

Class 4 & 7 Individual Researcher Protocol

In addition to the *License Application to Engage in a Controlled Substance Activity* (DOH-4330), complete and submit the following information for Class 4 & 7 Researcher (Individual) applications.

1. Applicant/Researcher:

(i) Qualifications & competence (Curriculum Vitae) of the applicant to engage in controlled substance research. (Attach CV)

A typical CV will include the following information:

- *Name & Contact Information*
- *Publications & Presentations*
- *Education*
- *Grants, Honors & Awards*
- *Employment & Experience*
- *Scholarly or Professional Memberships*

If applicant is a practitioner, provide his/her DEA Practitioner registration: _____

2. Research Project:

(i) Nature & objective of the project. (Attach additional sheets as necessary, but title must be completed below)

Title:

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Nature & Objective (Concise Summary must be completed below):

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(ii) Name, schedule & quantity of the controlled substance(s) involved. (Attach additional sheets as necessary)

| Name | Schedule | Quantity |
|------|----------|----------|
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(iii) Name, DEA registration & NYS controlled substance license for the manufacturer or distributor of controlled substance(s).

| Name | DEA Registration | NYS Controlled Substance License |
|------|------------------|----------------------------------|
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If controlled substances are to be obtained by any means other than via a DEA registered distributor or manufacturer, explain:

 _____ Attach additional sheets as necessary

(iv) If animals are to be utilized in the research, provide: N/A

| Species | Number of Animals | Dose Regimen (e.g., 10mg/kg, three times/week for five weeks) | Route of Administration |
|---------|-------------------|--|-------------------------|
| | | | |

(v) Will controlled substances be administered or dispensed to humans? Yes No

If administering or dispensing controlled substances to humans, attach the corresponding Institutional Review Board (IRB) approval & a detailed protocol setting forth:

- Provisions for the safe administration or dispensing of controlled substances to humans
- The proposed method of selecting humans.

Appendix A1

3. Applicant/Researcher:

Describe, in detail, all aspects of storage that will be utilized for this project. All storage must meet all requirements found in Article 33 and Part 80. A synopsis of these requirements can be found in the instructions for DOH-4330 on our website. Photographs of storage may also be submitted at the time of application. **ALL STORAGE MUST BE INSTALLED AND READY FOR INSPECTION WHEN SUBMITTING APPLICATION!**

4. Storage & Diversion Prevention Policies and Procedures:

Policies and procedures must be submitted with the application. These must state all aspects of storage and access to controlled substance and how prevention from diversion will be managed. If a Controlled Substance Supervisor and/or other "authorized users" will have access to the controlled substances, the policies and procedures must reflect how security of the controlled substances will be maintained and how access will be controlled only to those people directly involved with the research project.

Licnese Applicant's Name:

Print

Signature

Date