

## MMRI Policy for the Use of DEA Controlled Substance

The Molecular Medicine Research Institute (MMRI) is licensed for possession and use of controlled substances for laboratory research. MMRI's use of controlled substances is regulated by the Drug Enforcement Administration's (DEA) Office of Diversion Control, which is responsible for two distinct problems: the diversion of controlled pharmaceuticals and the diversion of controlled chemicals.

The Executive Director and Chairman of the Institute, Edward P. Amento, M.D. is responsible for the overall Institute's Controlled Substance Safety and Use Program.

Many of the narcotics, depressants and stimulants manufactured for legitimate medical use are subject to abuse, and have therefore been brought under legal control. The goal of controls is to ensure that these "controlled substances" are readily available for medical use, while preventing their distribution for illicit sale and abuse. The Chemical Diversion and Trafficking Act of 1988 extended the concept of commodity control to those chemicals most often used for the manufacture and synthesis of drugs of abuse.

Under federal law, all businesses which manufacture or distribute controlled drugs, all health professionals entitled to dispense, administer or prescribe them, and all pharmacies entitled to fill prescriptions must register with the DEA. Registrants must comply with a series of regulatory requirements relating to drug security, records accountability, and adherence to standards.

MMRI is committed to comply with the Code of Federal Regulations (CFR) Title 21 which provides specific guidelines for security, dispensing and accountability of all controlled substances used for research at MMRI. More information and a list of controlled substances can be found at <http://www.deadiversion.usdoj.gov> or see the MMRI Safety Officer for Controlled Substances.

**Only individuals authorized by MMRI can purchase controlled substances for use at MMRI.** For further information see the Safety Officer for Controlled Substances.

### **Procedures for Use and Purchase of Controlled Substances at MMRI:**

1. Notify the Controlled Substances Safety Officer of your plans for use of controlled substances. You will be asked to provide:
  - Name of the proposed controlled substance.
  - Vendor source of the proposed controlled substance.
  - Planned usage of the proposed controlled substance (e.g. animal testing, chemical synthesis)

- Social security number and date of birth of all individuals expected to use the proposed controlled substance.
- Building(s) the proposed controlled substance will be used.

**The information above will be provided to the DEA before ordering of the proposed controlled substance. Note that inquiries may be made concerning individuals criminal records.**

2. Fill out a Controlled Substance request form and return to the Controlled Substances Safety Officer or alternate.
3. The Controlled Substances Safety Officer or alternate will order the controlled substance. When the controlled substance arrives, it will be logged into the MMRI logs and stored in the MMRI safe.
4. **The Controlled Substances Safety Officer or alternate are the only individuals authorized to dispense the controlled substance. After dispensing, the individual using the controlled substance is responsible for the security of the materials during use and is responsible for accountability of all of the materials they are dispensed. On the same day of dispensing, unused materials must be returned to the Safety Officer for Controlled Substances or alternate.**
5. **Note:** According to Title 21 CFR Section 1301.11, “It is, therefore, the position of the DEA that an employee who has knowledge of drug diversion from his employer by a fellow employee has an obligation to report such information to a responsible security official of the employer. The employer shall treat such information as confidential and shall take all reasonable steps to protect the confidentiality of the information and the identity of the employee furnishing the information. A failure to report information of drug diversion will be considered in determining the feasibility of continuing to allow an employee to work in a drug secure area. The employer shall inform all employees concerning this policy.” MMRI is required by law to follow the above guidelines.

## **MMRI Policy for the Use of DEA Controlled Substance**

### **ACKNOWLEDGEMENT:**

I acknowledge that I have received, reviewed and understand the policies as described in the **MMRI Policy for the Use of DEA Controlled Substance**. I agree to comply with the policies and procedures set forth herein.

### **CERTIFICATION:**

**This is to certify that I have never been convicted of a felony offense relating to controlled substances.**

Company Name (Print) \_\_\_\_\_

Full Legal Name (Print) \_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_\_