

**Partners Human Research Committee**  
**Institutional Compliance with the**  
**Massachusetts Controlled Substances Registration (MCSR)**  
**To use Controlled Substances and Investigational New Drugs in Research**

The Drug Control Program issues the Massachusetts Controlled Substances Registration (MCSR) to health care facilities, manufacturers, distributors, community-based programs and other entities as well as to individual health care providers. The MCSR provides accountability for the manufacture, distribution, dispensing, possession, prescribing and administering of controlled substances that, in Massachusetts, includes all prescription drugs.

In accordance with [Massachusetts General Laws \(M.G.L.\) 94C Controlled Substances Act Section 8 governing research projects and studies](#) Partners Human Research Committee (PHRC) institutional compliance process includes obtaining *annual reports* on clinical investigations involving *drugs, both investigational and approved, for use in research*. The (PHRC) office provides this registration service to the departments at the Massachusetts General Hospital, Brigham & Women's Hospital and Faulkner Hospital. Some years ago, an agreement was struck between the Massachusetts Department of Public Health (MDPH) and the institutions, allowing Department Chiefs to hold the registration for all investigators in their departments. This has greatly simplified the process.

Designated personnel within the PHRC office receive and process the research registration documents. Information is collated and forwarded to Department Chiefs for review, designation of any schedule II drugs, and for signature. The documents are then returned to PHRC office. A check request is made and a check sent with the materials to MDPH. Once the registration documents are received from MDPH, *a copy of the registration is forwarded to the appropriate Department Chief*. These copies are available to you when study sponsors request the research registration document.

If you have questions about Partners Human Research Committee institutional compliance process, feel free to call Sarah White at 617-424-4137 or Vicki Mirabello at 617-424-4140.

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If you like to read more about the Drug Control Program requirements in Massachusetts, information can be found on the Mass Department of Public Health (MDPH) website:  
<http://www.mass.gov/dph/dcp/dcp.htm>