Controlled Drugs – Safe Custody Procedure	
Enabling Policy Statement; Executive Owner; Approval Route:	Our Safety - Chief Operating Officer - Compliance Committee
Is the Procedure for internal use only (Non-disclosable)?	Disclosable
Associated Policy Statements:	N/A
Authorised Owner:	Director of Health and Safety
Authorised Co-ordinator:	Health and Safety Officer (Hazardous Materials)
Effective date:	11 October 2023
Due date for full review:	10 October 2026
Sub documentation:	Controlled Drugs Standard Operating Procedures

Approval History

Version	Reason for review	Approval Route	Date
1.0	Reviewed and updated (including in accordance with new Policy Framework 2022). Replaces Controlled Drugs – Safe Custody Policy, dated October 2018).	Compliance (Health, Safety and Wellbeing) Committee.	4 October 2023

1. Purpose

This Procedure outlines the arrangements adopted by the University for the purpose of securing the safe, appropriate, and effective management of Controlled Drugs in accordance with statutory requirements.

The aim of this procedure is, therefore, to provide effective management arrangements to create a safe environment for our students, employees, contractors, and visitors.

This Procedure introduces controls to prevent Controlled Drugs from being misused, obtained illegally, or causing harm.

2. Scope and Exceptions to the Procedure

The Procedure applies to all staff, students and visitors using Controlled Drugs, and it is applicable to all areas of research and teaching activities.

This Procedure will govern the manner in which Controlled Drugs are requisitioned, stored, handled, recorded and checked.

This Procedure should be used in conjunction with the latest guidance available, including from the Home Office, Royal College of Veterinary Surgeons (RCVS), The National Institute for Health and Care Excellence (NICE), and the General Medical Council (GMC).

This Procedure is not applicable to the recreational use of Controlled Drugs. It is also not applicable to the safe handling, storage, and disposal of risk items which is covered by different arrangements.

3. Definitions and Terminology

Controlled Drugs – are defined as any drug listed in Schedule 1, 2, 3, 4 or 5 of the Misuse of Drugs Regulations 2001.

The legislation regarding Controlled Drugs is subject to change. The list of most commonly encountered Controlled Drugs under the misuse of drugs legislation and current information regarding Controlled Drugs can be found at: List of most commonly encountered drugs currently controlled under the misuse of drugs legislation

Controlled medicines – are classified (by law) based on their benefit when used in medical treatment and their harm if misused. In addition the Misuse of Drugs Regulations 2001 determines in what circumstances it is lawful to possess, supply, export, and import Controlled Drugs listed in the Schedules.

Classifications – Controlled Drugs are listed by 'Class' under the Misuse of Drugs Act 1971 (Schedule 2) and the Misuse of Drugs Regulations 2001.

- Class A (most harmful, and examples include 3,4-Methylenedioxymethamphetamine [MDMA or Ecstasy], Lysergic acid diethylamide [LSD], Heroin, Cocaine, Crack).
- Class B (examples include Cannabis, Spice, Speed, Ketamine).
- Class C (examples include Valium, gamma-Hydroxybutyric acid [GHB], and Steroids).

Competent Person – a competent person has the skills, knowledge, attitude, training, and experience to undertake the role effectively.

Controlled Drug Compliance Officer – responsible for legal compliance and regulatory affairs in respect of the area to be licenced by the Home Office to hold Controlled Drugs.

Controlled Drug Liaison Officer – member of the Police force who offers advice on safe storage, auditing,

destruction, suspicious activity, internal thefts, forged or stolen prescriptions as well as current crime trends.

Controlled Drug Register – required to record details of any Schedule 1 or 2 Controlled Drugs received or supplied.

Controlled Drugs Storage Cupboard/Cabinet – a specific cupboard in which all Controlled Drugs (unless exempted) must be stored. The Misuse of Drugs (Safe Custody) Regulations 1973 defines the standards to which the Controlled Drugs cupboard must be constructed.

Exempt Product – means a preparation of other product consisting of one or more component parts, any of which contains a Controlled Drug, where:

- The preparation or other product is not designed for administration of the Controlled Drug to a human being or animal.
- The Controlled Drug in any component part is packaged in such a form, or in a combination with other active or inert substances in such a manner, that it cannot be recovered by readily applicable means or in a yield which constitutes a risk to health, and
- No single component part of the product or preparation contains more than one milligram of the Controlled Drug or one microgram in the case of Lysergide or any other *N*-alkyl derivative of Lysergamide.

Schedules – the Misuse of Drugs Regulations 2001 divide the Controlled Drugs into 5 Schedules, each specifying the requirements governing activities such as import, export, supply, possession, prescribing, and record keeping.

- Schedule 1 – drugs to this Schedule are thought to have no therapeutic value and, therefore, cannot lawfully be possessed or prescribed. These include LSD, MDMA.

  NOTE: Schedule 1 drugs can be used for the purpose of research, but a Home Office Licence is required.

- Schedule 2 drugs have a therapeutic value but are highly addictive. Examples include Morphine, Diamorphine, Ketamine, Cannabis.

- Schedule 3 drugs have a low to moderate potential for abuse and or addiction and less dangerous that Schedules 1 or 2 include most of the Barbiturate family.

- Schedule 4 have viable medical use with low probability of use or misuse.

- Schedule 5 incudes preparations of certain Controlled Drugs (such as Codeine, Pholcodine or Morphine) which due to their low strength, are exempt from virtually all Controlled Drug requirements, other than retention of invoices for 2 years.

Standard Operating Procedure (SOP) – a step-by-step description of the way things are done in a particular setting. Written SOP's help to ensure the quality and consistency for the management of Controlled Drugs in each registered area.

Training and Briefing – Training is equipping staff, students and (others where the University has a duty-of-care) with relevant skills to deal appropriately with a given health and safety situation.

Briefing is informing such persons of relevant knowledge in relation to health and safety.

Veterinary Medicinal products are:

- Any substance or combination of substances presented as having properties for treating, or preventing disease in animals, or
- Any substance or combination of substances that may be used in or administered to animals with the view to either restoring, correcting, or modifying physiological functions by exerting pharmacological or metabolic action, or to making medical diagnosis.

4. Procedural Principles

4.1. Commitment

Compliance with the requirements of this Procedure will ensure:

- The University meets its statutory obligations in respect of Controlled Drugs.
- The safety of staff, students, and others from the use of Controlled Drugs.
- The safe and effective management of Controlled Drugs.
- That those who use Controlled Drugs during their work activities are appropriately informed, instructed, and where necessary, trained and supervised.

4.2. Arrangements

In order to meet the above objectives, the University will:

- Clearly define the organisational arrangements for achieving compliance (see Roles and Responsibilities section of this Procedure).
- Ensure resources are made available to achieve compliance.
- Appoint Controlled Drug Compliance Officer(s) to ensure all Controlled Drugs are adequately stored, used, disposed of and recorded correctly.
- Appoint an Authorised Witness for the Destruction of Controlled Drugs.
- Confirm that all Controlled Drug Storage Cabinets are suitably constructed and installed in accordance with the legislation.
- Ensure that records are maintained as required for the acquisition, storage, use and disposal of Controlled Drugs.
- Regularly audit the Controlled Drugs stored within the cabinets and report any discrepancies immediately to the Dean of the Faculty.
- Review Controlled Drugs arrangements periodically or whenever there are changes in relevant legislation, guidance, or University activities.

4.3. Roles and Responsibilities

4.3.1. Dean of Faculty is the most senior manager for areas where Controlled Drugs are used/stored and, as such, is identified under the Regulations as the 'User'. The User is responsible for overall compliance with the requirements of the Misuse of Drugs, Veterinary Medicines, Controlled Drugs Regulations, and Environmental Permitting Regulations. The User will:

- Ensure appropriate licences are obtained and maintained for all Controlled Drug activities under their control.
- Take whatever action necessary to ensure all staff act in accordance with specific conditions of the Home Office Licence and the standard operating procedures in place to comply with the Controlled Drugs, Misuse of Drugs and Environmental Permitting Regulations.
- Ensure that staff under their management control, including Principal Investigators, Researchers, Technicians, and academic visitors, who use Controlled Drugs or produce Controlled Drug waste:
    - Comply with conditions specified within any Faculty held Controlled Drugs Licence.
    - Comply with the requirements of the relevant regulations.

4.3.2. Controlled Drug Compliance Officer is appointed by the Dean of the Faculty and responsible for legal compliance and regulatory affairs in respect of the area to be licenced by the Home Office to hold Controlled Drugs. The Controlled Drug Compliance Officer will:

- Ensure there is full compliance with the statutory requirements of the Misuse of Drugs Act 1971 and Misuse of Drugs Regulations 2001.
- Ensure the conditions stipulated on the Licence are complied with.
- Ensure Standard Operating Procedures are in place, and available on request by the Home Office.
- Undertake independent audits and monthly stock control checks on Faculty held Controlled Drugs.
- Ensure that the Controlled Drug Register is maintained and kept up to date.

4.3.3. Controlled Drug Liaison Officer – member of the Police who will offer advice on:

- Safe storage
- Auditing
- Destruction (including acting as authorised witness for Schedule 1 and 2 drugs
- Suspicious activity
- Internal thefts,
- Forged or stolen prescriptions
- Current crime trends.

4.3.4. Supervisory Staff – academic, technical, and experimental staff who have supervisory responsibilities or exercise control over areas, activities or Controlled Drug processes involving either employees, visitors, or students, are accountable to the Dean of Faculty for the enforcement of statutory Health and Safety measures. In particular, supervisors must:

- Ensure that area Standard Operating Procedures are disseminated to all users of Controlled Drugs. The Standard Operating Procedures should cover the following matters:
    - Order, transport, and receipt.
    - Who has access to Controlled Drugs.
    - Where Controlled Drugs are stored.
    - Security in relation to the storage and transportation of Controlled Drugs.
    - Record keeping, management of errors and incidents including:
        a) Maintaining relevant Controlled Drug registers under the Misuse of Drugs Legislation.
        b) Who should be alerted should complications arise.
        c) Destruction and disposal of Controlled Drugs.

- Ensure that appropriate approvals and permissions (e.g., ethics, licensing, permissions, or sponsorship) are in place before research commences and follow the University Code on Good Research Practice.
- Ensure that an appropriate risk assessment is undertaken before work is undertaken or started (including for undergraduate and postgraduate project work).
- Staff and students have sufficient instruction and information and are adequately trained and supervised.
- Cooperate with responsible bodies (i.e., Police Controlled Drug Liaison Officer, Home Office Inspector) when they carry out their inspections and provide relevant documentation when requested.

4.3.5. Staff, Students and Visitors who undertake activities with Controlled Drugs must take reasonable steps to ensure their own health and safety and that of others who may be

affected by the things they do or fail to do. In particular, they must:

- Comply with the Standard Operating Procedures of their area concerning the safe custody of Controlled Drugs.
- Ensure all purchases, use and destruction of Controlled Drugs is recorded in the Controlled Drug Register.
- Report unsafe conditions, activities, accidents, near misses and property damage or loss to their supervisor.
- Ensure all uses of Controlled Drugs are recorded, as required by law and the area Standard Operating Procedure.

4.3.6. Authorised Witness for the Destruction of Controlled Drugs – it is a legal requirement for out of date or unusable Controlled Drugs to be destroyed by a person authorised by the Home Office, to witness the destruction of Controlled Drugs. Any person authorised to witness the destruction of Controlled Drugs should be either a) or b), in addition to c) and d):

a) Subject to a professional code of ethics, or
b) Subject to a satisfactory Disclosure and Barring Service (DBS).
c) Have received appropriate training.
d) Be independent of day-to-day Controlled Drug use or management in the premises that the destruction is carried out.

4.3.7. Director of Health and Safety is responsible for:

- The provision of guidance on the application of the requirements of legislation and this Procedure.
- Where necessary liaising with the enforcement authorities.
- With assistance of the Controlled Drug Compliance Officer, monitoring compliance with the requirements for this Procedure.

5. Governance Requirements

5.1. Implementation: Communication Plan

The Procedure will be available via the University procedures webpages.

Relevant Health & Safety Committees will be notified, and information disseminated through line management. Faculty Health and Safety Committees will also be informed, as required.

This Procedure and relevant supporting documentation is also published on the University Health and Safety intranet site.

5.2. Implementation: Training Plan

Training and Briefing will be made available in a range of formats according to the needs of the trainee and different groups of staff, students and others.

The Controlled Drug Compliance Officer will be trained to undertake their role.

All persons either directly or indirectly using Controlled drugs are required to be trained by the Controlled Drug Compliance Officer before any work can commence.

5.3. Review

The Director of Health and Safety will monitor for required changes and updates. Minor changes will be reviewed by the Hazardous Substances Working Group and approved by Compliance (Health, Safety and Wellbeing) Committee.

Major Changes will also be reviewed by the Hazardous Substances Working Group, prior to submission to the Compliance (Health, Safety and Wellbeing) Committee for approval, and if required, noted at Executive Board.
This Procedure will be reviewed every three years or in line with relevant changes in legislation, if sooner. The Health and Safety Consultative Committee will be consulted during the review process, as required.

5.4. Legislative Context and Higher Education Sector Guidance or Requirements

5.4.1. Applicable Legislation and Guidance

This Procedure complies with the requirements of the Health and Safety at Work Act 1974, and other Controlled Drug legislation, as follows:

- Misuse of Drugs Act 1971
- Misuse of Drugs (Safe Custody) Regulations 1973
- Misuse of Drugs Regulations 2001 (as amended)
- Misuse of Drugs (Safe Custody) (Amendment) Regulations 2007
- Veterinary Medicines Regulations 2013
- Misuse of Drugs (Amendment) (England, Wales and Scotland) Regulations 2015 in addition to the terms and conditions of Home Office Controlled Drug Licenses issued to Schools, Departments, Faculties, Directorates to ensure all Controlled Drugs are correctly purchased, stored, used, disposed of, and that adequate records are kept.

The following guidance is available to assist with compliance with the legislation:

- Royal College of Veterinary Surgeons (RCVS) – Controlled Drug Guidance A-Z, 2023.
- Veterinary Medicines Directorate (VMD)– Controlled Drugs: Recording, using storing and disposal, 2022.
- Home Office Guidance for all existing or prospective Home Office Controlled Drug Licensees and/or Precursor Chemical Licensees or Registrants. 2022
- Home Office Guidance for the Safe Custody of Controlled Drugs and Drug Precursors in Transit, 2022.
- Controlled Drugs – Care quality Commission, 2022.
- Home Office Security Guidance for all existing or prospective Home Office Controlled Drug Licensees and or Precursor Chemical Licensees or Registrants, 2022.

5.4.2. Legislative Context

This Procedure sets out to comply with the required ‘duty of care’ placed upon the University. Under Health and Safety Law a ‘duty of care’ is generated between organisations and individuals when carrying out activities that could foreseeably cause harm.

The primary duty of care is owed through the employer-employee relationship in which the employer owes a duty of care to ensure that work activities that could result in harm to the employee are assessed and controlled. That duty of care is put into practice by the line management responsibilities as set out in the hierarchy of the organisation.

This duty of care cannot be delegated away; instead, the act of delegation must be accompanied by a realistic and workable system of monitoring or supervision to ensure that the delegated task has been adequately implemented (i.e., the responsibility is not met by giving directions; it is met when those directions have been confirmed as carried out). The result is a cascade of delegated accountability that runs through the organisation via the line management network, accompanied by a system of monitoring, supervision, and feedback.

The duty of care extends to assurance that services provided by others (be they another department of the University or contractors) are undertaken safely. The level of assurance required should be commensurate with the risk of the activity. In addition, anyone carrying out an

activity owes a duty of care to anyone who may be put at risk by the activity, such as students, staff, and visitors.

6. Sustainability

Schedule 1, 2 and 3 Controlled Drugs are required by law to be denatured before disposal to ensure no material can be recovered, this is then disposed of via incineration. The quantity of Controlled Drugs used is kept to the minimum reducing the waste produced.

The containers (Burn Bins) used for disposal are manufactured from post-consumer plastic. Swapping previously used single-use clinical waste bins which were made from virgin plastic with ones made from responsibly sourced post-consumer recycled plastic, which helps cut equivalent carbon footprint by up to 50% a year.

The Waste Contractor became self-sufficient in green energy in 2021. By piping landfill gas from its adjacent former landfill site into a gas engine which is now generating around 350kW of renewable electricity. This generates enough to power the entire operation and still send at least a third of its output to the National Grid.

The Waste Collection Fleet of vehicles are Certified as Carbon Neutral.

7. Stakeholder Engagement and Equality Impact Assessment

7.1. An Equality Impact Assessment was completed on **25/08/2023** and is held by the Authorised Co-ordinator.

7.2. Stakeholder Consultation was completed, as follows:

Stakeholder	**Nature of Engagement**	**Request EB Approval (Y/N)**	**Date**	**Name of Contact**
Governance	Development and creation of this Procedure v1.0.	N	22/08/2023	Andrea Langley, Regulatory Compliance Manager (OIA)
Director of Health and Safety	Development and creation of this Procedure v1.0.	N	11/07/2023	Matthew Purcell, Director of Health and Safety (Cervus+)
Sustainability	Development and creation of this Procedure v1.0.	N	22/08/2023	Members of the Sustainability Team.
Members of the Compliance Management Group	Development and creation of this Procedure v1.0.	N	22/08/2023	Members of this Group.
Members of the Health and Safety Consultative Committee	Development and creation of this Procedure v1.0.	N	22/08/2023	Members of this Committee.

Members of the Hazardous Substances Working Group	Development and creation of this Procedure v1.0.	N	22/08/2023	Members of this Working Group.
Equality, Diversity and Inclusion	Development and creation of this Procedure v1.0.	N	22/08/2023	Jo McCarthy-Holland, Equality and Diversity Manager.