(A) Policy Statement

The University Of Toledo Medical Center Pharmacy Department will supply controlled substances intended for Institutional approved research to licensed individuals or departments, where research is being conducted or supervised by an individual licensed to prescribe or possess controlled substances only when other options are exhausted. Researchers or their appropriate supervisors need to order directly through the designated wholesaler for the University of Toledo.

(B) Purpose of Policy

To insure that all controlled substances schedules (II-V) are ordered, controlled and utilized in compliance with state and federal regulations and Good Clinical Practice (GCP).

(C) Procedure

1. Physicians with a valid DEA license may conduct research utilizing controlled drugs in schedules II-V and a copy of the terminal distributor’s license may order controlled substances for research purposes.

2. Departmental research in which a physician with a DEA license is not involved may apply to the DEA for a license to conduct research. The DEA requires the designation of a responsible individual. The DEA will also require that the responsible person have a valid Ohio category III(3) Terminal Distributor of Dangerous drugs license.

3. The pharmacy will retain these records for three years.

4. All requisitions for controlled substances must be signed by the responsible individual. The requisition must also include the valid DEA number. Requisitions are rejected if the signature is not legible or a DEA number is not included.

5. All requisitions for Schedule II controlled substances must be accompanied by a DEA controlled substance order form (DEA 222). The form must be completely filled out and signed. An incomplete order form will be returned to the ordering individual. (DEA 222 forms may be obtained by phoning the Drug Enforcement Administration, Detroit regional office at 1-800-230-6844).

6. All controlled substances must be picked up and signed for at the pharmacy department between 7:00 am and 3:30 pm, Monday through Friday.

7. Any destruction of investigational controlled substances must comply with GCP and all state and federal laws.

8. All records are maintained in accordance with GCP and state and federal laws.
References:
Terminal Distributor Licensing of Prescriber Practices Ohio Board of Pharmacy updated 2-2-2017
Ohio Administrative Code 4729-13-02

It is the responsibility of the reader to verify with the responsible agent that this is the most current version of the policy.