Use of Controlled Substances in Clinical Research

MUSC
MEDICAL UNIVERSITY of SOUTH CAROLINA

Established: June 26, 2019
Responsible Office: Office of the Vice President for Research
Latest Version: June 2019

SUMMARY:

A controlled substance is any drug or substance listed in the Controlled Substance Act of 1970 in Schedules I-V. When used in research in South Carolina, all controlled substances are subject to both Drug Enforcement Agency (DEA) and SC Department of Health and Environmental Control (SC DHEC) regulation. When the use of a controlled substance is being evaluated in a clinical trial, FDA regulations also apply (21 CFR 312).

POLICY STATEMENT:

The purpose of this policy is to:

a) Describe investigator responsibilities for the use of controlled substances in clinical research

b) Describe requirements for registration with DEA and DHEC

c) Describe drug accountability requirements

d) List institutional entities with oversight of controlled substances in research

RESPONSIBILITIES:

The Principal Investigator (PI) is responsible for working with the Controlled Substance Auditor of MUSC's Internal Audit Department to obtain appropriate DEA and DHEC registrations for the use of controlled substances in research. The PI is also responsible for storing controlled substances in a locked, limited access location that is approved by DHEC. The PI must also maintain an accurate running inventory of all controlled substances at all times.

POLICY:

1. Controlled substances used in inpatient research must be coordinated through Investigational Drug Services (IDS)[1] and the PI is responsible for following all procedures as defined in hospital policy C-136, "Research Involving Investigational Medicines within MUSC Medical Center Policy and Procedures."
2. Controlled substances used in outpatient research are subject to the MUSC Department of Pharmacy Policy E07, Controlled Substances: Procurement, Storage, Distribution, and Disposal Within and From Pharmacy Areas.
3. Instructions for researchers regarding state and federal requirements can be found on the Internal Audit Department website in the form of "Controlled Substance Registration Process and Record Keeping" (https://web.musc.edu/about/leadership/institutional-offices/internal-audit/controlled-substances/forms)
4. In addition to the above requirements, the PI must maintain a log for each controlled substance that includes participant name/study ID, quantity provided, prescriber name, and initials of the appropriately delegated individual who prepared/gave out the controlled substance.

[1] IDS is not registered to handle any Schedule I controlled substances.

5. The MUSC Internal Audit Department has oversight of the storage and drug accountability records of controlled substances. Drug Accountability may also be reviewed by the University Compliance Office.

Contact Information

For information regarding the overall policy and related documents, please contact the SCTR SUCCESS center, (843-792-8300, success@musc.edu). For questions related to specific department roles/responsibilities, please contact the applicable department directly.

Related Information

https://web.musc.edu/about/leadership/institutional-offices/internal-audit/controlled-substances/forms

Approved By	Information Contact	Effective On:
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