

Controlled Substance Use Authorization in Research

General instructions:

Fill out, sign, and submit this form to the EHS office by emailing csp@bu.edu or by fax at 617-638-8822. When approved, the Principal Investigator will be sent a formal email detailing the terms of approval, including the names of Authorized Handlers and approved storage facilities.

I. PRINCIPAL INVESTIGATOR SEEKING CS PRIVILEGES

Last Name

First Name

BUID (include U)

Primary BU Department Affiliation

Email Address

Office Phone

Office Building and Room #

Protocol #(s)

II. AUTHORIZED HANDLERS (AH)

Only individuals who report directly to the Principal Investigator are allowed access to controlled substance (CS) ordered by the Investigator. Faculty who do not report to the Principal Investigator named in Section 1 must apply separately and cannot appear on this application. The Principal Investigator is responsible for ensuring that all individuals designated below have completed and retaken annual training on CS security and record keeping as described in Section V, Summary of Principal Investigator Privileges and Responsibilities.

Last Name

First Name

UID

email

Position

Signature Sample

Last Name

First Name

UID

email

Position

Signature Sample

Last Name

First Name

UID

email

Position

Signature Sample

Last Name

First Name

UID

email

Position

Signature Sample

Last Name

First Name

UID

email

Position

Signature Sample

III. AUTHORIZED TRANSPORTER

List only 2-4 authorized handlers (AH) to pick up controlled substance. The individuals listed here should be senior personnel. The Principal Investigator is responsible for ensuring that all individuals designated below have completed and retaken annual training on CS security and record keeping as described in Section V, Summary of Principal Investigator Privileges and Responsibilities.

Last Name	First Name	UID	email
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Position	Signature Sample
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Last Name	First Name	UID	email
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Position	Signature Sample
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Last Name	First Name	UID	email
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Position	Signature Sample
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Last Name	First Name	UID	email
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Position	Signature Sample
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IV. STORAGE FACILITIES AND CS SCHEDULES INTENDED

Per DEA all schedules and prescriptions are required to be stored in a locked safe, bolted to the wall or floor. All proposed storage facilities listed below are subject to review and approval by the CS Program. If you do not have the required safe, leave the storage information blank and request access to a locker in a CS Program safe by emailing csp@bu.edu. If you would be interested in having a storage facility at the ASC facility directly.

STORAGE SITE LOCATION, BUILDING NAME & ROOM #
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STORAGE TYPE

CS NAMES & SCHEDULES TO BE STORED - SEE DEA WEBSITE
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ESTIMATED TOTAL MASS

V. SUMMARY OF PRINCIPAL INVESTIGATOR PRIVILEGES AND RESPONSIBILITIES

Privileges: Provided that the Principal Investigator continues to meet all the responsibilities described below, approval of this application authorizes the Investigator to:

- Obtain and hold controlled substance for use in authorized studies, by submitting requests to the CS Program.
- Allow Authorized Handlers and Transporters, as listed in Sections II and III, to access controlled substance for use in Principal Investigator's authorized studies.

Responsibilities: The use of controlled substance in research is subject to extensive Federal and Commonwealth of MA regulation. The BU Controlled Substance Program fulfills many of these regulatory obligations; however, Principal Investigators have five main responsibilities:

Ensure Security of Controlled Substance: When research is being conducted with CS, the Principal Investigator must ensure that only Authorized Handlers and Transporters, as listed in Sections II and III, can access them. When CS are not being used in research, the Principal Investigator must ensure that they are stored appropriately, as approved by the CS Program.

Record Controlled Substance Receipt and Use in a Logbook: Additions to and subtractions from the Principal Investigator's CS stocks must be recorded in a logbook, pursuant to Federal regulation. The CS Program will provide the Principal Investigator with a hardbound, pre-printed logbook for this purpose. The CS Program as well as Federal and Commonwealth of MA regulatory agencies may examine this logbook at any time, without warning; for that reason, it must be kept in a secure location near or with the CS materials.

Accommodate and Perform Physical Inventories: Annually the CS Program will conduct a physical inventory of the Principal Investigator's CS stocks, during which the Investigator must be present. Biennially, the Principal Investigator must conduct a thorough physical inventory and forward the results of that inventory to the CS Program within the designated time frame.

Notify CS Program Officer of Changes and Respond to Requests for Information: The Principal Investigator must notify the CS Program of all changes to contact information, Authorized Handlers and Transporters, and storage locations as described in Section I, II, III and IV above. The Principal Investigator must also respond promptly and completely to any audit or any request for information by the CS Program.

Report Any Loss, Diversion, or Noncompliance: In the event that Principal Investigator becomes aware of any loss, diversion, or noncompliance with regard to controlled substance - through his or her own observation, reports from research staff, results of audits, or other avenues - the Principal Investigator must notify the CS Program within 24 hours after the occurrence, or first awareness of it. The Principal Investigator should have in place adequate systems to ensure that he or she will be made aware of any such matters known within the research staff.

VI. PRINCIPAL INVESTIGATOR ACKNOWLEDGMENT

I agree to abide by the following requirements:

I certify that the information listed in this application is true and accurate.

I acknowledge and affirm that I understand and will fulfill my obligations to the Controlled Substance Programs, as described in Section V, and as subsequently directed by the Controlled Substance Program.

I agree to report any discrepancy between this request and the shipment when I receive it.

I agree to administer the controlled substance in accordance to section H and I of the approved IACUC protocol.

I will review the controlled substance logbook and the listed applications and train the staff to ensure accuracy and security of the Controlled Substance(s).

I will ensure that all laboratory workers are trained and qualified to work with controlled substances and handle animals.

I will supervise the staff and correct work errors and conditions that could result in breaches of the Biosafety Manual, Exposure Control Plan, Chemical Hygiene Plan and other plans as appropriate.

I will accommodate and perform physical inventories.

I will report any Loss, Diversion, or Noncompliances to the csp@bu.edu or 617-638-4510.

I will contact Research Occupational Health Program (ROHP) 24/7 at 617-414-7647 immediately after a potential exposure or accident in my lab.

I will submit the biennial inventory as requested.

I understand that if I do not fulfill my responsibilities, my ordering privileges may be suspended or revoked, and I may be subject to disciplinary action (e.g., loss of privileges, reprimand, suspension, or termination) by Boston University and/or BMC, as applicable.

I certify also that I have never been convicted of a crime connected with controlled substances under state or federal law, and that I have never surrendered, or had a federal controlled substance registration revoked, suspended, or denied.

Signature

Date

Printed Name

