Name of Policy:	**Distribution of Controlled Substances for Research Use**	
Policy Number:	3364-133-90	
Department:	Pharmacy	
Approving Officer:	Senior Hospital Administrator	
Responsible Agent:	Director of Pharmacy	Effective Date: 06/01/2023
Scope:	University of Toledo Medical Center	Initial Effective Date: February 14, 1992

_____	New policy proposal	_____	Minor/technical revision of existing policy
_____	Major revision of existing policy	X	Reaffirmation of existing policy

(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.

All controlled substances (investigational drugs and/or study drugs) to be used in human subjects research must be centrally managed by Investigational Drug Services of the pharmacy department for all aspects of drug accountability, including, but not limited to: drug ordering, receipt, storage, distribution, and disposition processes. See 003-IPP Investigational Drugs for details or contact Clinical Research Pharmacist.

(B) Purpose of Policy

To ensure that all controlled substances schedules (II-V) are ordered, controlled and utilized in compliance with state and federal regulations and Good Clinical Practice (GCP). The inpatient pharmacy's DEA license and registration does not permit the possession or distribution of schedule I controlled substances in accordance with University policy 3364-133-26. Schedule I requires individual DEA licensure as a Researcher with Schedule I substances.

(C) Procedure

1. Physicians with a valid DEA license may conduct research utilizing controlled drugs in schedules II-V, without obtaining a separate license for research. Controlled substances used in animal research must be compliant with University policy 3364-70-27.

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. 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.

4. 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).

5. 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.

6. All records are maintained in accordance with GCP and state and federal laws.

References:

DEA Form 2225 New Application for Registration. Available at: https://www.deadiversion.usdoj.gov/drugreg/reg_apps/225/225_instruct.htm. Retrieved February 14, 2020.
Terminal Distributor Licensing of Prescriber Practices Ohio Board of Pharmacy updated 2-2-2017
Ohio Administrative Code 4729-13-02

Approved by:		**Review/Revision Date:**
		04/93
		6/96
/s/	05/23/2023	04/99
Lindsey Eitniear, PharmD, BCPS, AAHIVP	Date	07/02
Director of Pharmacy		07/04
		1/08
		5/11
/s/	05/24/2023	2/14
Russell Smith, PharmD, MBA, BCPS, CPEL	Date	4/17
Senior Hospital Administrator		2/20
		2/23
Review/Revision Completed By:		
Pharmacy		
		Next Review Date: 2/1/2026
Policies Superseded by This Policy:		