

Controlled Substances in Research

Policy Statement

Certain research protocols conducted by faculty of the University may require the use of controlled substances. As part of the planning for the use of such substances in research, the research protocol must be reviewed by the Director of Research and Sponsored Programs and authorization given for the use of the specific substances.

In conducting research with controlled substances, all authorized personnel must comply with University policies, federal and state laws and regulations regarding background checks, use, licensure; storage requirements, inventory maintenance, substance disposal, reporting and record keeping in accordance with Title 21, Part 1300-1308 of the Code of Federal Regulations (CFR).

All matters related to the University Drug Enforcement Administration (DEA) Controlled Substances Registration Certificate are a function of the Office of Research and Sponsored Programs (ORSP) and the Director of Research and Sponsored Programs.

The Director of Research and Sponsored Programs will assist researchers in complying with applicable rules and regulations and provide information regarding University procedures.

Definitions

Controlled Substance – Section 802 (6) of Title 21, United States Code (USC) provides the legal definition of a controlled substance. The term means a drug or other substance included in schedule I, II, III, IV or V of part B of this subchapter.

Authorized Personnel – An individual working on a research protocol authorized by the Director of Research and Sponsored Programs.

Related Policies and Committees

Policy - [Institutional Review of Research Involving Human Participants](#)

Policy - [Educational Training in Human Participants Protection for Investigators](#)

Policy - [Educational Training in Human Participants Protection for IRB Members and IRB Administrators](#)

Policy - [Educational Training in Animal Research](#)

Committee - [Institutional Review Board for the Protection of Human Participants](#)

History of the Policy

03/02/09 - Approved by the President of the University as recommended by the Policy Committee of the University
09/13/12 – Editorial changes to correct website link.

10/12/16 – Request from the Office of Research and Sponsored Programs to change the title of a position and the name of the department was approved by the President of the University as recommended by the Policy Committee of the University.

Mary Theresa Gardier Paterson
Secretary of the University and General Counsel