Wake Forest Baptist Medical Center	The Use of Controlled Substances in Research Policy Number:	Type:	Tier 2
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Approval Signature:		Date Approved:	12/1/2012
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I. Policy Statement

Certain research activities require the use of controlled substances. Controlled substances, which are substances with high potential for abuse, are identified in the schedules contained within the "Controlled Substances Inventory List," published by the U.S. Drug Enforcement Administration (DEA). In conducting research with controlled substances, authorized employees must comply with federal and state laws and regulations regarding their use, including DEA registration and North Carolina Department of Health and Human Services licensure; storage requirements; inventory maintenance; substance disposal; and reporting and record keeping, in accordance with Title 21, Part 1300-1308 of the Code of Federal Regulations (CFR) and the North Carolina Controlled Substances Act.

II. Responsibilities

A. Principal Investigator. Principal Investigators or supervisors of research in which controlled substances are used, bear full responsibility for complying with Federal and state laws and regulations, and with institutional policy regarding their use. Specifically, they are responsible for:

- Obtaining a Controlled Substance Use Authorization from Environmental Health and Safety.
- Obtaining and maintaining appropriate licensure from the North Carolina Department of Health and Human Services.
- Obtaining and maintaining appropriate registration from the DEA.
- Establishing security measures for the purchase, acceptance, use, and ultimate disposal of the controlled substances used in their research.
- Providing the Director, Environmental Health and Safety with copies of the appropriate North Carolina License and DEA registration.

When applicable, investigators or supervisors of research in which controlled substances will be used are responsible for obtaining approval for their use from the appropriate institutional committees that oversee human subject and animal subjects research (e.g., the relevant Institutional Review Board or the Institutional Animal Care and Use Committee) and must report their intention to use controlled substances to external funding sponsors upon submission of grant applications. Individuals who have obtained the appropriate state and federal registration to use controlled substances and have submitted a notification of "Notification of Controlled Substances Registration or Renewal" form to EH&S are authorized to purchase, accept, and dispose of these substances (according to regulatory requirements).

If a Principal Investigator becomes aware of any loss, diversion, or substantial noncompliance with regard to controlled substances, the Investigator must notify the CS Officer within 24 hours of first knowledge. Investigators should have adequate systems in place to ensure that they will be made aware of any such matters known within the research staff.

B. **Senior Associate Dean for Research.** In the event the CS Officer (Director, EH&S) becomes or is made aware of a potential loss, diversion, or noncompliance with regard to controlled substances, the CS Officer will report all such matters to the Senior Associate Dean for Research. Upon receiving notice of the matter, the Senior Associate Dean, in consultation with and assisted by the CS Officer, will take appropriate steps to obtain additional information in order to assess the seriousness of the matter and determine if remedial action is necessary. WFBMC Security will provide investigatory assistance as necessary. The US DEA will be informed if warranted.

C. **Environmental Health and Safety.** The Director, Environmental Health and Safety will be designated the Controlled Substances (CS) Officer.

Environmental Health & Safety (EH&S) shall have responsibility for conducting annual surveys of any laboratories that have licenses to use Controlled Substances. EH&S will also provide procedural and documentation guidance for PIs and Authorized Individuals. EH&S shall also have responsibility for assisting in the disposal of Controlled Substances. Periodically, EH&S will provide an inspection summary report, including corrective action recommendations, to the Senior Associate Dean for Research.

III. Purchasing Controlled Substances

Orders for controlled substances by DEA registrants must be submitted according to institutional purchasing policies and procedures. DEA Form 222 and a copy of the DEA registration must accompany the requisition.

IV. Receiving Controlled Substances

Controlled substances must be shipped to the registrant and address as indicated on the DEA registration. Once received, the controlled substances should be opened to verify the contents and any discrepancies should be resolved with the supplier. From the time a controlled substance is accepted on campus until it is consumed or disposed of, a record of the chain of custody must be kept at each point where the substance changes hands or is used. The record is completed at each point by the person delivering the substance and includes the name of the substance, the quantity, and the signature of the person receiving it. The person making the withdrawal shall sign all records of withdrawals of controlled substances from storage.

V. Continuing Records

The registrant shall maintain an accurate continuing record or log of each controlled substance received, disposed of or otherwise used by him or her, in accordance with 21 CFR 1304.21 and 1304.24. The registrant for each registered location and for each

independent activity for which the registrant is registered shall maintain separate records. The registrant must maintain the continuing records for 3 years.

VI. Inventory

Each DEA registrant must maintain an accurate inventory of controlled substances. The registrant will conduct an annual inventory and reconciliation as part of a self-audit. Inventories for schedule I and II controlled substances shall be maintained separately from other laboratory records. A copy of the completed inventory must be retained for 3 years and be made available to institutional or regulatory authorities when requested.

Any discrepancy in the continuing record or inventory of controlled substances must be reported to the CS Officer immediately upon discovery.

VII. Storage and Security

All DEA registrants must provide effective controls and procedures to guard against theft and diversion of controlled substances. Considerations in determining security requirements: the type of activity, the type and form of controlled substance, the quantity of controlled substance, the location of the premises, the type of building construction, the type of vault, safe, and secure enclosures, the adequacy of key control systems, the adequacy of electric detection and alarm systems, the extent of unsupervised public access, the adequacy of supervision over employees with access, procedures for handling visitors, the availability of local police and adequacy of the use and disposal tracking system (CFR 1301.71-1301.76).

VIII. Disposal

The registrant having custody of the controlled substance shall make disposal in accordance with institutional policy and federal regulations. Any questions or difficulties regarding the disposal of controlled substances should be directed to Environmental Health and Safety.

IX. Relevant Federal and State Regulations concerning Controlled Substances

Federal: Title 21 CFR Part 1300

State: North Carolina Controlled Substances Act