University of CINCINNATI

OBP & DEA Lab Self-Assessment Checklist

This checklist is a self-evaluation tool to help your laboratory remain inspection-ready for an Ohio Board of Pharmacy (OBP) and/or Drug Enforcement Administration (DEA) audit.

Registrant & Authorized Agent Compliance

	Review UC's controlled substance policy and procedures.
	Know how to find controlled substances forms, FAQs, and resources on Bearcats Landing.
	Have completed UC training: "Controlled Substance Procurement and Use"
	Effective 2/1/2027: OBP TDDD Responsible Person either works a minimum of 8 hours per month at the licensed location OR conducts a documented quarterly in-person, on-site visit.
	Know who to contact with questions: • General Inquiries: Associate Dean for Research for your college, or department chair • Compliance & Training: Office of Research Integrity (UCORI)
	Know how to identify which drugs are considered OBP and DEA controlled substances. • OBP Controlled Substance Reference Table • DEA List of Controlled Substances
	Know how to dispose of controlled substances safely and securely. • OBP Drug Disposal Resources • DEA Drug Disposal Resources
	Keep the list of trained Authorized Agents working with controlled substances current.
	Registrant submits all license and registration changes (including address, schedule, drug codes, responsible person, and registrant) to the OBP, DEA, their college and department, and UCORI.

Drug Storage & Security

	All controlled substances are stored behind at least 2 differently keyed locks.
	Schedule I and II substances are stored in a safe or steel cabinet with an inner and outer door that are keyed differently.
	Schedule I and II substances are not stored with Schedule III, IV, and V substances.
	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.

Drug Labeling

	Stock containers/solutions are assigned and labeled with a unique identifier.

Diluted or "cocktail" solution labels include the:

	unique identifier of the stock containers/vials it was made from
	final dilution concentration/strength
	date the dilution/cocktail was made
	date of expiration
	initials of the individual who created the dilution

Drug Ordering, Usage, Inventory & Disposal

	Registrant or Authorized Agent(s) perform inventory of new drugs at the time of initial receipt.
	Registrant or Authorized Agent(s) perform inventory of all controlled substances annually (satisfies both OBP and DEA requirements).
	When there is a change in responsible person for an OBP TDDD license, a complete inventory is taken by the new responsible person on the effective date of the change.
	Copies of completed DEA Form 222s used to acquire Schedule I and II substances are on file with controlled substance records.
	Drug usage forms are up to date (all drug usage can be accounted for, no backlog of entries).
	Theft and significant loss of controlled substances are promptly reported to the OBP, DEA, and UCORI.
	Accidental drug breakage, spills, or other witnessed accidental losses of controlled substances are documented and witnessed by the Registrant or an Authorized Agent on the Controlled Substances Usage Log (stock) or Controlled Substances Administration Log (dilutions). *These do not need to be reported to the OBP or DEA*.

Recordkeeping

	All controlled substance records (including but not limited to ordering, inventory, use, and disposal) are retained for 5 years to meet institutional, state, and federal recordkeeping requirements.
	Registrant can quickly produce a copy (either paper or electronic) of their active OBP and DEA registration.
	Records for different DEA registrations are kept separate from one another.
	If performing research as a coincident activity under a DEA Practitioner registration, practitioner records are kept separate from research records.
	Schedule I and II drug records are maintained separately from all other laboratory and/or administrative records.
	Schedule III, IV, and V drug records are maintained separately from all other records OR are easy to quickly separate out from other laboratory and/or administrative records.