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. All sections must be completed. **Do not enter "See Attached" as an answer**.

Applicant Name:_____

1. Applicant/Researcher/PI:

(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 their DEA Practitioner registration: _____

DEA Practitioner Address:_____

(ii) Institution or company applicant is affiliated with for this research (name and address):_____

_____

2. Research Project:

(i) Nature & objective of the project. (Attach additional sheets as necessary)

Title of approved project:

State of purpose of research (Concise Summary):

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

Name	Schedule	Quantity

(iii) Name, DEA registration & NYS controlled substance license of suppliers of the controlled substance(s). All suppliers must have a NYS BNE license number. Applicant should obtain a copy of the suppliers BNE license for their records.

Name	DEA Registration	NYS BNE Controlled Substance License #

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

Must include copy of approval from Insitutional Animal Care and Use Committee (IACUC) for animal studies.

(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.
- Notice of Claimed Investigational Exemption for a New Drug (IND) for clinical studies