CONTROLLED SUBSTANCES POLICY AND PROCEDURES FOR MEDICAL CENTER RESEARCHERS

1) REGISTRATION

In order to use controlled substances for research purposes, a researcher must be registered with both The Department of Health of the State of New York, Bureau of Controlled Substances and with the US Department of Justice, Drug Enforcement Administration (DEA).

A) Bureau of Controlled Substances (NYS)

The Bureau of Controlled Substances of New York State issues two classes of research licenses (Class 4 or Class 7). An application for license can be obtained in the Grants and Contracts Office (GCO).

Class 4 Researcher License:

Each person engaged in research using controlled substances in Schedule II - V (defined below), must obtain an individual research license in Class 4.

Class 7 Research and Instructional License:

Each person engaged in research using controlled substances in Schedule I (defined below) must obtain an individual research license in Class 7 and file with the Bureau three copies of a research protocol describing the research project.

B) Drug Enforcement Administration (DEA) - Federal

A researcher registration is required by the DEA to conduct research with controlled substances in drug Schedules II through Schedule V. This must be done after approval by the NYS Bureau of Controlled Substances. An application for registration is available in the Grants and Contracts Office (GCO).

A researcher can obtain a separate research license from the DEA or be covered under a Departmental license. The DEA and The Mount Sinai School of Medicine recommend that each Department performing research using controlled drugs obtain a DEA research license.

In addition, a special registration from the DEA is required to conduct research using Schedule I substances.

C) Mount Sinai School of Medicine

When filing research protocols involving use of controlled substances with the Grants and Contracts Office (GCO), the following information must be provided on the appropriate GCO Form: name of licensed investigator or department, DEA and New York State research license numbers, class and expiration dates, and controlled substances to be used.

II. SCHEDULES OF CONTROLLED SUBSTANCES

A) Schedule I Substances:

The drugs in this schedule are those that have no accepted medical use in the United States and have a high abuse potential. Examples are heroin, marijuana and LSD.

B) Schedule II Substances:

The drugs in this schedule have a high abuse potential with severe psychic or physical dependence liability. This Schedule consists of certain narcotic, stimulant and depressant drugs. Examples are morphine, codeine, methadone, amphetamine (Dexedrine), methylphenidate (Ritalin) and secorbarbital.

C) Schedule III Substances:

The drugs in this schedule have an abuse potential less than those in Schedules I and II and include compounds containing limited quantities of certain narcotic drugs and non-narcotic drugs. Examples are glutethimide (Doriden) and paregoric. Any suppository dosage form containing amobarbital, secobarbital, or pentobarbital is in this schedule.

D) Schedule IV Substances:

The drugs in this schedule have an abuse potential less than those listed in Schedule III. Examples are phenobarbital, chloral hydrate, diazapem, (Valium), dextropropoxyphene (Darvon) and pentazocine (Talwin).

E) Schedule V Substances:

The drugs in this schedule have an abuse potential less than in Schedule IV and consist of preparations containing limited quantities of certain narcotic drugs generally for antitussive and antidiarreal purposes.

III. RECORDS

A) Researchers, licensed and authorized to possess and use controlled substances, shall keep a record of all such substances received and used by them.

1. A record of all controlled substances received shall include date of receipt, name and address of vendor, type and quantity of drug received. A duplicate invoice or separate itemized list furnished by the vendor will be sufficient to meet this record requirement providing it contains all the information required and is maintained in a separate file.

2. A record of all controlled substances used shall include the name of the person authorized to control and use such drugs, the date, type and quantity of drug and signature of the user.

3. In addition, such records shall contain the following information for each controlled substance:

⇒ Name of substance
⇒ Each finished form (such as 10 mg.tablet or 10 mg. concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container
⇒ The number of commercial containers of such finished form received from other persons, including the date of and number of containers in each receipt, and the name, address, and registration number of the person from whom the containers were received
⇒ The amount of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, and the written or typewritten name or initials of the individual who dispensed or administered the substance

B) A record must be kept of any drug disposed of or returned to the vendor, by loss or waste or by destruction by the New York State Bureau of Narcotics.

C) A Record of Utilization of Controlled Substances form (see Exhibit I) can be used to monitor the use of these controlled substances as directed in paragraphs A and B above. This form could also be used to record the results of physical inventories required by Paragraph IV, D.

D) Records must be kept for 5 years.

IV. SAFEGUARDING CONTROLLED SUBSTANCES

A) Controlled substances must be properly safeguarded and securely stored.

B) Access should be limited to a minimum number of personnel. Controlling access is the responsibility of the licensee.

C) At a minimum, a solid metal cabinet with separate outer and inner, key-locked doors is required for Schedules III, IV and V. A safe is required for Schedule I and II drugs. If you need assistance in determining the requirements for storage, contact the Department of Pharmacy.

D) A controlled drug access log should be utilized to record the identities of the approved staff members opening the locked drug storage cabinet.

E) A documented, physical inventory of controlled substances must be taken bi-annually. Expiration dates of all drugs should be checked on a regular basis.

F) In general, any controlled substance that has not been used within a six month period of time and/or has passed its expiration date should be returned to the vendor, if sealed, or sent for destruction (contact the Department of Pharmacy for details).

G). Drugs that are in a non-finished dosage form, without expiration dates, that are used solely in research and will not be administered to patients, may be maintained in inventory for as long as a relevant GCO-approved research project is ongoing or is pending renewal by an outside agency, or for one year after project termination by the GCO. The only exception to this policy is for drugs that are not available commercially

and have been custom-synthesized. These drugs may be maintained for the duration of their useful shelf life

V. ORDERING OF CONTROLLED SUBSTANCES

A) All orders for controlled drugs must be on approved Medical Center purchase order forms and follow Medical Center procedure for ordering supplies.

B) A Drug Enforcement Administration triplicate order from must be used for ordering Schedule I and II Controlled Substances, along with the Medical Center purchase order form.

C) Orders for Schedule III through V controlled drugs do not require a special government order form but the licensee DEA research number must be typed on the Medical Center purchase order form.

D) Quantities of controlled substances ordered should not exceed a six month supply, unless the smallest container to be provided by the manufacturer contains a larger quantity of the controlled substance than would be used within a six month period.

VI. LOSS OR THEFT

Any loss or theft of controlled substances must be reported to the Internal Audit Department for investigation to determine if further action is required.

VII. COMPLIANCE SAFEGUARDS

The Internal Audit Department will conduct periodic audits to ensure compliance with this Policy and its related procedures. Such audits will include physical inventories and comparisons of these results with inventory records, examination or required licenses, etc.