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### **1. PURPOSE**

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This Standard Operating Procedure (SOP) outlines the storage, use, and disposal of a controlled substance used for animal care research.

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### **2. RESPONSIBILITY**

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Principal investigator (PI) and their research staff.

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### **3. GENERAL**

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- 3.1. This SOP aims to ensure the health and safety of the BGU community working with controlled substances in laboratory animal research and teaching.
  - 3.2. This SOP does not apply to BGU-affiliated hospitals.
  - 3.3. For relevant questions, please contact the BGU veterinarians or the safety department.
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### **4. ENVIRONMENTAL HEALTH AND SAFETY CONSIDERATIONS**

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- 4.1 A researcher requiring a controlled substance must notify the BGU safety department and obtain permission to hold controlled substances in their laboratory.
- 4.2 A researcher must ensure that they and all other individuals participating in the same research project, under the researcher's direction and control, are familiar with the legislative and external regulations governing controlled drugs and substances and that they and these individuals follow this SOP and Israel Ministry of Health regulation.
- 4.3 Researchers must ensure that they and any individuals participating in the same project have received the appropriate training and orientation under the researcher's direction and control.
- 4.4 Researchers must maintain adequate recordkeeping for the **purchase**, if applicable, the **administration**, **location**, and **disposal** of controlled substances, both in writing, using the appropriate records appended to this SOP, with the understanding that they may, upon request, be required to make written records available to the Ministry of Health inspectors, and in the context of research involving animals, to the Facility Animal Care Committee (FACC), or **Veterinary staff**.
- 4.5 Researchers must ensure that the written records are maintained for the total period of the approved research.

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## 5. DEFINITIONS

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- 5.1 Controlled substances are drugs that have significant abuse risks. These include, but are not limited to:
- 5.1.1. Opioids:
    - 5.1.1.1 Buprenorphine
    - 5.1.1.2 Butorphanol
    - 5.1.1.3 Embutramide (as part of T61)
  - 5.1.2 Barbiturates:
    - 5.1.2.1 Pentobarbital
  - 5.1.3 Dissociative anesthetics:
    - 5.1.3.1 Ketamine

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## 6. STORAGE, ADMINISTRATION, AND DISPOSAL REQUIREMENTS

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- 6.1 The storage conditions and physical security requirements for controlled substances depend on the security level and classification assigned to the drug by Israel Health Ministry. The researcher must ensure that the storage conditions and physical security for controlled substances, including mixtures and dilutions, duly in their possession satisfies the requirements of the Israel Health Ministry.
- 6.2 Security requirements include a cupboard, refrigerator, a drawer in a steel cabinet, or an equivalent that may be used to contain controlled substances, and that the storage units are **in locked rooms** and fastened to the room's floor or wall. The storage unit **must** be secured with an **approved padlock or equivalent locking** mechanism. Records of the issuing of combinations and keys, under the authorization of a departmental designate, must be maintained and made available to Israel Health Ministry inspectors and the veterinarian staff upon request.
- 6.3 Researchers must store their controlled substances separately from the inventory of other researchers.
- 6.4 Only the researcher and authorized individuals can access the controlled substance storage unit.
- 6.5 The researcher cannot transfer any quantity of Controlled Substances in inventory to other researchers.
- 6.6 The researcher may appoint authorized persons to administer substances. The names and signatures of the authorized persons and storage units and locations to which they have access must be documented on the "**Controlled Substance Authorized Person Record**" (appendix 1) appended to this SOP.
- 6.7 Authorized individuals must follow the procedures outlined in this SOP and are obligated to immediately report any suspected loss or diversion of controlled substances to the licensee.
- 6.8 Only the researcher or authorized persons may access and administer controlled substances and must ensure to complete of the "**Ordering/Receiving Record, and Administration Record**" (Appendix 2 and 3) appended to this SOP accordingly.
- 6.9 Controlled substances **must never** be used after their expiration date.
- 6.10 The researcher must ensure that the "Administration Record" is completed each time they administer a controlled substance, dilution, or mixture.
- 6.11 When preparing a dilution and mixture of controlled drugs, the researcher must ensure that:
- the dilution or mixture is assigned a tracking number composed of the original tracking number with an added sequential letter, e.g., 131219-1A, 131219-1B
  - each dilution or mixture is separately and individually recorded

- an "Administration Record" is prepared for the dilution or mixture using the new tracking number
  - the tube or vial of dilution/mixture is identified with the new tracking number
  - all dilutions or mixtures containing a controlled drug are stored as described following the conditions and requirements.
- 6.12 The researcher is responsible for destroying any unused or expired controlled substance duly in their possession.
- 6.13 The destruction of a controlled substance must be witnessed by an individual participating in the same project.
- 6.14 The researcher, authorized person, and the witness must sign and print their names on a joint statement indicating that they witnessed the destruction and that the controlled substance destroyed has been altered or denatured to such an extent that its consumption has been rendered impossible or improbable.
- 6.15 Controlled substances, destroyed or otherwise, must never be flushed or poured down a drain.
- 6.16 The researcher must contact the BGU Biological Security department for the disposal of full disposal containers.
- 6.17 The researcher must ensure that the amount discarded, the date of destruction, and the reason for destruction are logged on the "Administration Record."
- 6.18 Any theft or loss must be reported immediately to BGU Security Office and the Biological Security department.

***SOP 603 CONTROLLED SUBSTANCES***

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*Approved by the BGU Animal Policy and Welfare Oversight Committee*





