Controlled Substances: Requirements for Acquisition, Use and Disposal in Laboratories

1. Purpose / Background

Controlled Substances are drugs or chemicals that have the potential to be addictive or habit forming. The Drug Enforcement Administration (DEA) has divided the Controlled Substances into 5 schedules (I-V) based on their potential to be habit forming and usefulness in medicine as a drug. Among controlled substances are many of the anesthetic and analgesic drugs used in research animals, as well as some drugs specifically formulated for animal euthanasia.

DEA controlled substance categories I – V indicate the relative levels of abuse potential with Category I being the highest. The Drug Enforcement Administration DEA has divided controlled substances into 5 schedules based on their potential to be habit forming and usefulness in medicine as a drug. Every person that engages in some manner of research with controlled substances must be registered with DEA. There are different activities that require different registration types. Further, one registration type may not cover two different activities. For example, a researcher will require a different registration than a practitioner or a pharmacist. Controlled substance use in Massachusetts requires registration with both the DEA and the Commonwealth of Massachusetts, Department of Public Health, Division of Food and Drugs (DPH). The DPH also regulates schedule VI materials which are not regulated by the DEA.

The drug scheduling is outlined below:

- **Schedule I** - Drugs or other substances that have a high potential for abuse; no currently accepted medical use in the United States and have a lack of accepted safety for use under medical supervision. Examples of schedule I drugs include heroin, LSD, and MDMA (ecstasy).
- **Schedule II** - Drugs or other substances that have a high potential for abuse; currently have an accepted medical use in treatment in the United States, or have a currently accepted medical use with severe restrictions; abuse may lead to severe psychological or physical dependence. Examples of schedule II drugs include cocaine, fentanyl, meperidine (Demerol) and pentobarbital.
- **Schedule III** - Drugs or other substances that have a potential for abuse less than Schedule I or II; currently have an accepted medical use in treatment in the United States; abuse may lead to moderate or low physical and high psychological dependence. Examples of schedule III drugs include anabolic steroids, buprenorphine and ketamine.
- **Schedule IV** - Drugs or other substances that have a low potential for abuse relative to those listed in Schedule III; currently have an accepted medical use in the United States; abuse may lead to limited physical or psychological dependence less than those in schedule III. Examples of schedule IV drugs include diazepam, midazolam, xanax and valium.
- **Schedule V** - Drugs or other substances that have a low potential for abuse relative to Schedule IV; currently have an accepted medical use in the United States; abuse may lead to limited physical or psychological dependence relative to those in Schedule IV. An example of a schedule V drug is robitussin A-C with a codeine preparation of 200mg/100ml.
- **Schedule VI** - Controlled by MA DPH but not the DEA. These are prescription medications not covered in DEA Schedules I-V. Examples include isoflurane and vasodilators.


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2. **Scope**

Controlled substances may only be used for duly authorized, legitimate medical or scientific research purposes to the extent permitted by the registrant’s license and registration and in conformity with state and federal statutes and regulations.

MIT does not maintain an institutional wide “blanket license” for DEA controlled substances. Principal Investigators (PIs) are expected to maintain their own individual license for use of these substances. Researchers may opt to purchase controlled substances for the purpose of animal anesthesia/analgesia from the MIT Division of Comparative Medicine (DCM).

The information in this document provides guidance to PIs that have their own registration, as well as for PIs that order controlled substances from DCM. Information pertaining to registration, storage, security, recordkeeping and disposal is available in this document, on the EHS website and by contacting the EHS Office.

3. **Prerequisites**

To process a Principal Investigator registration, PIs must first register with the Massachusetts DPH, and then with the DEA. PIs wishing to establish a registration must also register with and have approval from the MIT Committee on the Animal Care (CAC) for use of controlled substances in animals or Committee on the Use of Humans as Experimental Subjects (COUHES) for use of controlled substances in humans.

4. **Procedures**

4.1 **Principal Investigator Registration**

Any research activity using narcotic and non-narcotic controlled substances in Schedules I-V must be registered. The DEA form # 225 is submitted for this type of registration, and form #225A is used to renew this registration annually. The following information is required:

- Investigator information - Name, address, institution, state license, and a qualifications statement
- Project - Title, statement of purpose, controlled substance name and amount, location of research, security statement and a technical description of the substance use is required. The form must be submitted and approved before controlled substances may be ordered.
- There are additional requirements for use of schedule I controlled substances. Contact EHS for assistance with registration.
- Instructions and the application for completing the required state form for the Commonwealth of Massachusetts can be found at:[http://www.mass.gov/eohhs/docs/dph/quality/drugcontrol/app-researcher](http://www.mass.gov/eohhs/docs/dph/quality/drugcontrol/app-researcher).
- The DEA will not grant an applicant a license until the PI has already obtained a license from DPH, although both applications may be submitted at the same time.
- Fees are outlined below:
### 4.2 Termination of Registration

Registration holders who wish to terminate registrations must dispose or transfer any controlled substances in inventory, in accordance with applicable regulations, prior to termination. Actions to take include:

- Notify EHS of intent to close out the registration
- Send all remaining blank DEA form #222s (See link below for link to DEA form #222) and registration certificate to DEA. The state registration certificate will also need to be returned to DPH. Contact EHS for the mailing address for both the DEA and DPH.
- Transfer inventory to other registered user(s) or arrange for disposal. See section 4.8 of this document for procedures to dispose of controlled substances. Contact EHS to help facilitate this transfer and disposal
- Arrange for record retention within the Department, Lab, or Center (DLC). Records should be kept on hand for 2 years.

### 4.3 Procurement of Controlled Substances—Requirements for registered PIs and PIs ordering controlled substances from DCM

**Requirements for registered PIs**

- In general, to order Schedule I or II controlled substances, the registrant must provide two copies of the DEA form #222 to the drug supplier and keep one for record. The supplier will keep one copy and send the other to the DEA as a record of distribution.
- At MIT, Procurement will process controlled substance orders. To procure controlled substances, attach (staple) two copies of the completed and signed DEA form #222 to a completed and approved MIT requisition form on which the DEA Registration Number is

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clearly indicated, and submit to Procurement. Once the drug is received, the registrant must annotate the kept copy of the DEA form #222 with the amount and date received. DEA form #222 can be found at: http://www.deadiversion.usdoj.gov/faq/dea222.html.

- To order Schedule III-V controlled substances, the PI must invoice paper requisitions as usual. There is no need to fill out or attach DEA form #222. The registration number still must be provided on requisition forms.

Requirements for PIs ordering controlled substances from DCM
- Please contact DCM for procedures to acquire controlled substances. Contact: James G. Fox (617) 253-1757

4.4 Controlled Substance Tracking-Requirements for registered PIs and PIs ordering controlled substances from DCM

Records must be kept to track each container of controlled substances on hand as well as records that detail each time a controlled substance was used. Controlled substance use, transfers and losses should be accounted for in the inventory records. Both the MIT Continuous and Biennial Inventories are attached as appendices A and B, respectively.

Requirements for registered PIs
- Please note that it is a felony to provide a controlled substance to a person who is not registered with the DEA. All transfers of controlled substances can only occur between two DEA registrants.
- When transfers of schedule I or II controlled substances occur between two appropriately licensed PIs, the transfer must be accompanied by a DEA form #222 completed by the registrant receiving the substance(s). The supplying PI should keep 1 copy of the form, while the receiving PI should mail a copy to the local DEA field office and keep one for record. Whenever possible, the PI should order controlled substances through the established procurement process.
- A biennial inventory reconciliation is required. This inventory documents the total finished form (pill, liquid volume, powder mass) of materials per container.
- The continuous log is kept to monitor daily use of controlled substances. This log records each daily amount used, as well as any disposal or transfer of materials. This log will be used to facilitate filling out the Biennial Inventory every two years. See Appendices A & B.
- In the event new substances are added to the drug schedules, the inventory must reflect the new substances in recordkeeping on the effective date of the addition.

Requirements for PIs ordering controlled substances through DCM
- The continuous log is kept to monitor daily use of controlled substances. This log records each daily amount used, as well as any disposal or transfer of materials.
- No transfers of drugs obtained from DCM should occur between PIs. If there is request for controlled substances, this transfer should be handled between the requestor and DCM.

4.5 Security Requirements for Controlled Substances –Requirements for both registered PIs and PIs ordering controlled substances through DCM

Researchers are permitted to keep controlled substances in a securely locked, sturdy cabinet or safe. Different requirements exist for Schedule I and II substances versus schedule III-V. Depending on
the quantities and type of controlled substances, security must include a safe or cabinet, which follow DEA specifications. Access must be strictly limited. Controlled substances in use must be under the direct supervision of a designated, responsible individual (e.g., PI). EHS will help define specific lab security requirements (See appendix C for the MIT Controlled Substance Security Assessment Form). General requirements include:

- All controlled substances must be kept in a double locked enclosure. Minimum requirement is a locked cabinet stored within a locked room.
- For higher schedules (schedule II), storage may be in any built in case work of lab benches with sufficient locking structures. No bicycle locks, clasp locks or any other locking structure that can be easily cut off the cabinet should be used.
- Schedule I substances must have 750 lb safe (or safe bolted to floor) with central station alarm control.
- If controlled substances in III-V are to be stored with controlled substances in Schedule I and II, the storage area must meet the more rigid requirements for the higher schedules.
- Access to storage and use areas must be strictly limited to the authorized individuals assigned by the PI. When the areas might be accessed by unauthorized individuals, such as cleaning and maintenance staff, the drugs will be secured.
- All controlled substances must be under the control of a designated, authorized individual.
- The storage cabinet or safe must be adequately sized to maintain stock containers and waste materials.

4.6 Theft or Loss Reporting-Requirements for registered PIs and PIs ordering controlled substances through DCM

Requirements for registered PIs
Thefts and losses of controlled substances must be closely monitored by the registrant. Normal losses, including drips or liquid volumes in spills, need not be reported. However, these losses must be inventoried and accounted for at all times. Thefts, suspect thefts, unauthorized uses, or other losses of controlled substances that can not be reasonably explained must be reported immediately to the EHS Office and MIT Police upon discovery.

- DEA Form 106, available on DEA’s website, is required to be used by both DEA and DPH when a formal report is made, after an initial investigation. The form should be submitted within 1 business day of the discovery. The form can be found at the following website: http://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html
- In addition, any unauthorized persons who gain access to controlled substances for the purpose of diversion or theft may be reported to the MIT Police Department.
- To determine what constitutes a significant loss, the following should be considered:
  - What is the actual quantity of controlled substances lost?
  - What is the schedule of the controlled substances lost- are the controlled substances likely candidates for diversion?
  - Can the loss be attributed to access by specific individuals over unique patterns of time?
  - What local trends or indicators of diversion potential exist for the controlled substance in question?

Requirements for PIs ordering controlled substances through DCM
- As the registration holder, DCM has the reporting accountability to DEA and DPH. In the event that an unexplained loss or theft occurs, notify DCM, EHS, and the MIT Police immediately.

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4.7 Listed Chemicals
The mission of DEA’s Chemical Control Program is to disrupt the illicit production of controlled substances by preventing diversion of chemicals used to manufacture controlled substances. The production of illegal drugs such as methamphetamine, cocaine, heroin, and MDMA (ecstasy) requires enormous quantities of precursor and essential chemicals. The Chemical Control Program seeks to minimize the regulatory burden on the legitimate chemical industry while instituting effective anti-diversion policies. DEA registration, record keeping and suspicious order reporting requirements apply to importers, exporters, manufacturers, distributors and certain retailers of 40 listed chemicals (http://www.deadiversion.usdoj.gov/chem_prog/34chems.htm)

No regulatory burden exists on the MIT researcher unless they are importing or distributing listed chemicals above threshold values as determined by the DEA and international regulatory bodies. Synthesis of chemicals or drugs that have been deemed illegal or illicit by the DEA or state authority are prohibited unless pre-approved by an appropriate MIT review board** and are consistent with a research protocol that is submitted to the DEA or state authority with an appropriate application.

In the event that drugs will be synthesized, please contact the EHS Office to help facilitate that the appropriate review and registration be filed. Regarding use of DEA Listed Chemicals, please refer to the MIT Chemical Hygiene Plan, or contact the Industrial Hygiene Program (IHP) for information pertaining to the safe handling of these chemicals. According to the MIT Chemical Hygiene Plan, access to all hazardous chemicals, including toxic substances, should be restricted. Specifically, these materials should be stored in laboratories or storerooms that are kept locked when laboratory personnel are not present.

** The mechanism for oversight and review of possible chemical synthesis at MIT is currently under review.

4.8 Disposal-Requirements for registered PIs and PIs ordering controlled substances through DCM
MIT is authorized to dispose of expired or surplus controlled substances quarterly in accordance with the procedures outlined in the DEA letter on file (4/2010). This document describes the specific procedures that will be employed to conduct controlled substance destruction & disposal at MIT. See Appendix D for full destruction procedures, schedule and contacts.

Higher schedule materials may require DEA witnessing or institutional official oversight upon destruction. For assistance in disposing of an abandoned controlled substance, please contact the EHS Office.

Requirements for PIs ordering controlled substances through DCM
- Controlled substances ordered from DCM should be returned to DCM for ultimate disposition.
- Any unused controlled substance returned to DCM should be logged on the continuous inventory.

Requirements for PI registrants & DCM
DCM pharmacies and PI registrants will be contacted by EHS according to a schedule maintained
4.9 Shipping Procedures

- Federal law prohibits the export of controlled substances unless certain requirements are met, including, in most cases, export and import permits or declarations. Violators of the law risk arrest or fines both in the United States and the foreign country. Licensed brokers are available for transport of controlled substances. Contact the EHS Office for assistance in arranging for any necessary transport of controlled substances.
- Any shipment of controlled substances requires transfer between two registered entities, specifically registered for the material to transfer. Before shipment, DEA form #222 must be processed.
- Shipment of listed chemicals above international or domestic threshold is a regulated transaction and requires a DEA import/export or distributor registration.

5. Roles & Responsibilities

5.1 Environment Health and Safety Office-Biosafety Program (BSP)

- The BSP is responsible to provide training on the proper recordkeeping, inventorying, and storage of controlled substances.
- The BSP is responsible for helping the research community with corrective actions to maintain compliance with the DEA and DPH requirements for use and storage of controlled substances. When the CAC cites any controlled substance deficiencies or when controlled substance issues are identified by EHS Coordinators, BSP staff will follow up to make certain that appropriate corrective actions are taken and applicable information is provided.

5.2 EHS Coordinator

- The EHS Coordinator will provide guidance to the labs using controlled substances, and will triage questions regarding the use of controlled substances in the research lab.

5.3 Procurement

- Procurement is responsible for invoicing and processing controlled substance orders.
- Procurement is responsible to notify the EHS Office when issues or registration deficiencies arise. Examples of these issues might include a researcher trying to order a controlled substance for which they are not registered, or an unregistered individual trying to order controlled substances.
- Procurement is responsible for forwarding 2 copies of DEA form #222 to the drug supplier.

5.4 Division of Comparative Medicine (DCM)

- DCM is responsible for the ensuring that controlled substances obtained from DCM are being properly stored, handled and inventoried. Controlled substance use is a component of animal care, and various aspects of the controlled substance use is reviewed on semi-annual Committee on Animal Care (CAC) site visits.
- DCM consults EHS when updating any policies or procedures regarding controlled substances.
- DCM pharmacy technicians provide security information and approved inventory templates to researchers obtaining drugs from DCM.
5.5 Principal Investigator (PI)-responsibilities for registered PIs and PIs ordering controlled substances through DCM

5.5.1 Registered PIs

- The PI is responsible for submitting a registration to both the DEA and to the DPH, and is responsible for annual renewals of these documents.
- The PI shall have responsibility for ensuring that controlled substances are licensed and registered for use in their labs and stored and accounted for in the manner that is required for the particular drug classes authorized by the license holder’s registration, as indicated on the license.
- The PI is responsible to designate authorized personnel that will have access to or responsibility for managing controlled substances.
- The PI is responsible to enforce access controls, as necessary, to controlled substances used in the lab.
- The PI is responsible to maintain a continuous inventory to document the use, disposition or transfer of controlled substances within the lab. See Appendix B for example.
- The PI is responsible to reconcile a biennial inventory every two years.
- The PI is responsible to notify the EHS Office and MIT Police immediately of any unauthorized access, theft or unexplainable loss of controlled substances. The PI is also responsible for submitting appropriate forms to both the state and the federal government.
- The PI is responsible to dispose of controlled substances in accordance with applicable regulations.

5.5.2 PIs ordering drugs from DCM

- The PI is responsible to enforce access controls, as necessary, to controlled substances used in the lab.
- The PI is responsible to maintain a continuous inventory to document the use, disposition or transfer of controlled substances within the lab. See Appendix B for example.
- The PI is responsible to return unused supplies of controlled substances to DCM.
- The PI is responsible to notify DCM, the EHS Office and MIT Police immediately of any unauthorized access, theft or unexplainable loss of controlled substances.

6. Training

All users of controlled substances or DEA listed chemicals must complete General Chemical Hygiene training and annual Lab Specific Chemical Hygiene training. Users of controlled substances may also complete the classroom training “Use of Controlled substances within the Laboratory.” In addition, any controlled substance user must also receive the necessary training “Human Subjects Training” from the Committee on the Use of Humans as Experimental Subjects (COUHES) for any experiment involving controlled substances used in humans in clinical trials, or online CAC certification training for usage of controlled substances in animals. For issues relating to controlled substance use in human in clinical trials contact the COUHES Office. For issues relating to controlled substance use in animals, contact the CAC Office.

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7. Monitoring Requirements
Several opportunities exist for inspection of controlled substances. CAC inspections occur twice per year. Proper storage, inventorying, and use will be reviewed during these events. BSP may also do periodic audits of spaces that use controlled substances.

8. Record Management
Each laboratory that uses controlled substances is required to maintain the following records for a period of two years from inception of an approved registration. The following records should be maintained at the registrant's location (as identified on the registration) and be available for review during inspection by appropriate authorities and audit personnel:

- Copies of DEA Registration and DPH Registration
- Executed order forms including MIT paper requisition and copy of DEA form #222
- Disposal records; copies of DEA form #41
- Theft record; copies of DEA form #106
- Shipping receipts: bill of lading, waybills
- Inventory records; both records of the Biennial Inventory and Continuous Inventory Log should be kept for 2 years. See Appendix B & C for examples.
- In the event that a PI registration will be closed, the PI should arrange with his or her DLC to archive the existing records for long term storage.

9. References
9.1 Standards
- 105 CMR 700.00-700.020, Massachusetts Department of Public Health, Implementation of M.G.L. c. 94c
- 21 CFR 1300-1399,
- Codified Controlled substances Act, Title 21 United States Code

9.2 Supplementary Documents
- Security Outline of the Controlled Substances Act
- SOP-EHS 003- Hazardous Waste Removal and Disposal
- MIT Chemical Hygiene Plan

10. Definitions
10.1 Authorized Personnel-An MIT employee authorized to use controlled substances by a PI.
10.2 Controlled Substance-The term “controlled substance” means a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V as defined by 21 CFR 1300-1399.
10.3 Continuous Inventory-Document used to track daily usage of controlled substances
10.4 Disposal-Of a controlled substance that is outdated, excess or no longer intended for use. Disposal also refers to controlled substance that is residual (often referred to as waste) or is contaminated through use or spills.
10.5 Drug Enforcement Administration (DEA)-The unit within the United States Department of Justice that establishes and enforces regulations for the handling and use of controlled substances under the Controlled substances Act.
10.6 Label-The term “label” means a display of written, printed, or graphic matter upon the controlled substance container that list the contents of the container and other information related to use.

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10.7 Practitioner-Real person such as a physician, dentist, veterinarian, or scientific investigator authorized to distribute, dispense, conduct research with respect to, administer or use in a teaching hospital

10.8 Record-An accurate, continuous and current record used to track the acquisition, receipt, use and disposal of controlled substances.

10.9 Registration-Formal grant of specific authority by the DEA and/or MDPH Bureau of Narcotic Enforcement.

10.10 Reverse distributor-A registrant that receives controlled substances from another registrant for the purposes returning unwanted or unusable to manufacturer or processing these substances for disposal
Massachusetts Institute of Technology
Controlled Substances Security Assessment

1. What is the number of employees who have access to the controlled substances? ________
2. Give location of the registrant: ________________
3. Describe use of an effective alarm system, access controls, and other facility security capabilities.
   __________________________________________________________________________
   __________________________________________________________________________
   __________________________________________________________________________
   __________________________________________________________________________

4. What quantities of controlled substances are kept on hand?
   __________________________________________________________________________
   __________________________________________________________________________

5. Is there a prior history of theft or diversion in this area?
   __________________________________________________________________________
   __________________________________________________________________________
   __________________________________________________________________________

Given the range of built in security measures, crime rate, and access to controlled substances, the determination for locked cabinet is:
   __________________________________________________________________________
APPENDIX B

Continuous Inventory of DEA Controlled Substances
Massachusetts Institute of Technology

Registrant ___
DEA Registration Number___________
Drug name_________________________Schedule______________________________
Concentration______________________Volume_______________________________
Lot #_____________________________Bottle #_______________________________
Location of Inventory_______________Start date of Inventory_________________
Date returned to DCM_______________

<table>
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<tr>
<th>Date accessed</th>
<th>Volume removed</th>
<th>Volume remaining</th>
<th>Purpose (anesthesia, analgesia, euthanasia)</th>
<th>Initials of user</th>
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Massachusetts Institute of Technology
Biennial Inventory of Controlled Substances

Registrant ______________________  Current Date ________

DEA Registration Number _________________________  Last Inventory Date ________

<table>
<thead>
<tr>
<th>Name of Substance</th>
<th>Finished Form</th>
<th>Number of Units or volume of each container</th>
<th>Number of containers</th>
<th>Total Units</th>
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Reconciled By________________________________________  Print

Signature ____________________________________________

Registrant Signature
MIT Quarterly Destruction of DEA Controlled Substances

Schedule Destruction

- Contact registrant, EHS technician and 2 EHS witnesses to arrange time and location. Ask registrant for itemized list of materials including number of vials and amount in each.
- Prepare 0.2 N NaOH in EHS fume hood.

EHS technician, employee and EHS witnesses should wear the following PPE during destruction: Gloves, lab coat & eye protection.

- Witnesses check materials against list provided by registrant.
- EHS technician removes crimp & cap from each container using crimp cutters (DEA Program Manager maintains these). The entire vial/bottle is placed in container of NaOH.
- EHS technician coordinates with Clean Harbors for disposal of the containers through hazardous waste stream. The containers will be going into a normal basic labpack drum due to the sodium hydroxide.
- DEA Program Manager completes form 41 & notification letter to DEA and sends either via certified US Mail or FedEx.
- DEA Program Manager keeps a copy of the return manifest along with Form 41 for each disposal.
- DEA Program Manager sends copy of Form 41 to DCM Pharmacy or PI registrant.

SCHEDULE:

<table>
<thead>
<tr>
<th>Nov/Dec</th>
<th>PI registrants: CCR, Media, Magnet &amp; Biology</th>
<th>See DEA program manager for contacts</th>
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<tbody>
<tr>
<td>Feb/Mar</td>
<td>E25 Pharmacy</td>
<td>Catrina Wong</td>
</tr>
<tr>
<td>May/June</td>
<td>46 Pharmacy &amp; PI registrants: BCS, PILM, MCG</td>
<td>Monica Siddalls</td>
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<tr>
<td>Aug/Sept</td>
<td>As needed</td>
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</tbody>
</table>

CONTACTS:

EHS approved witnesses:

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claudiam@mit.edu  
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