted electronically. Further information can be found at Notifying the loss or theft of drugs under Poisons and Therapeutic Goods legislation.

Part D - Drugs of Addiction (S8)

Authorisation to Possess and Use

(25) Possession and use of S8 drugs of addiction is restricted to authorised personnel and is prohibited without written authority from NSW Health Pharmaceutical Services. Authorised personnel are not permitted to supply drugs of addiction under any circumstances. Suitably qualified persons will generally have scientific qualifications and be in charge of a laboratory used for the purpose of analysis, research or instruction, and may also be a person who has received approval from an ethics committee to conduct research. Authority issued to a person is not transferable.

(26) Researchers with authority from NSW Health Pharmaceutical Services (i.e. Authorised Personnel) are permitted to allow persons acting under their direct supervision to possess and use scheduled drugs for research and teaching.

(27) NSW Health Pharmaceutical Services requires submission of an Application for Authority to Possess Drugs of Addiction or Prohibited Substances for the Purpose of Research, Analysis, or Instruction. This form must first be completed, saved, printed off and submitted to the relevant Dean or Director for approval and signature prior to submission to NSW Health Pharmaceutical Services.

(28) Refer to the NSW Pharmaceutical Services Checklist for an application for Authority to Possess Drugs of Addiction or Prohibited Substances for the Purpose of Research, Analysis or Instruction for assistance when completing the application.

(29) Applications to NSW Health Pharmaceutical Services for authority should be emailed and include the following

documents:

a. a completed form Application for Authority to Possess Drugs of Addiction or Prohibited Substances for the Purpose of Research, Analysis, or Instruction;
b. a cover letter signed and dated by the applicant (and co-signed by the relevant Dean or Director); and
c. written ethics approval (where the application is for authority to possess substances for use in animal or human research).

(30) The cover letter should be addressed to:

> Chief Pharmacist
>
> Pharmaceutical Services
>
> Legal and Regulatory Services Branch
>
> NSW Ministry of Health

(31) All documents should be scanned and emailed to pharmserv@doh.health.nsw.gov.au.

Maintain Scheduled Drugs Authority Register

(32) It is recommended that the relevant Dean of School, Director, Research Institute, or their nominee, should ensure that a record is maintained of Authorised Personnel (S8 drugs), Approved Personnel (S4 drugs) and all persons working with S4 or S8 drugs under their authority. The records should be held in a Scheduled Drugs Authority Register.

Secure Storage and Transport of Drugs of Addiction

(33) Authorised Personnel must ensure that drugs of addiction are stored apart from all other goods in a separate room, safe, cupboard or other receptacle securely attached to a part of the premises and kept securely locked when not in immediate use. Access to drugs of addiction will be issued to researchers authorised by NSW Health Pharmaceutical Services, and a copy will be held by the relevant Laboratoty Manager or other officer nominated by the relevant Dean of School or Director, Research Institute, for the purpose of inspections and/or inventories.

(34) The activity of maintaining a drug store may be delegated in writing to a Competent Person.

(35) Drugs of addiction must always be transported in a secure manner and with the intent to maximise security.

(36) For transport outside the building where the drugs of addiction are usually stored, a lockable, metal container must be used, and only approved personnel may have access to the key. The transport container must:

a. not indicate it contains drugs of addiction;
b. be designed in a way to prevent breakage of any enclosed bottles; and
c. be kept out of direct sunlight and away from sources of heat.

(37) During road transport, the container holding the drugs of addiction must not be visible from outside the vehicle. The vehicle transporting the drugs of addiction must:

a. remain locked whenever stationary, with the keys remaining in the possession of the driver; and

b. not be left unattended while the engine is running.

Supply and Receipt of Drugs of Addiction

(38) Drugs of addiction may only be ordered by an authorised person.

(39) Drugs of addiction may only be received by an authorised person. Once received, the authorised person must notify the supplier of the receipt of the drug within 24 hours after that receipt. This notice must be in writing and must be dated and signed by an authorised person.

Maintain a Drugs Register

(40) Authorised Personnel must ensure that a drugs register specifically for S8 drugs of addiction is kept at the place where the drugs are stored or used. The activity of maintaining a drugs register may be delegated in writing to a Competent Person. The name of the person responsible for maintaining a drugs register must be recorded on the register.

(41) A 'Register of Drugs of Addiction' can be purchased from Rolls Filing Systems (1300 600 192 http://www.rollsfiling.com.au/).

(42) The drugs register must be a bound book with consecutively numbered pages and space for the particulars required to be entered. A separate page must be used for each drug and for each form and strength of drug.

Data Entry in Drugs Register

(43) The person who receives, administers or uses a drug of addiction is responsible for entering the details in the relevant drugs register. Each entry must be:

a. made on the day on which a person receives, administers or uses a drug of addiction;
b. written in ink in English;
c. legible, complete and in sufficient detail;
d. dated and signed by the person by whom it is used; and
e. true and correct.

(44) The following details relevant to the transaction must be entered in the drug register:

a. the date of entry;
b. the quantity of the drug received, administered or used;
c. the name and address of the manufacturer/supplier;
d. the name and address of the person to whom the drug was supplied;
e. the purpose for which the drug was used in the laboratory; and
f. the quantity of drugs held at the end of the transaction (i.e. the balance).

(45) Where the drug of addiction has been administered to an animal, the following details must also be included in the register:

a. the species of animal and the name and address of the animal's owner (for animals owned by the University, use the University's facility address; for animals at the University but not owned by the University (e.g. those on agistment), use the owner's name and the University's facility address); and
b. the name of the authorised person by whom, or under whose personal supervision, the drug was administered.

(46) The balance recorded in the drug register should always coincide with the actual stock on hand. A mistake in any entry in a drug register must be corrected by making a marginal note or footnote and by initialling and dating it. If the cause of the discrepancy is identified and found to involve a minor error (e.g. arithmetic) or departure from procedures (e.g. omission of recent use) include a comment to that effect against the amending entry. Alterations, obliterations or cancellations in a register are not permitted. Although it is not required by regulation, multiple repeated errors must be reported to the relevant Dean of School or Director, Research Institute.

(47) Opening and closing balances should be verified and signed when the drug register is completed and a new drug register is commenced. In addition balances should be checked and verified from page to page. Whenever possible balances carried forward to a new page or book should be verified by a second authorised person.

Inventory of Drugs of Addiction

(48) The person responsible for maintaining a drugs store and register must:

a. make an accurate inventory of drugs of addiction in March and September of each year (or as specified by the Director-General of Health);
b. endorse the drugs register, immediately under the last entry for each drug of addiction, with the quantity of each drug actually held and the date on which the inventory was made; and
c. sign each entry in the drug register.

(49) When checking stock, opened containers of drugs must be physically counted. Sealed packs should not be opened, but rather checked that the seals are intact and, if they are sealed, the quantity recorded as per the label. The volume of liquid drugs should be estimated by observation and the entry noted as 'estimated'. Measure the volume of drugs in liquid form only when removing the last of the contents. If there is reasonable discrepancy (e.g. up to 3%), make a note of that fact against the entry.

(50) There are two additional circumstances in which an inventory must be made:

a. in the event of loss or destruction of a drugs register (see Loss or Destruction of Drugs Register); and
b. when a person assumes control for a period of one month or more over any drugs of addiction store.

Loss or Destruction of a Drugs Register

(51) Any suspected or actual loss or destruction of a drugs register must be immediately reported to the Dean of School or Director, Research Institute for the purpose of reporting to the Director-General of Health. The Director-General must immediately be given written notice of the circumstances of the loss or destruction of the drug register.

(52) In the event of loss or destruction of a drugs register an accurate inventory must be made of all drugs of addiction held (see Inventory of Drugs of Addiction) and the details entered into a new drugs register (see Maintain a Drugs Register and Data Entry in Drugs Register).

Security and Reporting of Loss/Theft

(53) Drugs of addiction and associated records must be maintained in a secure manner. Discrepancies in holdings of drugs of addiction must be immediately and thoroughly investigated by those involved. Any unresolved discrepancy should be reported to the Dean of School or Director, Research Institute. The Dean of School or Director, Research Institute will further investigate (in conjunction with the relevant Chief Investigator), and report any unresolved discrepancies to the relevant authorities as described below.

(54) Any loss or theft of a drug of addiction or a prescribe restricted substance, regardless of the amount, must be immediately reported by the Dean of School, Director, Research Institute, or their nominee, to:

a. University Security for reporting to the Police; and
b. Director-General, NSW Ministry of Health, initially by telephoning Pharmaceutical Services, followed by submission of the notification form Notification of Loss or Theft of Accountable Drugs. Where more than three different preparations have been lost or stolen a Supplementary Page: Notification of Loss or Theft of Accountable Drugs must also be completed and submitted. These forms must be completed and submitted electronically. Further information can be found at Notifying the loss or theft of drugs under Poisons and Therapeutic Goods legislation.

Disposal of Drugs of Addiction

(55) Authorised Personnel must ensure that drugs of addiction are not wilfully destroyed except under the direct personal supervision of a police officer or inspector.

(56) The disposal of drugs of addiction should be arranged by contacting the Duty Pharmaceutical Advisor at Pharmaceuticals Services.

Retention of Records

(57) Drugs registers must be kept for at least two years, from the last date on which:

a. any entry was made in the register; or
b. any drug of addiction was received, administered or used.

Inspection of Drugs Register

(58) Drugs registers must be made available for inspection on demand by Pharmaceutical Services, the Police or any authorised University officer (e.g. WHS Representative).

Part E - Provide Information, Training and Supervision

(59) The Dean of School/Director, Research Institute or their nominee, should ensure that all Authorised Personnel and Approved Personnel are provided with information and training in the secure storage, handling and record keeping of poisons, restricted substances and drugs of addiction.

(60) Authorised Personnel and Approved Personnel are responsible for the training and ongoing supervision of persons working under their authority poisons, restricted substances and drugs of addiction and for compliance with the relevant legislative requirements.

Part F - Monitor Compliance

(61) The Work Health, Safety and Wellbeing will monitor compliance with this procedure. Schools and Research Institutes will verify compliance through the Dean or Director signing an annual University Compliance Statement.

Section 5 - Guidelines

(62) Refer to the Associated Information page for links to key pieces of legislation, forms and other related documentation.

Status and Details

Status	Current
Effective Date	18th August 2015
Review Date	1st October 2024
Approval Authority	Vice-Chancellor and President
Approval Date	12th August 2015
Expiry Date	Not Applicable
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