Appendix B

Class 4 & 7 Institutional Researcher Statement

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 (Institutional) applications.

1. Applicant/Institution:
   (i) Controlled Substance Project Approval Committee List: Name, qualifications & competence (e.g., degree & department) of each member of the institution’s controlled substance project approval committee. (Attach committee list)
   (ii) Controlled Substance Project System: Description of the system within the institution for approving, supervising & evaluating controlled substance research projects. (Attach system description)

2. Research Project(s):
   (i) Description (Title) of the project(s). (Attach additional sheets as necessary)
   (ii) Name & schedule of the controlled substance(s) involved.
   (iii) Name(s) & qualifications (e.g., degree, position) of the individual(s) working on the project and of the individual(s) designated to supervise the project:
   (iv) Name, DEA registration & NYS controlled substance license of the provider(s) of controlled substance(s).

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If controlled substances are to be obtained by any means other than via a DEA registered distributor or manufacturer, explain (Note: Identify the specific project and method of obtaining):

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

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

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