1. PURPOSE AND SCOPE

This Standard Operating Procedure (SOP) describes the process for the purchase, storage and use of Category 1 Drugs Precursors and Schedule 1 Controlled Drugs within the University of Warwick.

2. INTRODUCTION

Controlled drugs as listed in schedule 1 to the Misuse of Drugs legislation requires research establishments to be licenced to possess or use those materials. Similar requirements apply to materials listed as Category 1 controlled drugs precursors. The legislation aims to prevent illicit use via licences issued by the Home Office. In order to maintain the licence, the material needs to be handled and stored in an appropriate manner. This SOP sets out detail to allow the University to meets its obligations.

3. POLICY

It is the University's policy that a central SOP is maintained and shared via the relevant web pages, and that any department carrying out research with Precursors or Controlled Drugs will have a local arrangements detailed in their own SOP documents.

4. DEFINITIONS

Drug Precursor

A drug precursor is defined as a substance that can be, and is being, used to manufacture synthetic drugs that may then be traded illicitly. Some drug precursors are specific substances with well-established routes of drug manufacture (Category 1); others may be common chemicals found in most laboratories (Category 2 and 3).

Controlled Drug

Controlled drugs are any drugs that are named in the 5 schedules to the Misuse of Drugs legislation. A licence is required for the possession of any drug in Schedule 1 and the production of any drug in all the schedules.

5. RESPONSIBILITIES

Responsible Officer

The Director of Health and Safety as the Responsible Officer for the University for Classified Materials

- Authorises each purchase
- Approves control measures
- Instructs a witness for each ultimate disposal
- Maintains records for each bottle of classified material supported by the Principle Investigator for the research
- Maintains register of classified materials (by department)
- Checks with others including the Chair of the Departmental Health and Safety committees and Head of Security before authorisation

Guarantor

A senior person within the organisation that agrees to guarantee the responsible officer's performance of their obligations. The Deputy Registrar performs this role.

Advisor
A member of the Health and Safety team who may be assigned roles within this procedure to support the Director of Health and Safety.

Departmental Contact
Normally a member of the Technical Services team within the relevant department.

Principle Investigator (PI)
A senior academic with responsibility for the intellectual leadership of the research project and for the overall management of the research group.

Academic Owner
This is normally the PI, although under certain circumstances it could be some other senior researcher within the group who takes lead on the project and reports to the PI as well as acting as a principle point of contact

Authorised User
A member of the research group who has demonstrated an appropriate level of competence to the PI. The PI (or Academic Owner) maintains a list of authorised users for the classified materials and shares this with the Director of Health and Safety.

6. PROCEDURE

6.1 Information and Documentation

The Health and Safety Webpages provide an overview of the 'Requirements for Controlled Substances', which includes links to this SOP and the 'Request to Purchase' form, which initiates the authorisation process.

6.2 Approval of orders for new substances

Before any consideration is given to the purchase of a new Controlled Substance, it must first be demonstrated that current stock holdings have been checked. Where the current stock has been found to be suitable for the planned research then an application to use the material must be submitted noting that it is existing stock.

Where a new material is required, then the PI must submit an application to the Director of Health and Safety using the 'Request to Purchase' form on the H&S website. The request must be approved by the head of department or the departmental health and safety committee chairperson before submission to the Responsible Officer, and must be supported by an assessment of the security arrangements and a draft local SOP. Where the requested quantity is in excess of 50 grams, the Responsible Officer will request further justification to support the application.

6.3 Acceptance of deliveries & procedures upon receipt

Upon receipt of a Controlled Substance into departmental stores, the materials must be held in a secure location, under lock and key in stores. The Stores Manager will inform the designated Departmental Contact immediately so that they can take receipt and place in the designated storage location as soon as possible.

6.4 Suitability of designated storage

Maximum stock holding in any single location should not exceed 500g in total. The ***minimum requirement*** is a cabinet which meets the specifications set out in the Misuse of Drugs (Safe Custody) Regulations 1973, although a small safe might be more appropriate. The storage cabinet / safe must be secured to a wall or floor within its chosen location.

Special permissions and arrangements will be required for temperature sensitive materials, and such special arrangements will need Home Office approval before any such materials are acquired.

6.5 Security arrangements relating to designated storage

The Security team need to be made aware of the storage facility and they will need to prepare a security response plan in conjunction with the user department. The plan needs to include the actions to take following a security breach and upon discovery that some material is missing. Once the arrangements and plan have been agreed a copy needs to be registered with the Director of Health and Safety.

Key control

Where access to the secure storage area is via a key, then appropriate key management facilities and arrangements needs to be adopted. A 'key safe' is required for the secure storage of the keys to the storage area and cabinet.

Consideration must be given to the general security arrangements in relation to the location of the designated storage against the latest Home Office Guidance[(1)], looking in particular at whether one or more of the following might be required:

- An electronic access control system with a clear audit trail (such as swipe card controlled access)
- An alarm system
- CCTV coverage (which is recorded and detector-activated).

In making a risk based assessment of the above consideration also needs to be given to whether any additional controls are proportionate, and whether they do actually improve the overall security. A security risk assessment form, which provides a useful checklist of things to consider, is available from the Health and Safety team.

6.6 Controlling the use of controlled substances

All research involving the use of Classified Materials must be approved by the Director of Health and Safety. Only persons who are deemed competent by the PI or the Academic Owner will be authorised to handle such materials. Access to the Classified Material is controlled by the Departmental Contact or the designated PI.

Local controls for the security of Controlled Substances must be documented in the relevant SOP, and should cover how the materials will be secured after they have been 'signed-out' for use: they must be secure at all times during transit and use. Materials must not be left unattended at any time during use, unless they are kept in a secure room or temporary storage. Any substances being used must be returned to the designated storage at the end of each day and secured, after having been weighed. No substances can be 'signed-out' to researchers overnight.

6.7 Record keeping and cross-checking processes

Each occasion of use must be recorded on the appropriate electronic form and copies kept with the researchers lab book or other approved means of recording research activities and the Departmental Contact. The standard Excel based record log, which can be accessed and updated by the Departmental Contact as and when required, must be updated by the Departmental Contact at the time of each use, showing opening and closing weights for the substance in question. This electronic format enables ready access by the Responsible Officer for audit purposes and can be shared across the departments when others are considering research involving such materials. This will allow a simplified compilation of Controlled Substances records when statutory annual returns are required. In essence a paper copy still needs to be kept, in addition to the Excel based record, and local arrangements should require the Authorised User to document any usage in their own Laboratory Book.

6.8 Audits, inspections and stock checks

The Departmental Contact will weigh the substances each and every time they are signed-out or returned and records updated accordingly. The Departmental Contact will also carry out stock checks at least annually and will review stocks when a request has been made to use some material. Annual Inspections will be carried out by the Head of Safety Committee, the Departmental Contact and the Advisor. The report of the inspection to be shared with the Director of Health and Safety and the Head of Department.

6.9 Operative and management responsibilities, authorisation and competence requirements

It is the responsibility of the PI to ensure that all involved in the research with the Controlled Substances are competent for the work. The PI may divest that responsibility to an Academic Owner who will in turn ensure that all who are involved in the research work will operate in a safe and secure manner. It is the responsibility of the Academic Owner/PI to ensure users of the materials are registered with Department and the Director of Health and Safety, and have received appropriate training to allow them to understand and follow the procedures.

6.10 Controlled drug destructions and witnessed disposal arrangements

The PI / Academic Owner must inform the Director of Health and Safety on the appropriate form ('Request to Purchase' form will suffice) when there is classified material requiring destruction. The Director will agree the destruction method and appoint a witness for the destruction. The witness must not be a member of the department requiring the disposal. The witness will normally be an Advisor as defined in this procedure.

6.11 Theft, loss or adverse incident reporting and handling

Any theft, attempted theft, or any other incident involving the use, handling or storage of Classified Material must be reported to the Director of Health and Safety using the Incident Report Form.

7. STORAGE AND ARCHIVING OF THIS SOP

This SOP is saved within the H&S filing system at M:\SF\OCH 2006\OHSMS\03 System Folders WIP\03 Develop and Implement Controls\04 SOPs (B5)\01 H&S Team SOPs

8. RELATED DOCUMENTS

None

9. REFERENCES

Security guidance for all existing or prospective Home Office Controlled Drug Licensees and/or Precursor Chemical Licensees or Registrants
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/271565/SecurityGuidanceBusinessesOrganisationsJan14.pdf

10. CREATION AND CHANGE HISTORY

Document creation and approval

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Change history

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