

9960 Mayland Drive, Suite 300 Henrico, Virginia 23233 (804) 367-4456 (Tel) (804) 527-4472 (Fax)

pharmbd@dhp.virginia.gov
www.dhp.virginia.gov/pharmacy

## APPLICATION FOR A CONTROLLED SUBSTANCES REGISTRATION CERTIFICATE

Check Appropriate Box(es):  New*		\$120.00	☐ Change to Drug Schedule			No Fee		
Change of Ownership	\$65.00 Change of Trade							
Change of Location		\$300.00	☐ Change of Respon			No Fee		
Remodel		\$300.00			ising Practitioner	No Fee		
Reinstatement	Call	board for fee		8 · · · · · · · · · · ·				
Application fees are not refundable. Applications are valid for one year from the date of receipt. The required fees must accompany the application. If "No Fee", application may be sent electronically to <a href="mailto:pharmbd@dhp.virginia.gov">pharmbd@dhp.virginia.gov</a> . Make check payable to "Treasurer of Virginia".								
Type of Activity	☐ Alternate Delivery Site <sup>1</sup>		Ambulatory Surgery Center 1		☐ Analytic Laboratory	2		
	☐ Animal Shelter or Pound <sup>1</sup>		☐ Drug Dispensing Device		☐ EMS Agency <sup>1</sup>			
☐ Government Official <sup>2</sup>	☐ Hospital <sup>1</sup>		☐ Manufacturer		■ Naloxone Dispensing <sup>4</sup> *No fees for this type of activity			
☐ Out-patient Clinic <sup>1</sup>	☐ Teaching Ins	titute <sup>2</sup>	☐ Telemedicine <sup>1&amp;5</sup>		☐ Third Party Logistics Provider	s		
Researcher <sup>2</sup>	☐ Warehouser		☐ Wholesale Distributor		Other <sup>1 or 2</sup>			
Name of Entity UVA Department of			Telephone Number Researcher's number		Controlled Substance So Requested: select what is	needed		
Street Address Research street address, building & room where the substances are securely stored			Fax Number		☐ I <sup>3</sup> ☐ II	X IV		
City Charlottesville State VA		State VA	Zip Code 2290	VA CSR numb 0220- Leave	mber (if applicable) ave <u>Blank</u>			
RESPONSIBLE PARTY INFORMATION:								
Name of Responsible Party			Email Address of Responsible Party					
Researcher Name			Researcher Email					
Type of Professional License to administer drugs (if applicable)			Professional License Number of Responsible Party (if applicable)					
NONE - research			NONE - research					
Signature of Responsible Party Date		Telephone Number						
Researcher signs here Date of Application			Researcher's number					
SUPERVISING PRACTITIONEI	R INFORMATI	ON:						
Name of Supervising Practitioner (if applicable) <sup>1</sup>			Email Address of Supervising Practitioner					
Leave Blank			Leave Blank					
Street Address			Telephone Number					
Leave Blank			Leave Blank					
City Leave Blank	State <i>Leave</i>	Zip Code Blank	Professional License Number  Leave Blank					
Signature of Supervising Practitioner De		Date	DEA Number of Supervising Practitioner <sup>1</sup>					
Leave Blank		Leave Blank	Leave Blank					

## **Controlled Substances Registration Application**

INSPECTION INFORMATION:		<del></del>						
Expected Opening Date	Requested Inspection Date Date the Researcher will be ready for the inspection							
Date the Researcher will be ready for the inspection								
An inspection is not required for naloxone dispensing, telemedicine, or for EMS agencies obtaining a CSR for solely the purpose of one-to-one exchange of Schedule VI drugs in accordance with 18VAC110-20-500 (B).								
Ownership Type	rporation	<b>□</b> Partnership	In	ndividual	X Other			
Name of ownership entity if different from name on application: University of Virginia - Office of Vice President for Research								
Street Address: Varsity Hall, 136 Hospital Drive			Phone Number: 434.924.3502					
City: Charlottesville S		State: VA		Zip Code: 22098				
States of Incorporation: Leave Blank								
List all other trade or business names used by this facility:								
Name: Leave Blank								
Name: Leave Blank								
LIST OF OWNERS/OFFICERS AND RESIDENCE ADDRESSES, OR LIST IS ATTACHED								
Name: David J. Hudson		Title: Sr. Assoc. VP for Research						
Contact Address: Varsity Hall, 136 Hospital Drive, Charlottesville, VA 22908								
Name: Frederick H. Epstein		Title: VP	Title: VP for Research					
Contact Address: Varsity Hall, 136 Hospital Drive, Charlottesville, VA 22908								
Name: Leave Blank		Title: Le	eave Blank					
Contact Address: Leave Blank								

## **FOOTNOTES**

- Entities applying under this activity code must submit a description of the processes/business practices for which this registration is being sought, and must have a <u>supervising practitioner</u> as follows:
   A practitioner licensed in Virginia shall provide supervision for all aspects of practice related to the maintenance and use of controlled substances as follows:
  - In a hospital without an in-house pharmacy, a pharmacist shall supervise.
  - In an emergency medical services agency, the operational medical director shall supervise
  - In an animal shelter or pound, a licensed veterinarian shall supervise
  - For any other person or entity approved by the board, a practitioner of pharmacy, medicine, osteopathy, podiatry, dentistry, or veterinary medicine whose scope of practice is consistent with the practice of the person or entity and who is approved by the board shall provide the required supervision.

If supervising practitioner is a pharmacist, give DEA number of the provider pharmacy supplying drugs.

- 2. Persons applying under this activity code must submit, with the application, a protocol which specifically names the controlled substances to be used and provides details as to the intended use of these controlled substances within the work. Additionally, persons applying under this activity code must provide documentation showing competence (curriculum vitae, educational credentials, professional licensure, training) to use the controlled substances within the scope of this activity. Registration is required to perform laboratory analysis with controlled substances in Schedules II through VI, tetrahydrocannabinol, or marijuana.
- 3. Practitioners registered under federal law to conduct research with Schedule I substances, other than tetrahydrocannabinol, may conduct research with Schedule I substances within this Commonwealth upon furnishing the evidence of that federal registration. Schedule I must be approved by DEA prior to Board approval. A copy of the DEA license must be sent to the Board in order for the Virginia controlled substance registration to be updated to reflect Schedule I.
- 4. Naloxone dispensing Submit a description of the process/business practices for which this registration is being sought. The responsible party shall be a prescriber, nurse, pharmacist, or other person authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of injectable naloxone and proper disposal of a hypodermic needle or syringe. No inspection is required for this type of CSR. Note: a controlled substance registration is not required for the dispensing of intranasal or auto injector formulations of naloxone.
- 5. Telemedicine The responsible party shall be a prescriber, nurse, pharmacist, or other person who is authorized by provisions of § 54.1-3408 of the Code of Virginia to administer controlled substances. No inspection is required for this type of CSR.

**A 14-day notice is required for scheduling an inspection.** An inspector will call the responsible party prior to the requested date to confirm readiness for inspection. If the inspector does not call to confirm the date, the responsible party should call the Enforcement Division at (804) 367-4691 to verify the inspection date with the inspector.

FOR OFFICE USE ONLY						
□ I □ II □ III □ IV □ V □ VI □ Marijuana/THC □ DEA Approval for Schedule I received (DEA Number):						
Date Processed:	Check No:	Receipt No:	Application No:			
Date sent to Enforcement:	Date Reviewed/Issued:	Reviewed/Issued By:	0000			
			0220-			