



Researcher Application for Registration (Form DHHS 225-C)

NC Department of Health and Human Services

Division of Mental Health, Developmental Disabilities, and Substance Abuse Services – Drug Control Unit
3008 Mail Center Service Center
Raleigh, North Carolina 27699-3008
(919) 733-1765

Application Instructions – PLEASE READ THESE INSTRUCTIONS CAREFULLY

This application will be used by the North Carolina Department of Health and Human Services’ Drug Control Unit to initiate a registration for the applicant under the North Carolina Controlled Substances Act of 1971 as well as assist in determining whether or not the applicant is in compliance with State and Federal laws pertaining to controlled substances. Therefore, please fill out this application in its entirety. Do not leave any fields blank, rather indicate that a field is not applicable by typing “N/A” in the space provided. Failure to complete the entire form will result in the application being returned to the applicant along with a request for additional information. To submit this Application for Registration, e-mail both the completed electronic PDF and a signed PDF copy to nccsareg@dhhs.nc.gov along with a signed PDF copy of an Applicant Disclosure of Loss, Diversion, or Destruction of Controlled Substances (Addendum to Forms DHHS 224 and 225). In accordance with 10A NCAC 26E.0104, the applicant must also submit a required, **nonrefundable** application fee in the amount of \$125.00.

Attestation

By signing below, you attest that you are an administrator or an agent of the applicant who is authorized to answer the questions presented in this document. Furthermore, you attest that all of the information provided on this form is true, accurate, and complete to the best of your knowledge. All responses are subject to verification by the North Carolina Department of Health and Human Services’ Drug Control Unit.

		Date	
Signature		Phone Number	
Name and Title		E-Mail Address	

Section A - Applicant Information

Applicant Name			
Facility’s Address		Facility’s County	
Facility’s State, City, Zip			
Mailing Address		Facility’s Phone Number	
Mailing State, City, Zip			
Administrator	Name:	Title:	

Section B - Registration Classification

B1. Check all applicable drug schedules in which you are applying for:

Schedule I
 Schedule III (Narcotic)
 Schedule V
 Schedule II (Narcotic)
 Schedule IIIN (Non-narcotic)
 Schedule VI (NC General Statutes §90-94)
 Schedule IIN (Non-narcotic)
 Schedule IV

B2. Are you currently authorized to manufacture, distribute, dispense, prescribe, conduct research, or otherwise handle controlled substances in the schedules for which you are applying under the laws of North Carolina or the Federal Government?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
B3. Has the applicant been convicted of a felony under State or Federal law relating to the manufacture, possession, distribution, or dispensing of controlled substances?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
B4. Has any previous registration held by the applicant, corporation, firm, partner, or officer of applicant under Federal CSA or NCCSA been surrendered, revoked, suspended, denied, or is it pending such action?	<input type="checkbox"/> Yes	<input type="checkbox"/> No

If you answered “Yes” to questions B3 and/or B4, please submit a letter along with this application setting forth the circumstances of such action.

Section C - Point of Contact

A Drug Control Inspector may conduct an unannounced inspection of the applicant's facility at some point during the registration period. Please provide a list of up to three individuals for whom the Inspector should ask for upon arrival at the facility. The names and titles provided should be listed in the desired order of contact and should include individuals who are knowledgeable of and possess some degree of responsibility for the disposition of controlled substances at the facility. Any phone numbers provided for points of contact in Section C should be a direct line in order to assist the Drug Control Unit with reaching the correct individual(s) if needed – the central phone number provided in Section A will serve as a backup. Please note that the Inspector may also interview other persons other than those listed below at his/her discretion.

Primary Contact	Name:	Title:
	E-mail:	Phone:
Secondary Contact	Name:	Title:
	E-mail:	Phone:
Tertiary Contact	Name:	Title:
	E-mail:	Phone:

Section D - Research Protocol

D1. Is a copy of the research protocol(s) on hand and readily available? Yes No

D2. List the identification numbers of all research protocols in which the applicant will be using controlled substances for.

D3. List controlled substances with DEA drug code numbers that are used in research. Are these substances listed in the protocol(s) noted above?

Section E - State Registration History

E1. Please select the event below that best describes your reason for submitting an Application for Registration (Form DHHS 225) and provide an answer to each supporting question for that event (choose only one answer from below)

<input type="checkbox"/> The application is for a new researcher / first time registrant Anticipated Opening Date: _____	<input type="checkbox"/> The application reflects a name change for a registrant Name on Previous Registration: _____ Previous DHHS Registration No: _____
<input type="checkbox"/> The application reflects a change of location/address for a registrant Name on Previous Registration: _____ Previous Address (Line 1): _____ Previous Address (Line 2): _____ Previous City: _____ Previous DHHS Registration No: _____	<input type="checkbox"/> The application reflects a change in ownership Name on Previous Registration: _____ Previous DHHS Registration No: _____ Was Business Sold or Merged: _____ Percentage of Ownership Sold: _____ Corporate or Branch Level Sold: _____

Section F - Drug Enforcement Administration (DEA) Registration

F1. Does the applicant currently possess any controlled substances? Yes No

F2. What is the current status of the applicant's DEA Registration? *(choose only one answer from below and provide the requested information)*

Valid Registration in possession Name on Registration: _____ DEA Number: _____

Applied for Registration Applicant's Name: _____ Date Applied: _____

DEA Registration will be applied for pending approval of NC DHHS Registration

Other *(explain)*: _____

F3. Who is responsible for controlled substances? *(this is the individual who signed DEA Form 224):*

F4. Has the applicant granted Power of Attorney to any individuals for ordering controlled substances? Yes No

If yes, please provide the name(s) of the individual(s): _____

Section G - Primary Supplier of Controlled Substances

Supplier Name			
Address		City	
State		Zip Code	
Sales Rep's Name		Phone Number	

Section H - Secondary Supplier of Controlled Substances

Supplier Name			
Address		City	
State		Zip Code	
Sales Rep's Name		Phone Number	

Section I - Storage and Security

I1. How many total storage locations are utilized for the storage of controlled substances? Provide the physical address of the location(s) in which the controlled substances are stored and describe the type of storage equipment for each location (i.e. wall cabinet, combination safe, keyed safe, etc.).

I2. Who has access to the controlled substance inventory location(s)? List the persons and/or titles and number of individuals with access, describe how key control is practiced, and provide any other information deemed pertinent to assuring the security of controlled substances at the facility.

3. How are unexecuted controlled substance order forms stored?

Section J - Records

J1. Biennial Inventory Date

J2. Describe the procedure for purchasing and receiving Schedule I, Schedule II, and Schedule VI controlled substances. How are DEA Form-222s, invoices, and any other documents acknowledging the purchase and receipt of Schedule I and Schedule II controlled substances recorded and maintained? Schedule VI refers to North Carolina's controlled substances schedule. If the applicant is not applying for Schedule I, Schedule II, and/or Schedule VI, please write/type "N/A" for this question.

J3. Describe the procedure for purchasing and receiving Schedule III, IV, and V controlled substances. How are pharmacy provider requisition forms, invoices, and any other documents acknowledging the purchase and receipt of Schedule III, IV, and V controlled substances recorded and maintained? If the applicant is not applying for Schedule III, IV, and/or V, please write/type "N/A" for this question.

J4. Describe the procedure for dispensing controlled substances. What type of records are maintained to document the dispensation (i.e. sign out logs, automated dispensing technology reports, etc.)?

J5. Describe the records that are maintained for the administration of controlled substances (i.e. patient chart, MAR, eMAR, etc.).

Section K - Effective Controls for the Prevention of Diversion

K1. Other than physical security measures that have already been discussed in previous sections of this document, what steps is the applicant taking to maintain effective controls for the prevention of diversion of controlled substances? Answers should include, but are not limited to, software reporting systems being utilized to monitor user and drug activity as well as the frequency and individuals involved in the review of such material.

Section L - Supplemental Materials

The following documents are required as part of your Application for Registration:

1. *Copy of all research protocols in which controlled substances are used.*
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