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|  | **Commonwealth of Massachusetts**  **Department of Public Health, Bureau of Health Professions Licensure**  **Drug Control Program**  **250 Washington Street, 3rd Floor, Boston, MA 02108**  **Telephone 617-973-0949 Fax 617-753-8233**  **Application for Massachusetts Controlled Substances Registration to Use Controlled Substances and Investigational New Drugs in Research** | |
| Please be sure to:   * Submit completed application – front and back. * Attach the *Additional Documents Required to be Submitted with Your Application*. See list on page 3. * Enclose check or money order for $150 made payable to “Commonwealth of Massachusetts”. * Have the form signed (not initialed) and dated. * Mail to the address above.   Incomplete applications will be returned causing a delay in issuance of the MCSR. Only send copies of supporting documents. Originals will not be returned. For further information, visit: <http://www.mass.gov/dph/dcp> | |

Application Type: (Please select one) ❑ New ❑ Renewal ❑ Amended Information *(No fee)*

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| In the boxes below enter the requested information. |
| 1. Degree: Add PI degree/s here |
| 1. Board of Registration in Medicine No. (If possessed): |
| 1. DEA Controlled Substance Registration No. (If possessed): |
| 1. Name of (Select one): **X** Principal investigator ❑ Department head   First: Add PI name here Middle:  Last: Suffix: (Jr., Sr., II, III) |
| 1. Company, department, and location where drugs will be stored: (Submit a separate application for each location where drugs are stored. If no drugs are being stored, you do not have to register. Registrations are not transferable from one individual to another or from one location to another. Applications with a P.O. Box number and no street address cannot be processed.)   Boston Medical Center Investigational Drug Pharmacy  840 Harrison, ME-B378  840 Harrison Ave ME-B378  Boston Medical Center Investigational Drug Pharmacy  840 Harrison, ME-B378  840 Harrison Ave ME-B378  Boston Medical Center Investigational Drug Pharmacy  840 Harrison, ME-B378  840 Harrison Ave ME-B378  **Boston Medical Center Investigational Drug Pharmacy**  **840 Harrison, ME-B378**  City  **Boston** State **MA** ZIP **02118** |
| 1. Mailing address (If different from Company, department, and location where drugs will be stored) :   Add PI work mailing address here  City **Boston** State **MA** ZIP **02118** |
| 1. Business Telephone No.: Add PI work phone here |
| 1. Social Security No.: (Required by M.G.L. c. 30A, s. 13A) Add PI SS# |
| 1. E-mail address: (Optional) Add PI email here |
| 1. Select ONLY the drug Schedules currently in use:   List the name of EACH specific drug used. Include attachments if more space is needed.  ❑ IND  ❑ I  ❑ II  ❑ III  ❑ IV  ❑ V  ❑ VI  (Schedule VI includes all prescription drugs not in Schedules II-V.) |
| 1. What is the source of the Controlled Substances and/or INDs supplied to/obtained by the researcher?   **The drugs are provided by the sponsor.** |
| Has the study been approved by an Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC)? Please attach copy of approval letter. **X** Yes ❑ No |
| 1. For what purpose will the Controlled Substances and/or INDs be used? Please be specific.   **To determine the efficacy and/or safety of the test articles.** |
| 1. Describe, in detail, the manner in which the Controlled Substances and/or INDs be secured.   **The IND and other research drugs are kept in the investigational pharmacy within the hospital pharmacy that is in an authorized personnel restricted area in the hospital basement. Only authorized investigational pharmacy staff have tap card access. There is a dedicated buzzer to contact investigational pharmacy staff outside of the pharmacy area.**  Exact location: **Boston Medical Center Investigational Pharmacy, 840 Harrison, ME-B378, Boston MA 02118.**  Construction of storage area: **Investigational drugs are kept in locked rooms within the hospital buildings.**  Accountability system**: The Boston Medical Center Investigational Pharmacy conducts perpetual and monthly inventories of all investigational drugs. They can be contacted at** [**IPS@bmc.org**](mailto:IPS@bmc.org)  Names of all individuals (including P.I. and sub-investigators) permitted access: **These investigational pharmacists have access to the research drugs- Nitasha Sanil, Husam Dennaoui, Michael Camuso, Nisha Verma, and Ratna Dodhia. The PI and these sub-Is ?????? also have access to the specific drug/s for their studies**. |
| Have you ever been convicted[[1]](#footnote-1) of any violation of State or Federal law relating to the manufacture, possession, distribution or dispensing of controlled substances? ❑ Yes \* ❑ No |
| Has any previous professional license or registration held by you under any name or corporate name or legal entity been surrendered, revoked, suspended or denied or is such action pending or been subject to limitations on prescriptive practice or other professional limitations, including but not limited to conditions of probation?  ❑ Yes \* ❑ No |
| \* If you answered “Yes” to Question No. 15) or No. 16), a letter must be attached setting forth circumstances of such action(s). |

I hereby certify that the information on this application is true to the best of my knowledge, and that I will comply with the laws of the Commonwealth of Massachusetts and all applicable rules and regulations promulgated by the Department of Public Health. I also certify, in accordance with M.G.L. c. 62C, section 49A, that I have to the best of my knowledge and belief complied with all laws of the commonwealth relating to taxes, reporting of employees and contractors, and withholding and remitting of child support.

Signed under the pains and penalties of perjury.

Signature of applicant Date

Principal Investigator/ Department Head

Print name

Additional Documents Required to be Submitted with Your Application

* Enclose a copy of your current DEA Researcher Registration if applying for Schedules II –V. If a new DEA Researcher Registration application is needed, call the DEA Boston office.
* Attach a copy of an IRB or IACUC approval letter for any human/animal research.
* Attach a copy of an FDA Form 1572 for any human research which involves investigational new drugs

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| For Office Use Only | |
| Application approved by: | Comments: |
| Date: |

1. An applicant for employment or for housing or an occupational or professional license with a sealed record on file with the commissioner of probation may answer 'no record' with respect to an inquiry herein relative to prior arrests, criminal court appearances or convictions. An applicant for employment or for housing or an occupational or professional license with a sealed record on file with the commissioner of probation may answer 'no record' to an inquiry herein relative to prior arrests or criminal court appearances. In addition, any applicant for employment or for housing or an occupational or professional license may answer 'no record' with respect to any inquiry relative to prior arrests, court appearances and adjudications in all cases of delinquency or as a child in need of services which did not result in a complaint transferred to the superior court for criminal prosecution. [↑](#footnote-ref-1)