

OBP/DEA Audit Checklist

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

Y	N	N/A	Registrant/Authorized Agent(s) – Knowledge Check
			Know where to find UC resources: - 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: - General Inquiries: Associate Dean for Research (college) or department chair - Compliance/Training: Office of Research Integrity (UCORI) integrity@uc.edu
			Registrant and/or Authorized Agent(s) can describe their role in the lab's process for acquiring, using, and disposing of controlled substances.
Y	N	N/A	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.
Y	N	N/A	Drug Acquisition, Usage, Inventory, and Disposal
			The controlled substances kept by the lab are congruent with an approved protocol: ☐ IACUC ☐ IBC ☐ <i>In vitro</i> ☐ Other (describe):
			Newly received controlled substances are added to the Individual Drug Log .
			Drug inventory forms are completed annually to satisfy both OBP & DEA requirements.
			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 accidental controlled substance breakage, spills, or other accidental losses? • If yes, is the loss recorded on the related usage or administration log? ☐ YES ☐ NO
			Has the lab experienced theft or loss of controlled substances? • If yes, were they reported to the OBP, DEA, and UCORI? ☐ YES ☐ NO
Y	N	N/A	Recordkeeping
			Registrant's OBP/DEA registration(s) are current (not expired).
			Registrant and authorized agents have completed requisite training.
			Registrant and authorized agents have completed the Security Form.
			Authorized Agent List is current.
			Records for different DEA registrations are kept separate from one another.
			All controlled substance records for the last 5 years have been retained.