

June 5, 2008

TO: BIDMC Investigator Community

FROM: Randy Mason, Vice President, Research Operations
Frank Mitrano, Pharmacy Director

RE: New policies for researchers using controlled substances

Two new policies were recently approved by the Research Advisory Council (ReAC), both in regards to the use of controlled substances by researchers. The first policy, "Obtaining Controlled Substances for Research Use" address changes in the procurement of medications by BIDMC investigators. The second policy, "Controlled Substance Registrations for Researchers", outlines the Federal and State requirements for Researchers to hold specific registrations (also called licenses) for the procurement and use medications for research.

The evolution of these policies stems from increasing vigilance by state and federal regulatory bodies regarding management of controlled substances, as well as a direct charge by the Massachusetts Department of Public Health that BIDMC was not operating appropriately within the boundaries of our license to use controlled substances.

Policy 1) Obtaining Controlled Substance for Research Use: Researchers will no longer have the option to order controlled substances (i.e. ketamine, buprenorphine) from the BIDMC pharmacy department. Instead all medications should be ordered directly from the vendor (i.e. Webster Veterinary). To place orders, investigators should contact their research administrators and request that a purchasing account be set-up through the Peoplesoft system (if one does not already exist.) For questions regarding new account set-ups in the Peoplesoft system, please contact Maureen Kearney at (617) 667- 1417 or mkearney@bidmc.harvard.edu.

Policy 2) Controlled Substance Registrations for Researchers: Investigators from all research areas will be required to hold both a Federal Researcher DEA and a Massachusetts Controlled Substance Researcher Registration, if they plan to procure and use controlled substances (Schedule I-VI and INDs) in any of their research; clinical trials, animal studies and lab experiments. If you are conducting research without the use of any medications (i.e. behavioral studies, radiological studies), you will not be required to hold these registrations.

From our initial discussions, it appears that many of our Animal and Lab Researchers do not hold Researcher registrations, and therefore will need to apply for a Federal DEA registration as a *Researcher* and a Massachusetts Controlled Substance Registration as a *Researcher*.

Clinical Researchers have the option to use their Practioner license for their Federal Researcher registration. The Chief Academic Officer, Vikas Sukhatme, has applied for a Massachusetts controlled substance registration as the institutional licensee for all clinical investigators.

The chart below lists the specific requirements for each researcher type.

Researcher Type	Location where the Controlled Substance(s) will be stored.	Federal Requirement	State Requirement
Clinical Researcher	IND Pharmacy	Practitioner or Researcher DEA Registration	Massachusetts Controlled Substance License as a Researcher: The Registration will be held by the Chief Academic Officer.
Animal/Lab Researcher	BIDMC Research Labs Only	Researcher DEA Registration. The registration must be held by one designated researcher per lab location.	Massachusetts Controlled Substance Registration as a Researcher. The registration must be held by one designated researcher per lab location.

The approved plan is to have all researchers licensed appropriately and vendor accounts set-up by **September 1, 2008**. If your lab move is scheduled after September 1st, extensions will be allowed as long as an application has been started and is in progress.

Assistance will be available for the application of the Federal DEA and State Controlled Substance Registration. A web reference page will be posted at the Research Administration site with links to the new policies, federal and state registration sites and contacts for additional questions. Questions about applications, due dates, ordering medications, etc., may be directed to Mia Cha, Clinical Pharmacist Supervisor (pager #91846 or mcha@bidmc.harvard.edu).

Thank you for your assistance.