

OBP/DEA Audit Checklist

PI Last Name:	Room(s) Audited:	Audit Date:	Auditor:
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Audits must be performed when no controlled substances are being used in the inspected laboratory.

Registrant/Authorized Agent(s) – Knowledge Check

	Know where to find UC resources: <ul style="list-style-type: none"> UC policy and procedure: “Individual Investigator Use of Controlled Substances in Non-Therapeutic Research” UC forms for controlled substance acquisition, inventory, and use UC training: “Controlled Substance Procurement and Use”
	Know who to contact with questions: <ul style="list-style-type: none"> <u>General Inquiries</u>: Associate Dean for Research (college) or department chair <u>Compliance/Training</u>: Office of Research Integrity (UCORI) integrity@uc.edu
	Registrant and/or Authorized Agent(s) are able to describe their role in the lab’s process for acquiring, using, and disposing of controlled substances.



Use the above QR code to access UC resources.

Drug Storage, Security, and Labelling

	All controlled substances are stored behind at least 2 differently keyed locks.
	Refrigerated controlled substances have a lock present on the refrigerator door.
	Non-controlled substances are not stored with controlled substances.
	Lockbox keys are not stored by the lockbox or together in the same location.
	Expired and/or contaminated drugs awaiting disposal are clearly labeled “do not use” and stored separately from active/non-contaminated drugs.
	Stock containers/solutions are assigned and labeled with a unique identifier.
	Dilution and “cocktail” solutions are labeled with a date of expiration and the initials of the individual who created the solution.

Drug Acquisition, Usage, Inventory, and Disposal

	The controlled substances kept by the lab are congruent with an approved protocol. <ul style="list-style-type: none"> Which type(s) of protocol(s)? Select all that apply. <input type="checkbox"/> IACUC <input type="checkbox"/> IBC <input type="checkbox"/> <i>In vitro</i> <input type="checkbox"/> Other (describe): _____
	Newly received controlled substances are added to the Controlled Substance Individual Drug Log .
	Drug inventory forms are completed initially and annually. <i>Note: annual inventory satisfies both OBP and DEA inventory requirements.</i>
	Copies of completed DEA Form 222s used to acquire Schedule I and II substances are on file with controlled substance records.
	The volume of controlled substances in each container/vial is visually approximate to the remaining balance listed on the related drug usage logs.
	Has the lab experienced theft or loss of controlled substances? <ul style="list-style-type: none"> If yes, were they reported to the OBP, DEA and UCORI?

Recordkeeping

	Registrant is able to quickly produce copies of their active OBP/DEA registration(s). <ul style="list-style-type: none"> Print and keep a paper copy with related controlled substance records, <u>OR</u> Keep an electronic copy on file in an accessible area (e.g. laboratory shared drive)
	Authorized agents are able to provide proof of training completion (e.g. certificate).
	Records for different DEA registrations are kept separate from one another.
	All controlled substance records for the last 5 years are retained and can be quickly produced.