Propofol Handling and Security in Research

Propofol, also known as [2,6-DIISOPROPYLPHENOL], is not a controlled substance, however, the policy of the University of Michigan is that propofol will be stored, handled, and tracked with the same internal controls that are applied when working with federally-regulated controlled substances. The Principal Investigator (PI) using propofol for research is responsible for applying effective internal controls to guard against theft and diversion of propofol, including maintaining accurate records and properly storing propofol according to University of Michigan (U-M) policy and procedures (see U-M Policy on the Use of Controlled Substances in Research and Education).

## Authorized Personnel

The PI holds ultimate responsibility for restricting access to propofol and is **required** to:

1. Keep an updated [Authorized Personnel Log](http://research-compliance.umich.edu/files/authorizedpersonnel-logdocx) on file that lists the authorized agents and authorized personnel.
2. Complete and keep on file a signed [UM-Authorized Personnel Screening Statement Form](http://research.umich.edu/files/CSIR/AuthorizedPersonnel_ScreeningForm.pdf) for **each** authorized individual. This form is based on the screening questions outlined in [Title 21, CFR.1301.90](http://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_90.htm).

### Denying access

Deny access to propofol to any individuals with a known/confirmed:

* Controlled substance abuse problem (unless the individual is actively enrolled in a health professional recovery program with a current monitoring agreement)
* Suspended, revoked, denied, or surrendered-for-cause controlled substance license/registration
* Current sentence for the conviction of a crime that involves controlled substances

## Ordering and Receiving

Propofol may be obtained from the U-M Central B2 Pharmacy or an approved outside supplier. Propofol receipts must signed, dated, and filed in an easily accessible location. Only authorized personnel may order and receive propofol.

## Secure Storage Requirements

Propofol must be stored in the same manner as state and DEA-regulated controlled substances. At minimum, this is to include a locked, substantially constructed cabinet or safe.

* Propofol requiring refrigeration must be locked in a container securely fastened within a refrigeration unit unless the refrigeration unit can be locked from the outside.

![C:\Users\bethwend\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\8C22VYYI\MC900434750[1].png]() Portable storage boxes or storage in high-activity areas (e.g., corridors) are not allowed.

## Recordkeeping

Propofol use must be documented in the same manner as state and DEA-regulated controlled substances and per U-M policy. See [Maintain Controlled Substance Records](http://research-compliance.umich.edu/maintain-controlled-substance-records) for more detailed information. Use logs must be filed in an easily accessible location.

## Annual Inventory

A list (i.e., inventory) of all propofol currently being stored must be taken each year at the same time. The annual propofol inventory must be filed with the other required propofol records.

## Disposal

Expired or unwanted propofol must be stored in the secure location until it can be picked up by a licensed reverse distributor. Once pickup occurs, detailed disposal information must be recorded on the appropriate use log and chain of custody form. See [Dispose of Controlled Substances](http://research-compliance.umich.edu/dispose-controlled-substances) for more detailed information.

## Waste

Propofol that is spilled or contaminated must be cleaned up in a manner that is consistent with state and DEA-regulated controlled substances. A witness **must** be present to observe the cleanup and record their initials on the associated use logs. See the waste section of the [Dispose of Controlled Substances](http://research-compliance.umich.edu/dispose-controlled-substances) document for more detailed information.

## Questions?

Contact the Controlled Substance Monitor (Kelli Christman) at 734-764-2003 (x42003) or

cs-monitors@med.umich.edu.