Controlled Drugs
Standard Operating Procedures

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University of Sussex

Controlled Drugs Standard Operating Procedures

Contents

1. Introduction and Scope

This Standard Operating Procedure supports the University's Controlled Drugs Policy and defines the minimum operational requirements for Schools' and Units' safe, appropriate and effective management and use of Controlled Drugs within the University of Sussex.

Schools' and Units' own Standard Operating Procedures will support and define how Schools or Units will implement the University's Controlled Drugs Standard Operating Procedures and Controlled Drugs Policy.

2. Legislative Framework

Adherence to this Standard Operating Procedure will ensure that the University complies with all relevant legislation regarding Controlled Drugs, including:

- Health Act 2006
- Misuse of Drugs (Safe Custody) Regulations 1973
- Misuse of Drugs Regulations 2001
- Misuse of Drugs (Amendment) (No.2) Regulations 2015
- Veterinary Medicines Regulations 2013
- Environmental Permitting (England and Wales) Regulations 2010

Failure to comply with the requirements of the Controlled Drugs Policy, Standard Operating Procedures and the above legislation could result in prosecution.

3. Definitions

Controlled Drug (CD) is any drug or therapeutic agent, commonly understood to include narcotics, with a potential for abuse or addiction, which is held under strict governmental control.

Standard Operating Procedure (SOP) is a step-by-step description of the way things are done in a particular setting. Written SOPs help to ensure the quality and consistency of the management of controlled drugs in each registered facility. They can help to identify and minimise risks and to trace the cause of any errors.

4. Responsibilities

Operational responsibilities are defined in the University's Controlled Drugs Policy.

5. Operating Procedures

5.1 Drug Schedules

The requisitioning, holding, use and disposal of certain substances are controlled under the Misuse of Drugs Act 1971 and associated regulations. The legislation splits these substances into 5 groups; each group is listed in a Schedule that is reviewed periodically. An up to date list can be found at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/164222/controlled-drugs-list.pdf

Drugs listed in each Schedule share common restrictions and requirements in relation to supply, record keeping and destruction, with Schedule 1 drugs being subject to the most stringent restrictions and requirements and Schedule 5 being least stringently controlled.

It is the responsibility of each user to know the Schedule of each drug used / anticipated and to ensure that appropriate measures are in place for each drug.

Dilution / Concentration

Irrespective of quantity, concentration or dilution, drugs in each Schedule must be treated in accordance with the full requirements for that Schedule, e.g. 10ml of 2mg/ml cocaine in saline requires the same measures as 10g of pure cocaine (Schedule 2).

Drugs listed in Schedule 1

The purchase, production, storage, supply and use of Schedule 1 drugs requires a specific licence from the Home Office. This licence is not a generic licence for the University and a separate licence must be obtained by each management unit that wishes to undertake the work.

Drugs listed in Schedules 2 to 5

Universities are permitted to purchase, store and use the Controlled Drugs in Schedules 2-5 in their research activities without need to apply for a licence.

5.2 Requisition of Controlled Drugs

Human Use: CDs for human use must be requisitioned using NHS form FP10CDF completed in ink. Form FP10CDF is obtainable by the clinician from NHS England South, email: england.surreysussex-cds@nhs.net. This requisition form is secure stationery and the clinician is legally responsible for storing them in locked storage and for recording all serial numbers of forms held and used.

Animal Use: CDs for animal use must be requisitioned from the vet / wholesaler in writing. Dedicated requisition forms are available from veterinary wholesalers and should be used where available. For CDs not supplied by a veterinary wholesaler, a written prescription for stock is acceptable providing it contains:

- Name, address and profession of the recipient.
- Purpose for which the drug is required (e.g. for research use).
- Total quantity required.
- Signature of the recipient, **in ink.**
- It is an offence to supply Schedule 2 or 3 CDs from a faxed or electronic requisition.

In Vitro Use: CDs for in vitro work shall be requisitioned in accordance with the above procedures for either human or animal use, as dictated by the nature of the supplier of the drug being used, e.g. pharmacy, veterinarian.

Where stock is collected by a representative on behalf of a purchaser, a written authorisation must be provided to the authorised supplier (e.g. pharmacist, veterinarian, wholesaler, etc) that empowers the representative to receive the medicines on behalf of the purchaser.

5.3 Production of Controlled Drugs

It is a criminal offense to produce (synthesise) any control drug (or its structural analogue) in any quantity without a Home Office licence for CD production.

Information regarding licences for the production of controlled drugs can be found at https://www.gov.uk/guidance/controlled-drugs-licences-fees-and-returns

For further advice and guidance contact the SEF QSHE team: HealthSafety@sussexestatesfacilities.co.uk

5.4 Storage/Location

5.4.1 Locations: Schools / Units will maintain a register of where their CDs are held on campus.

5.4.2 Storage Construction and Security

Controlled Drug Cabinets: The physical security measures outlined in the Misuse of Drugs (Safe Custody) Regulations 1973 are, in practice, seen as acceptable minimum standards to be met for the storage of all controlled drugs, irrespective of schedule or activity.

The size of the stocks of drugs held will determine whether it is necessary to hold them in a strong room or an approved safe/cabinet. Advice for storage should be sought through the Sussex Estates Facilities QSHE Team: HealthSafety@sussexestatesfacilities.co.uk

Fridges: Fridges must be locked, either by design or with a lock retrospectively fitted, but do not need to be secured to the wall or floor. Fridges must be located within a secure room. As at September 2015 there were no fridges manufactured to regulatory CD storage standards.

Combination Locks: Where combination locks are used, the combinations should not be shared with anyone else, including colleagues. These should not be written down, and should be changed regularly, or at least every six months as a minimum, to prevent the locks from being compromised.

Combinations should be changed whenever a member of a group or an individual leaves the University or otherwise no longer requires access to the lock.

Securing Keys: The Home Office suggests that premises apply the same levels of security controls to all key(s) (including spares) to safes as they would to the CDs contained within them, since failure to do so compromises the security arrangements and undermines the value of the safe. Access to individual keys should be audited and recorded, with a key signing in/out procedure.

It is recommended that spare keys should be kept in a separate safe to which only very few employees (senior managers) have access.

Key boxes may be considered for holding the key for a cabinet or a small safe. The Home Office recommend a model that is formed from steel sheeting, which is at least 3mm thick, has a combination lock without a separate key override and is secured by internal bolts to a solid wall.

It is not acceptable key management to lock a key in a desk drawer or in other office furniture, irrespective of whether the key is locked in an additional box.

5.4.3 Storage Requirements by Schedule

Schedules 1, 2 and specified Schedule 3 (containing diethylpropion, buprenorphine, temazepam and flunitrazepam)

- Must be stored in a locked controlled drug cabinet securely bolted to the wall or floor. Storage must meet the requirements of the Regulations.
- Fridges must be locked and be located within a secured room. Small quantities (no minimum) used in a surgery or lab, must be stored locally in the surgery or lab in a locked drugs cabinet.
- Irrespective of quantity or concentration, transportation around campus must be in a locked container, e.g. a cash box, or a heavy duty leather doctor's or vet's bag. A locked canvas or other lightweight bag is not permitted as these may be easily cut open. The container must be unlabelled and not give any indication that it contains controlled drugs.
- It is not necessary for key holders to be DBS (formerly CRB) checked.

Schedule 3 (excluding those containing diethylpropion, buprenorphine, temazepam and flunitrazepam) and Schedule 4

- University policy is for locked storage, this can be as simple as a locked drawer or lab cabinet.
- No specific requirements for transportation around campus.

Schedule 5

- Do not require locked storage, but it is best practice to do so. This could be as simple as a locked drawer or lab cabinet.

- No specific requirements for transportation around campus.

5.5 Record Keeping

Schedule 1 and 2

A Controlled Drug Register is a legal document and must be used to record details of any Schedule 1 or 2 CD received or supplied. A single CD Register is required per building, but not per user, and it is essential that all building users liaise with each other and agree a set location for the CD Register to be held.

The register is required to be a bound book which does not include any form of loose leaf register or card index, or a computerised system which is in accordance with best practice guidance endorsed by the Secretary of State under section 2 of the National Health Service Act 1977.

The legislation requires specific information be recorded in the CD Register for Schedule 1 and 2 CDs, as defined in Appendix 1.

Schedule 3, 4 and 5

The PI will maintain an inventory of Schedule 3, 4 & 5 drugs in their control, listing name of drug, volume held and location. It must be separate to the Register of Schedule 1 and 2 drugs and must be clearly marked to avoid confusion.

5.6 Broach Dates/Expiration Dates of Medicines

Where a medicine's summary of product characteristic (SPC) states that the product must be discarded after a certain time once broached (opened), then that requirement must be adhered to. This applies to all human and animal medicines including CDs.

Multidose vials should be marked with the date of first opening (broached) and the date of expiry.

When medicines reach their expiry date they must be taken out of use, and denatured ready for disposal, see 5.8 below. **NB. It is a legal offence to administer a medicine that has expired.**

5.7 Wastage

It is necessary to account for wastage in the CD Register when using Schedule 2 CDs, since there will be some wastage within the needle and hub of the syringe each time the product is withdrawn.

If numerous doses are withdrawn, there will be considerably more product lost to this 'dead space' than if fewer doses are given. It is not possible to quantify exactly how much product might be wasted in the syringe hub and needle.

There are international manufacturing standards which specify the maximum amount of 'dead space' that is permitted in needles and syringes of different sizes and gauges. You can obtain this information from manufacturers or wholesalers.

Other potential factors that may increase wastage are:

- The use of a separate, larger bore needle to withdraw the product from the vial before changing to a smaller needle to administer the product
- The process of expelling air from the syringe prior to injection.

5.8 Disposal

It is not permissible to dispose of CDs by returning them to a vet or pharmacy and they must be destroyed locally on campus using a CD denaturing kit, e.g. https://www.sellesmedical.co.uk/store/product/3395-Controlled-Drug-Destruction-Kit

CDs requiring disposal must be stored and clearly segregated in a separate container clearly marked for disposal and must not be used. These can be held for a period of time, e.g. three months, and then disposed of collectively. Schedule 2 and 3 drugs awaiting disposal must be stored in the controlled drug safe.

Schedule 1 and 2 drugs must be destroyed in the presence of the 'Authorised Witness'. Currently the Authorised Witness is the local Police Controlled Drugs Liaison Officer.

Schedule 3 and 4 drugs can be destroyed by an individual in the presence of a witness who is a member of University staff and who is not the Authorised Witness.

Schedule 5 drugs do not need to be destroyed but can go into the waste stream as pharmaceutical waste, when properly documented and in a suitable container.

Once CDs have been added to the denaturing kit it must be stored in the controlled drugs cabinet for 24 hours until denaturing is complete, i.e. the drug and denaturing medium mixture has set.

See Appendix 2 on denaturing advice agreed by the Home Office.

Controlled drug waste must not be disposed of in the general black bag or clinical waste but must be documented and disposed of as pharmaceutical waste:

- Human drugs: waste class 18 01 09
- Animal drugs: waste class 18 02 08
- For CDs used in in vitro work the waste class will be dictated by how the drug was requisitioned, e.g. from a pharmacy or veterinarian.

By law, the maximum permissible period for holding drug waste on campus is 6 months; therefore it needs to be removed by the authorised waste management contractor prior to this deadline.

In the event that a waste management contractor requires details of the University's T28 waste exemption certificate, a copy can be obtained from the UoS Director of Health, Safety and Compliance.

6. Training

Heads of Schools and Units should ensure that all staff receive suitable and sufficient training to ensure they are competent in the purchase, storage, use and disposal of CDs.

The SEF QSHE team will deliver in-house training for users on legislative requirements and CD compliance. Enquiries should be made to: HealthSafety@sussexestatesfacilities.co.uk

PIs should ensure that all Postgraduate students receive local inductions and information/guidance with regards to the SOP for the school/unit.

7. Discrepancies / Incidents

Schools/units should appoint a Health and Safety Coordinator/Controlled Drugs Officer or similar representative to carry out regular stock checks and inspections of the premises and registers. Checks should be carried out monthly or more often, depending on the volume of controlled drugs, by a person other than the user of the drug. If discrepancies arise, more frequent reconciliation should be undertaken until the problem is resolved.

Where a CD discrepancy is identified, it must be reported immediately to the Head of School who should investigate the incident promptly. A physical record should also be made on the University Incident Recording system via Sussex Direct (the school/unit HSC will have access to report onto this system).

If the discrepancy cannot be resolved or the discrepancy is such that there is immediate cause for concern, the University Health and Safety and Compliance Director, the SEF QSHE Compliance Manager, the Controlled Drugs Liaison Officer or other appropriate investigating authority should be notified in order that further advice can be given and appropriate action taken.

School/Unit SOPs should clearly define the action that should be taken if a discrepancy between the theoretical and actual balance of stock arises, stating, for example, what action should be taken, when and how the Head of School should be notified and what records should be made.

Those who become aware of discrepancies must make checks to ensure that the reasons for the discrepancy are established. If resolved, a note should be made in the register (by a dated marginal note or footnote), correcting the discrepancy in the balance.

8. Monitoring

There shall be a planned programme of monitoring the ongoing effectiveness of measures that are critical for the control of risk. Schools and Units are expected to conduct routine safety inspections and the SEF QSHE Team will accompany school/service safety coordinators and trade union representatives on an annual

safety inspection. The QSHE Team will also conduct independent audits, inspections and compliance checks throughout the year.

The running balance of drug remaining should be calculated and recorded after each transaction and balances should be checked with the physical amount of stock at regular intervals by Principal Investigators (PI) or those under the PIs supervision.

Appendix 1

Controlled Drugs Register (Schedule 1 and 2)

The Misuse of Drugs Regulations 2001 requires that the class, strength and form of a drug be specified at the head of each page of the controlled drugs register. The register is required to be a bound book which does not include any form of loose leaf register or card index, or a computerised system which is in accordance with best practice guidance endorsed by the Secretary of State under section 2 of the National Health Service Act 1977. It is also a requirement that different classes are kept in a separate part of the register and that, within each class, a separate page is used for different strengths and formulations of each drug.

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All entries made in the controlled drugs register must be:

- **Entered chronologically** – entries must be made in chronological sequence
- **Entered promptly** – entries must be made on the day of the transaction or, if that is not reasonably practicable, on the following day
- **In ink or indelible** – entries and corrections must be in ink or indelible (or computerised)
- **Unaltered** – entries must not be cancelled, obliterated or altered. Corrections must be made by way of marginal note or footnote which shall specify the date on which the correction is made.

The following points regarding record keeping must be adhered to when maintaining controlled drugs registers:

- **Location** – each register should be kept at the premises to which it applies
- **Duration** – registers must be kept for two years from the date of the last entry
- **Form** – records can be kept in their original form or copied and kept in an approved computerised form
- **Inspection** – a copy of the register, and other details of stock, receipts and supplies, must be available to authorised persons (e.g. Controlled Drugs Liaison Officer) upon request.

The headings in respect of entries made for drugs obtained are:

- Date supply received
- Name and address from whom received
- Quantity received.

The headings in respect of entries made for drugs supplied are:

- Date supplied
- Name/Address of person or firm supplied
- Details of authority to possess - prescriber or licence holder's details
- Quantity supplied

The following headings apply only in respect of drugs specified in Schedule 2:

- Details of person collecting Schedule 2 controlled drug (patient, patient's representative, healthcare professional) and if healthcare professional, name and address
- Was proof of identity requested of patient/patient's rep (Yes/No)
- Was proof of identity of person collecting provided (Yes/No).

These are the minimum fields of information that must be recorded. Additional, but relevant, information can be added without contravening the Misuse of Drugs Regulations 2001.

Appendix 2

Annex A

Destruction of Controlled Drugs

All medicines should be disposed of in a safe and appropriate manner. Medicines should be disposed of in appropriate waste containers that are then sent for incineration. They should not be disposed of into the sewerage system.

All controlled drugs in schedule 2, 3 and 4 (part I) should be destroyed by being denatured and rendered irretrievable before being placed into pharmaceutical waste containers and sent for incineration. The context of destruction by denaturing and rendering irretrievable is to guard against the misuse of drugs, harm to the environment or people and prevent the supply of easily retrievable controlled drugs to waste carriers. These methods are not expected to render the detection of active ingredients, or to modify the chemical composition or properties of CDs.

Dosage Form	Method of Destruction
Solid dosage forms (i.e. capsules and tablets)	Grind or crush the solid dose formulation before adding to the CD denaturing kit to ensure that whole tablets or capsules are not retrievable. The use of a small amount of water whilst grinding or crushing may assist in minimising particles of dust being released into the air. An alternative method of denaturing is to crush or grind the solid dose formulation and place it into a small amount of warm, soapy water stirring sufficiently to ensure the drug has been dissolved or dispersed. The resulting mixture may then be poured onto an appropriate amount of cat litter (or similar product) and added to an appropriate waste disposal bin supplied by the waste contractor.
Liquid dosage forms	Pour into an appropriately sized CD denaturing kit. Alternatively pour onto an appropriate amount of cat littler (or similar product) being careful so that the people destroying are protected from harm and the environment is protected from pollution.
Ampoules and vials	For liquid containing ampoules, open the ampoule and empty the contents into a CD denaturing kit, or dispose of in the same manner as liquid dose formulations above. Dispose of the ampoule as sharps pharmaceutical waste. For powder containing ampoules, open the ampoule and add water to dissolve the powder inside. The resulting mixture can be poured into the CD denaturing kit and the ampoule disposed of as sharps pharmaceutical waster. An alternative but less preferable, disposal method is where the ampoules are crushed with a pestle inside and empty plastic container. Once broken, a small quantity of warm soapy water (for powder ampoules) or cat litter (for liquid ampoules) is added. If these methods are used, care should be taken to ensure that the glass does not harm the person destroying the CD. The resulting liquid mixture should be disposed of in a CD denaturing kit or in the bin that is used for disposal of liquid medicines.
Patches	Remove the backing and fold the patch over on itself. Place into a waste disposal bin or a CD denaturing kit.
Aerosol formulations	Expel into water and dispose of the resulting liquid in accordance with the guidance above on destroying liquid formulations. If this is not possible because of the nature of the formulation, expel into an absorbent material and dispose of this as pharmaceutical waste. Alternatively consider if it would be safe to open or to otherwise compromise the container to release the controlled drug safely. The resulting liquid mixture should be disposed of in a CD denaturing kit or absorbed onto cat litter and disposed of as pharmaceutical waste.

Appendix 3

References / Related Documents

Health Act 2006
http://www.legislation.gov.uk/ukpga/2006/28/contents

The Misuse of Drugs Regulations 2001
http://www.legislation.gov.uk/uksi/2001/3998/contents/made

The Misuse of Drugs (Safe Custody) Regulations 1973
http://www.legislation.gov.uk/uksi/1973/798/contents/made

Misuse of Drugs (Amendment) (No.2) Regulations 2015
http://www.legislation.gov.uk/uksi/2015/891/contents/made

Veterinary Medicines Regulations 2013
http://www.legislation.gov.uk/uksi/2013/2033/contents/made

Environmental Permitting (England and Wales) Regulations 2010
http://www.legislation.gov.uk/uksi/2010/675/contents/made

Controlled Drugs, Home Office
https://www.gov.uk/controlled-drugs-licences-fees-and-returns

Denaturing of Controlled Drugs, Home Office
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