

**UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
AUDIT AND ADVISORY SERVICES**

**Controlled Substances in Labs
Project #20-031**

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University of California
San Francisco

Audit & Advisory Services

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SUBJECT: Controlled Substances in Labs, Project 20-031

As a planned internal audit for Fiscal Year 2020, Audit and Advisory Services (“A&AS”) conducted a review of UCSF’s management of controlled substances used in research labs. The purpose of this review was to evaluate the controls over the procurement, administration, and security of controlled substances used in research laboratories – including DEA Schedule I controlled substances.

Our services were performed in accordance with the applicable International Standards for the Professional Practice of Internal Auditing as prescribed by the Institute of Internal Auditors (the “IIA Standards”).

Our review was completed and the preliminary draft report was provided to department management in February 2020. Management provided us final comments and responses to our observations in February 2020. The observations and corrective actions have been discussed and agreed upon with department management and it is management’s responsibility to implement the corrective actions stated in the report. A&AS will periodically follow up to confirm that the agreed upon management corrective actions are completed within the dates specified in the final report.

This report is intended solely for the information and internal use of UCSF management and the Ethics, Compliance and Audit Board, and is not intended to be and should not be used by any other person or entity.

Sincerely,

Irene McGlynn
Chief Audit Officer
UCSF Audit and Advisory Services



EXECUTIVE SUMMARY

I. BACKGROUND

As a planned audit for Fiscal Year 2020, Audit and Advisory Services (A&AS) conducted a review of UCSF's management of controlled substances used in research labs. The acquisition, use and disposal of controlled substances at UCSF is subject to federal Drug Enforcement Administration (DEA)¹ and state regulations², as well as University of California (UC)³ and UCSF policies⁴. Additionally, registration with the DEA and the California Attorney General's Office is required to conduct research with controlled substances. UCSF holds two DEA registrations for research involving DEA Schedule II through V controlled substances. EH&S is pursuing five additional DEA research registrations. Research involving DEA Schedule I controlled substances requires a separate, individual DEA registration directly between the Principal Investigator (PI) and the DEA.

At UCSF, the roles, responsibilities and procedures governing the use of controlled substances in campus research are documented in UC policy BUS-50: Controlled Substances and UCSF's Controlled Substances Program Manual – maintained by Office of Environment, Health and Safety (EH&S). The Controlled Substances Program Manual specifies the responsibilities of participating departments and faculty members, and EH&S in the administration of the Controlled Substance Program. The following are their specific responsibilities (among other duties):

Supply Chain Management:

- Verifies that PI's or authorized requestors who submit requests are authorized to order controlled substances.
- The requested controlled substance is on the lab's Controlled Substances Authorization and within its established limits.
- Issues Purchase Orders for acquisition of controlled substances. Completes 222 forms for purchase of DEA Schedule II drugs. Maintains a database of DEA orders for research and provides reports to EH&S.
- Sends Purchase Orders to EH&S and labs for verification.

EH&S:

- Reviews and approves internal applications to the UCSF Controlled Substances Program.
- Coordinates and performs annual unannounced compliance audits.
- Investigates drug diversion reports and issues Agency Notification.
- Maintains files of internal authorizations, inspections and disposal.
- Coordinates removal and disposal of controlled substances.
- Coordinates DEA requests for biennial inventory with labs and collates data to determine total amount of individual controlled substances labs have on hand.

PI:

- Responsible for proper storage, utilization, record keeping and disposal of all controlled substances purchased on their internal number.

¹ DEA: Title 21 Code of Federal Regulations, Part 1300

² California Uniform Controlled Substances Act, Division 10, California Health and Safety Code

³ University of California Policy BFB-BUS-50: Controlled Substances

⁴ UCSF Controlled Substances Manual

- Reports theft or loss of controlled substances to EH&S and UCPD immediately upon discovery.
- Contacts EH&S for disposal of controlled substances and used controlled substance containers.
- Completes physical biennial inventory as directed by EH&S.

Failure to properly manage any aspect of the Controlled Substance Program increases the risk of loss, theft and diversion of these substances and potential damage to UCSF's reputation.

II. AUDIT PURPOSE AND SCOPE

The objectives of this review were to evaluate the controls over the procurement, administration, and security of controlled substances usage in research laboratories – including labs using DEA Schedule I controlled substances. The scope of the review covered transactions and activities for the period July 2018 to June 2019 at research labs on the Parnassus, Mission Bay and ZSFG campuses.

Procedures performed as part of the review included interview of key stakeholders integral to the implementation of the Controlled Substance Program, review of related policies and procedures, testing, on a sample basis, controlled substance transactions, and review of lab operations. Advice on the application of the controlled substance regulations and vetting of issues was discussed with UCOP General Counsel during the review. For more detailed steps, please refer to Appendix A.

Work performed was limited to the specific activities and procedures described above. As such, this report is not intended to, nor can it be relied upon to provide an assessment of compliance beyond those areas specifically reviewed. Fieldwork was completed in December 2019.

III. SUMMARY

Based on work performed, in general, existing controls surrounding the procurement, administration, and disposal of controlled substances were adequate. The established policies and procedures, primarily the Controlled Substances Program, were generally adhered to. Opportunities for improvement exist in the areas of physical security, inventory, and authorization documentation. Specific observations from this review are listed below.

EH&S Monitored Labs

- Physical access to controlled substance was not adequately secured.
- Controlled substance records were not sufficiently maintained.
- Documentation of controlled substance authorization did not comply with the UCSF Controlled Substance Program.

DEA Schedule I Controlled Substances

- Procedures are not in place for ensuring that Lab personnel researching DEA Schedule I controlled substances complete Controlled Substances training.
- Labs experiencing challenges with disposing of DEA Schedule I Controlled Substances

Additionally, during the course of this review, potential opportunities for improvement were noted for documentation of procedures for establishing annual limits on controlled substance orders and governance of labs researching DEA Schedule I controlled substances.

IV. OBSERVATIONS AND MANAGEMENT CORRECTIVE ACTIONS (“MCA”)

A. EH&S MONITORED LABS

No.	<u>Observation</u>	<u>Risk/Effect</u>	<u>Recommendation</u>	<u>MCA</u>
<p>1</p>	<p><i>Physical access to controlled substances was not adequately secured.</i></p> <p>All of the labs visited kept their controlled substance supplies in securely locked cabinets (or, in some cases, refrigerators). However, two labs (out of the five visited) kept keys to their controlled substance cabinets in an unlocked desk drawer in the lab with potential access to unauthorized personnel.</p> <p>Per UCSF’s Controlled Substance Program, physical security controls must be sufficient to guard against theft and diversion of controlled substances. Leaving the keys to the controlled substance cabinets unattended may allow unauthorized access of these controlled substances.</p>	<p>Security of controlled substances needs to be guarded at all levels of usage. Allowing the keys for the controlled substance storage areas to be kept unattended, may not be sufficient to prevent theft or diversion of these substances.</p>	<p>To prevent unauthorized access of controlled substances, keys to the storage cabinets should be secured and access restricted to authorized personnel.</p>	<p>Action: EH&S management will address access of controlled substances to the specific labs noted in the observation.</p> <p>Additionally, EH&S will issue a Safety Update to the entire research community to reinforce the requirements for maintaining the security over controlled substances.</p> <p>Target Completion Date: February 28, 2020.</p> <p>Responsible Party: Executive Director EH&S</p>
<p>2</p>	<p><i>Controlled substance records were not sufficiently maintained.</i></p> <p>For two of the five labs visited we noted the following:</p>	<p>Without accurate controlled substance inventories, or appropriate records</p>	<p>EH&S should remind lab personnel of their responsibility for the proper</p>	<p>Action: a. EH&S management will address the specific controlled substance</p>

No.	Observation	Risk/Effect	Recommendation	MCA
	<ul style="list-style-type: none"> Controlled substance inventory records were not accurately maintained in one lab. The lab ordered and received two 50 milliliter (ml) vials of fentanyl, however, only one bottle was recorded on the lab's inventory. This controlled substance did not appear to be diverted; lab personnel located the empty bottle in a sharps container. Disposal records for controlled substances are not appropriately retained by another lab. Copies of their signed Controlled Substances Disposal Request Forms after the waste was retrieved by EH&S was not retained. The Form documents the chain of custody for the controlled substance passing from the lab to EH&S. The UCSF Controlled Substance Program requires labs to maintain copies of their Disposal Forms for at least three years. Additionally, for one purchase order (PO), out of 21 reviewed (5%), the amount of controlled substance ordered per the PO and the amount ordered as recorded on UCSF's electronic controlled substance inventory management system (RIO) did not match. Per the PO, the lab ordered 300 milliliters (ml) of Euthasol (sodium pentobarbital); RIO recorded 200 ml of Euthasol as being ordered for the lab. RIO recorded 300 ml being received, this agrees with lab inventory records. This discrepancy appears to be due to a data entry error into RIO. 	<p>documenting the proper disposal of controlled substances, the theft or diversion of these substances may not be detect.</p>	<p>recordkeeping, including retention of disposal records, for all controlled substances in their custody.</p> <p>EH&S management should emphasize with personnel responsible for RIO data input the importance of controlled substance inventory records to help ensure that they are accurately maintained.</p>	<p>recordkeeping deficiencies directly with the labs noted in the observation.</p> <p>Additionally, EH&S will issue a Safety Update to the entire research community to reinforce the requirements for controlled substance recordkeeping.</p> <p>Target Completion Date: February 28, 2020.</p> <p>Action:</p> <p>b. EH&S management will review the possibility of creating a report from the RIO system to periodically compare controlled substance amounts ordered and received as entered into RIO to identify data entry errors.</p> <p>Target Completion Date: April 30, 2020.</p>

No.	Observation	Risk/Effect	Recommendation	MCA
	<p>Accurate inventory records are required to document the types and amounts of controlled substances on hand to help ensure that these substances are not diverted.</p>			<p>Responsible Party: Executive Director EH&S</p>
<p>3</p>	<p><i>Documentation of controlled substance authorization did not comply with the UCSF Controlled Substance Program.</i></p> <p>In our review of “Information on Authorized User of Controlled Substances” (Authorized User) forms, we noted the following:</p> <ul style="list-style-type: none"> Employee screening procedures for one (out of 39, 3%) of the authorized controlled substance users reviewed was not complete. The form was signed, however, the questions regarding felony convictions and unauthorized use of controlled substances were not answered. <p>To enroll in UCSF’s Controlled Substance Program, applicants must fill out and sign Authorized User form. The Authorized User form is an essential element of UCSF’s employee screening procedures for personnel with access to controlled substances (as required per 21 CFR 1301.90).</p> <ul style="list-style-type: none"> One of the 25 (4%) Controlled Substance Release Signature Cards reviewed, was not signed by the Principal Investigator (PI). The Signature Card evidences the PI’s authorization for lab personnel to retrieve controlled substances from EH&S custody. 	<p>Without adequate employee screening procedures, access may be granted to unqualified personnel, as a result, the risk of a drug security breach may increase.</p> <p>Unauthorized access to controlled substances increase the risk these substance may be stolen or diverted from their authorized use.</p>	<p>EH&S management has asked the lab inspector to obtain a completed Authorized User form.</p> <p>Additionally, there is an opportunity to enhance the employee screening process by aligning the recertification of the Authorized User form with required controlled substance training</p> <p>Going forward, Controlled Substance Release Signature Cards should be closely reviewed to ensure that they are complete.</p>	<p>Action:</p> <p>a. EH&S will issue a Safety Update to the entire research community that will include reinforcement of the requirements for documenting controlled substance authorizations.</p> <p>Target Completion Date: February 28, 2020.</p> <p>Action:</p> <p>b. EH&S management will explore the possibility of adding attestation to the Authorized User questions to the required online controlled substance training on the Learning Management System. The attestation will be</p>

No.	Observation	Risk/Effect	Recommendation	MCA
				<p>required to be completed every four years to align with training renewal.</p> <p>Target Completion Date: June 30, 2020.</p> <p>Responsible Party: Executive Director EH&S</p>

B. SCHEDULE I CONTROLLED SUBSTANCES

No.	Observation	Risk/Effect	Recommendation	MCA
1	<p><i>Procedures are not in place for ensuring that Lab personnel researching DEA Schedule I controlled substances complete Controlled Substances training.</i></p> <p>We reviewed five labs researching DEA Schedule I controlled substances. Of these labs, the controlled substances for three are held by an investigational drug pharmacy (either at UCSF or Zuckerberg San Francisco General Hospital). We visited the other two labs to review their controls for controlled substances. We noted that the lab personnel of one of these labs had not taken controlled substance training.</p> <p>To help ensure that research personnel handle and manage controlled substances appropriately and in compliance with applicable regulations, it is a good practice to have a training program</p>	<p>While researchers working with DEA Schedule I controlled substances operate under their own research registration, there is a reputational risk for UCSF should controlled substances, acquired for research purposes, be diverted from their authorized use.</p>	<p>The personnel for the identified lab should take the on-line EH&S Controlled Substances Training to help ensure that they are aware of the appropriate internal controls to the management of controlled substances.</p>	<p>Action: EH&S will send out guidance to the research labs using Schedule I controlled substances in a Safety Update and related publications highlighting good practices, and the availability of EH&S to provide consultation services.</p> <p>Target Completion Date: February 28, 2020.</p>

No.	Observation	Risk/Effect	Recommendation	MCA
				Responsible Party: Executive Director EH&S
2	<p>Labs experiencing challenges with disposing of DEA Schedule I Controlled Substances.</p> <p>In our discussion with personnel researching DEA Schedule I controlled substances, they expressed concerns over their ability to find vendors to dispose of small quantities of unneeded substances. Either the quantity the lab has is too small or the lab does not have a National Drug Code (NDC) to provide to a reverse distributor to dispose of the unused substance.</p>	Retaining controlled substances no longer required for their intended and authorized research purpose may increase risk of theft or diversion of these substances.	EH&S may want to consider assisting these labs with the disposal of these substances as a recharge service.	<p>Action: EH&S will send out guidance to the research labs using Schedule I controlled substances offering consultative services for the management of these substances.</p> <p>Target Completion Date: February 28, 2020.</p> <p>Responsible Party: Executive Director EH&S</p>

V. OPPORTUNITIES FOR IMPROVEMENTS

No.	Observation	Risk/Effect	Recommendation
1	<p>Document procedures for establishing annual limits on controlled substance orders.</p> <p>UC's Controlled Substance Policy (BUS 50) requires campuses to develop procedures that include identification of orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency (among other requirements).</p>	Insufficiently restricting the amount of controlled substances ordered and the frequency of these orders may lead to diversion of these substances	In a future revision of the UCSF Controlled Substances Program, EH&S management should consider documenting the policy of setting

No.	Observation	Risk/Effect	Recommendation
	<p>As a control on ordering controlled substances, it is EH&S management practice to set annual limits on the amount of controlled substances labs are allowed to order. These limits are based on the specific research protocol of the lab, taking into consideration the number and type of subjects and the dosage per subject.</p>	<p>from their authorized use.</p>	<p>limits for controlled substances orders and the procedures for granting exceptions to these limits.</p>
<p>2</p>	<p><i>Governance and oversight of labs researching DEA Schedule I Controlled Substances.</i></p> <p>Per UC's Controlled Substance Policy (BUS 50), research projects at UCSF using DEA Schedule I controlled substances operate under separate, individual DEA research registrations held by the Principal Investigators (PIs). EH&S has no oversight of these labs (unless these PIs also have a UCSF Controlled Substance Authorization for DEA Schedule II-V controlled substances). Consequently, there is no local campus oversight of these labs. According to the Research Advisory Panel of California 48th Annual Report (December 2018), there are currently eight research projects at UCSF using DEA Schedule I controlled substances.</p>	<p>While researchers working with DEA Schedule I controlled substances operate under their own research registrations, there is a gap of oversight of these labs which may increase the risk of diversion.</p>	<p>At the next revision or BUS 50, EH&S should work with UCOP to address this policy question and review the system-wide approach to DEA Schedule I controlled substances.</p>

APPENDIX A

To conduct our review the following procedures were performed for the areas in scope:

- Reviewed relevant regulations and university policies to gain an understanding of the requirements governing controlled substances.
- Interviewed key personnel from EH&S and Supply Chain Management to gain an understanding of the processes and procedures for the procurement, delivery, inventory, physical security and disposal of controlled substances.
- Inspected a sample labs to determine whether controlled substances were securely stored and inventory records were properly maintained.
- Reviewed a sample of controlled substance Purchase Orders to determine whether proper approvals were obtained from the Principal Investigators and the Controlled Substances Officer (when required).
- Reviewed a sample of controlled substance orders to determine if chain of custody records were complete and accurately recorded, and that the recipient was authorized to receive the controlled substance.
- Reviewed findings from EH&S inspection reports and reports of losses to determine whether any unusual patterns existed.
- Reviewed documentation for a sample of authorized individuals to determine whether their personnel screening and training appropriately documented.
- Reviewed a sample of usage and disposal records in research labs to determine whether they adequately documented the disposition of controlled substance.
- Reviewed sample of lab using DEA Schedule I CS in their research to determine if they followed appropriate procedures and kept adequate records.
- Discussed topics concerning controlled substance with UCOP Office of General Counsel to gain an understanding of issues regarding DEA Schedule I substances.