

Monash University Procedure

Procedure Title	High Risk Scheduled Drugs and Poisons Procedure (S8/9/11)
Parent Policy	OHS Policy
Date Effective	19 September 2017
Review Date	September 2020
Procedure Owner	Manager, OH&S
Category	Operational
Version Number	1
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Scope	This procedure is relevant for all Monash University activities including teaching, research and clinical activities in Australia.
Purpose	<p>The purpose of this procedure is to control the purchase, access, use and destruction of schedule S8/S9/S11 poisons. All new Poisons Control Plans (PCPs) must use this procedure as a reference guide for poisons control implementation.</p> <p>Exemption - Where a PCP defines a requirement that conflicts this procedure, the PCP requirements must be implemented.</p>

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1. Abbreviations

DH	Department of Health
OH&S	Monash Occupational Health & Safety
PCP	Poisons Control Plan
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons

2. Definitions

A comprehensive list of definitions is provided in the [Definitions tool](#). Definitions specific to this procedure are provided below.

Approved Area: An area in which a scheduled poison is handled or stored as listed in the Poisons Control Plan (PCP).

Approved Persons: Responsible to handle drugs supplied by a responsible person.

Management Representative: A person whom has been given the authority to represent the interest of the Faculty/Division with regards to the Management of S8/S9/S11 poisons. This person should have the autonomy to make business decisions on behalf of the area.

Permit Holder: A person that is named on the PCP and license to hold a poison, whom has been approved by the Department of Health (DHS).

Poison: A poison is a substance that causes injury, illness, or death, especially by chemical means. Drugs, poisons and controlled substances are defined and controlled in the Poisons Standard 2012 under the Drugs, Poisons and Controlled Substances Act 1981.

The National Drugs and Poisons Schedule Committee classifies drugs and poisons into schedules, which are published as the Standard for the Uniform Scheduling of Medicines and Poisons No.3 (SUSMP 3).

A drug, poison or controlled substance can also be a hazardous substance and/or a dangerous good.

For the remainder of this document, drugs, poisons and controlled substances will be referred to as poisons.

Poisons Register: A register of all scheduled poisons and drugs of addiction.

Responsible Person: A person endorsed by the Permit holder to supply S8/S9/S11 poisons. This would typically be someone in the position of a Medical Practitioner, Veterinarian, Pharmacist or equivalent qualification to supply restricted scheduled drugs.

Transaction: The removal or transfer of a poison from a container.

3. Scheduling Descriptors

The National Drugs and Poisons Schedule Committee classifies drugs and poisons into schedules, which are published as the Standard for the Uniform Scheduling of Medicines and Poisons No.3 (SUSMP 3). This is summarised in the below table for the relevant schedules for this procedure:

Scheduled Poison descriptor	Primary label requirement	Description	Examples
Schedule 4 (S4)	Prescription Only Medicine OR Prescription Animal Remedy.	Prescription Only Medicine, or Prescription Animal Remedy – Substances, the use or supply of which should be by or on the order of persons permitted by State or Territory legislation to prescribe and should be available from a pharmacist on prescription.	Local anaesthetics, antibiotics, strong analgesics (such as Panadeine Forte®)
Schedule 11 (S11)	S4 Drugs of Dependence	These drugs are classified as Schedule 4, however as they are drugs of addiction they are further restricted in to subcategory S11 with additional required control strategies.	Benzodiazepines, midazolam, Duromine® and anabolic steroids.
Schedule 8 (S8)	Controlled Drug.	Controlled Drug – Substances which should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence.	Pethidine, fentanyl, morphine (MS-Contin®, Kapanol®), oxycodone (Oxycontin®, Endone®), methadone (Physeptone®) and buprenorphine. Ketamine, GHB
Schedule 9 (S9)	Prohibited Substance.	Prohibited Substance – Substances which may be abused or misused. The manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities.	Heroin, MDMA, Cannabis, LSD, Mescaline

4. Permit to Obtain a Scheduled Poison or Drug

- New permits obtained through a Faculty/Division must be responsible through the S8/S9/S11 Chemical review panel before an application is submitted to the DH;
- In addition to meeting the DH requirements, all new permits must adhere to this procedure.

5. Acquisition

Only Monash staff or students who are responsible persons are allowed to receive S8/S9/S11 poisons or drugs.

5.1. Purchasers for S8/9/1 – Verification (Purchasing Hubs)

- A purchaser must ensure a permit exists for the poison being received by cross referencing the permits register; and
- If a permit does not exist, the poison must not be purchased.

5.2. Receivers for S8/9/11 – Documentation (Purchasing Hubs)

The receiver of a drug or poison must document the following upon receipt:

- Date received/released;
- Time received/released;
- Quantity received; and
- Condition of packaging (Intact or Compromised).

5.3. **Receivers for S8/9/11 – Authorisation to Receive (Purchasing Hubs)**

Stores personnel handling S8/S9/S11 poisons or drugs must be responsible persons.

5.4 **Receivers for S8/9/11 – Storage (Purchasing Hubs)**

All stores must have an appropriate vault/safe that complies with this procedure in a secure location.

5.5 **Receivers for S8/9/11 – Condition of Goods (Purchasing Hubs)**

- Upon receiving a S8/S9/S11 poison the responsible person must inspect the goods and contact the supplier to confirm safe delivery of intact goods; and
- If there is any reason to believe that the container has been tampered with, the contents may be measured / weighed to confirm that the correct quantity has been received; or if there is any indication that the received quantity is less than that which was ordered; it should be investigated without delay, the responsible person contacted and the S8/S9/S11 Chemical review panel notified.

5.6 **Drugs of Dependence (S8/11)**

- Only responsible persons should be permitted to order drugs of dependence to be supplied to a research facility;
- Two responsible persons should review an order for a S8/S11 poison;
- One responsible person who reviews the order should not regularly work in the same area as the other person.

5.7 **Supplying S9 Poisons**

- A Responsible Medical practitioner is the only person able to supply a S9 poison in a research area.

6. **Labelling – Additional Requirements**

Labels must have the following on the container:

- Name of substance, hazard phrases, pictogram;
- Include the name of the Chemical controller (Responsible Person);
- Date received;
- The following identifier:

Scheduled Poison descriptor	Primary label requirement
Schedule 11 (S11)	S4 Drugs of Dependence
Schedule 8 (S8)	Controlled Drug.
Schedule 9 (S9)	Prohibited Substance.

7. **Transactions**

7.1. **Recording Schedule 8/9/11**

All transactions must be individually recorded. These transaction records must include:

- The date of the transaction;
- The quantity of the substance involved in the transaction;
- The details of the substance:

- The name of the substance;
 - The form of the substance (e.g. tablets, liquid, powder etc);
 - The strength of the substance;
 - The name of the person carrying out the transaction;
 - The quantity of substance remaining after each transaction (This quantity balance must always be measured (i.e. the quantity must be weighed or counted). The balance should not simply be calculated based on what the previous recorded balance was and what the amount used was);
- Sometimes a page may contain multiple transactions of the same substance. In such a case, the details of the substance may only need to be recorded once on the page.
 - Suggested template format:

Name of substance		Supplier		Original weight received from supplier (including container)		Permit Number	Allowable maximum quantity on permit	
Date of transaction	Person conducting transaction	Current volume	Amount removed	Amount remaining	Purpose of transaction	Responsible persons name	Responsible persons signature	Transaction error detected (Yes/No)

2.

- Be made in a way so that the records cannot be altered, obliterated, deleted or removed without detection – No electronic records;
- Be made in bound books;
- Contain consecutive page numbers;
- Users are not permitted to remove pages.

7.2. Additional Requirements for S11 Drugs of Dependence

- A dedicated drug of addiction register booklet must be used for all S11 drugs; and
- If a drug of dependence is being used for multiple, different purposes at different times, it would not be sufficient to record a single daily transaction to encompass all such varied usages throughout a day. Individual records of drugs of dependence should be documented for individual transactions.

7.3. Transaction Discrepancies

- If there is any reason to believe that the container has been tampered with, the contents may be measured / weighed to confirm that the correct quantity has been received. If there is any indication that the received quantity is less than that which was ordered, it should be investigated without delay; and
- If a discrepancy indicates that a substance has gone missing or variation in measured balances, it has been investigated, and no acceptable explanation can be determined, then it must be reported to OH&S within 48 hours from the date of initial detection.

8. Storage

- The quantity of any scheduled substance being stored should never exceed the maximum holding quantity stated on the permit;
- Storage vaults/safe must comply to Drugs and Poisons Regulations (2017) Point 74 section 2;

- Additional Schedule 8/9 storage facility constructed of mild steel plate of 10 mm thickness, constructed with continuous welding of all; and
- Edges, fitted with a door constructed of mild steel plate of 10 mm thickness, swung on hinges welded to the door and body of the cabinet, the door being flush fitting with a clearance around the door of not more than 1.5 mm, fitted with a fixed locking bar, welded to the inside face of the door near the hinge edge, which engages in a rebate when the door is closed, fitted with a 6 lever lock securely affixed to the rear face of the door, securely attached to a wall or floor in such a manner that it will resist attack by hand tools for 30 minutes or power tools for 5 minutes.

9. Handling

- All remaining S8/S9 substances must be returned back to the responsible person and noted in the Chemical Register immediately after use;
- If a S8/S9 substance is to be held overnight it must be stored and returned to the safe and logged back into the safe/vault;
- Poisons must not be left unattended in a laboratory; and
- It is recommended that a responsible person should supervise the approved person until the poison is fully used/consumed or returned to the storage area.

10. Animal Ethics Exemption

- A Responsible Person may supply a S8/S9/S11 poison overnight if a research experiment involves an animal that may require euthanasia or appropriate treatments;
- If a S8/S9/S11 poison is supplied to an approved person it **MUST** be returned and accounted for by the approved person back into an appropriate S8/S9/S11 poisons safe; and
- The Responsible person must verify the use and return of the S8/S9/S11 poison within 24 hours.

10.1. Mandatory Overnight Storage Requirement

- Where the supply of S8/S9/S11 drugs is approved for overnight use by an approved person, the area must have a transitional safe installed that will allow secure storage of the drug overnight until it can be returned to the original safe.

11. Synthesis of Drug

- All compounds that are able to be synthesised in a single synthesis to a S8/S9 drug are to be controlled as if the poison was an S8/S9/S11. e.g. codeine methyl ether and oripavine.

12. Compliance Monitoring

- Faculties obtaining S8/S9/S11 must monitor the use of all poisons; and
- The Chemical review panel is responsible for auditing their local poisons registers.

13. Destruction of Poisons

- If a substance has not been consumed through research usage, and it is no longer required, arrangements should be made to destroy the substance; and
- Out of date (use by date) S8/S9/S11 poisons must be destroyed.

13.1. **Recording Substances for Destruction**

When either destroying substances on the premises, or sending the substances away for destruction, the following details should be recorded (to comply with Sub-regulation 40(1)):

- The details of the substance, including;
- Name of the substance;
- Form of the substance (e.g. tablets, liquid, powder etc);
- Strength of the substance;
- Date of the transaction; and
- Quantity of the substance involved.

If substances are being sent away for destruction, then also record:

- The name of the place where the unwanted substance is being sent to;
- The address of where the unwanted substance is being sent to.

If Schedule 8 or 9 substances are being destroyed on the premises, then (to comply with Regulation 51) also record:

- The method of destruction;
- The place of destruction; and
- The name of the witness(es).

13.2. **Pharmacy Destruction (Off Site)**

If they are willing to accept substances for destruction, it would be acceptable to send any substances to a pharmacist working in a pharmacy, or possibly to send the substances back to the original supplier.

13.3. **Chemical Contractor Destruction (Off Site)**

- For schedule 4 substances, the research organisation should check that the waste company holds a poisons permit for schedule 4 poisons;
- The research organisation should be aware that currently there are no waste companies in Victoria that have lawful authority to be in the possession of substances that can be identified as Schedule 8 or 9 substances.

13.4. **Destruction On Site**

- When destroying substances on premises, it should be ensured that the destruction process renders the substances non-recoverable and non-identifiable;
- After rendering the substances non-recoverable and non-identifiable, the resulting waste material may be sent to a waste company that specialises in chemical and/or pharmaceutical material (but should not be placed in general waste); and
- Any organisation that chooses to destroy Schedule 8 or 9 substances on their premises must ensure that the destruction is carried out by two health practitioners who are either registered medical practitioners, pharmacists, dentists, veterinarians or nurses; however, the two persons cannot include the combination of two nurses where one is not a nurse practitioner. These requirements are outlined in Regulation 51 of the Drugs and Poisons Regulations (2017).

14. Transfer

- All recipients of a transfer intercampus or between campuses must be a Responsible person;
- All responsible persons of the permit holder can transfer S8/S9 poisons on a campus as long as the poisons remains in their possession;
- All transfers off campus must be conducted by an Responsible courier who has a permit to do so; and
- Must be transported in a metal locked container.

15. Training

Areas must provide training for the handling of high risk poisons such as S8/S9/S11.

16. Responsibility for Implementation

A comprehensive list of OHS responsibilities is provided in the document [OHS Roles, Committees and Responsibilities Procedure](#). A summary of the specific responsibilities relevant to this procedure are provided below.

16.1 **Senior Executive, Deans and Directors, Heads of Academic/Administrative Units:**

Senior Executive, Deans and Directors, Heads of Academic/Administrative units must ensure:

- A safe system of work is implemented with the use of scheduled poisons; and
- That all poisons adhere to their PCP through a monitoring process.

16.2 **Permit Holder:** The permit holder is responsible for:

- Maintaining the status and currency of the permit;
- The selection of responsible persons;
- The review of all records check of responsible persons and approved persons;
- Participating in the Chemical Review panel and ensuring the correct management of poisons in line with the PCP; and
- In conjunction with the responsible person, notifying any individual that requires physiological testing.

16.3 **Chemical Review Panel – Management Representative:**

- Responsible for representing the Faculty/Division for the Management of S8/S9/S11;
- Must report the status of poisons control planning and performance to the Senior Executive of the Faculty/Division.

16.4 **Department of Health (DHS) Responsible Person:**

- Person listed on the PCP as the Responsible Person that is reportable to the Department of Health.

16.5 **Responsible Person to Supply S8/9/11 Poisons:**

- All S8/S9/S11 responsible persons must be scrutinised by the area and in which they are deployed;
- Are responsible to ensure all poisons are managed locally as per the PCP.

All responsible persons must:

- Have a current National Police Check conducted and be free of drug related offences;
- Free of recreational drug usage;
- Have acquired sufficient knowledge and training to enable them to handle S8/S9/S11 drugs;
- Must be registered on the Monash University responsible persons register to handle S8/S9/S11 drugs;
- Ensure that if a medical practitioner (or nurse) provides a poison, it must have a stated purpose and only be used for that purpose; and
- Monitor the use of all S8/S9/S11 drugs.

The following is recommended:

- A review of all work history for the abuse or misuse of scheduled drugs;
- Physiological screening (e.g. blood, urine, saliva testing for drugs); and
- Authorisation is dependent upon the permit holder and the responsible person being listed on the permit as a responsible person.

16.6 **Approved Person:**

An approved person must be listed on the University register.

Approved persons must:

- Have a National Police Check conducted and be free of drug related offences; and
- Have adequate training and knowledge to handle S8/S9/S11 when supplied by a responsible person.
- Approved persons are subject to if requested by a responsible person or permit holder to conduct an investigation of:
 - All work history for the abuse or misuse of scheduled drugs;
 - Education and experience;
 - Physiological screening (e.g. blood, urine, saliva testing for drugs).

16.7 **S8/9/11 Chemical Review Panel:**

All Faculties and Divisions with organisational units dealing with S8/S9/S11 poisons must set up a review panel to manage and monitor their use within the faculty.

The review panel must minimally comprise of:

- Permit holder;
- Responsible person; and
- Management Representative

The committee must review for S8/S9/S11:

- Applications for new drugs;
- Management of drugs as per the PCP;
- Monitor adherence to permit conditions and this procedure; and
- Manage the Faculty/Division permits register.

The committee may be either face to face or an online committee as long as it achieves its objectives.

16.8 **Managers and Supervisors:**

Managers and Supervisors are responsible for ensuring:

- That that all staff and students using S8/S9/S11 poisons are responsible or approved persons;
- That all persons handling poisons have been adequately trained to do so;
- All their staff/students are competent in the use of scheduled poisons; and
- Access is denied to poisons if a responsible/approved person is no longer involved in the poisons activities (this may include re-coding a safe/vault).

16.9 **Monash Occupational Health & Safety (OH&S):**

OH&S are responsible for:

- Auditing University drugs and poisons management; and
- Maintaining the Monash University High Risk Drugs and Poisons Procedure.

17. **Records**

For OHS Records document retention please refer to:

[Monash University OHS Records Management Procedure](#)

Status	
Approval Body	Monash University OHS Committee (MUOHSC)
Legislation Mandating Compliance	Occupational Health and Safety Act 2004 (Vic) Drugs, Poisons and Controlled Substances Act (1981) Drugs, Poisons and Controlled Substances Regulations (2017)
Related Policies	OHS Policy
Related Documents	Australian and International Standards AS/NZS 4801:2001 Occupational Health & Safety Management Systems – specifications with guidance for use. OHSAS 18001: 2007 Occupational Health and Safety Management Systems- Requirements Standard for the Uniform Scheduling of Medicines and Poisons No.3 (SUSMP 3). Poisons Standard 2012

18. Document History

Version	Date of Issue	Changes made to document
1	September 2017	High Risk Scheduled Drugs and Poisons Procedure (S8/9/11), v1