

Controlled Substances Research Policy

XXXX.1 Purpose and Scope

The purpose of this policy is to help University students and personnel comply with applicable laws and regulations when conducting research involving Controlled Substances.

This policy does **not** apply to the bona fide possession or use of any Controlled Substance by an individual for whom the Controlled Substance has been properly prescribed. This policy also does **not** apply to the clinical prescription, dispensation, or administration of a Controlled Substance, in accordance with the applicable standard of care, by any Ohio-licensed healthcare professional.

The Office of General Counsel is available to answer questions related to this policy and applicable laws and regulations. If there is any irreconcilable conflict between this policy and applicable laws and regulations, such laws and regulations shall supersede this policy. Please alert the Office of General Counsel to any perceived conflicts.

XXXX.2 Definitions

As used in this policy:

- A Chief is an individual Controlled Substance Researcher (CSR) who is a member of the Controlled Substance Research Team (CSRT) of a Controlled Substance Research Project (CSRP) who has been designated to serve as both the Responsible Person (in accordance with the Ohio Revised Code and State Board of Pharmacy regulations) and the Principal Investigator (in accordance with the U.S. Code and Drug Enforcement Administration regulations). The Chief bears ultimate legal responsibility for the safe procurement or manufacturer, storage, use, disposal, and recordkeeping of all Controlled Substances obtained using the Chief's license and registration. The Chief may not delegate such responsibility. In the event a CSRP's Chief is no longer willing or capable to serve in such capacity, such Chief shall promptly notify the Workgroup, who will consult with the remainder of the applicable CSRT.
- A Controlled Substance is a substance (including its analogues) classified under the U.S. Controlled Substances Act or the Ohio Controlled Substances Act, or the implementing regulations promulgated by the U.S. Drug Enforcement Administration (or "DEA") or the Ohio State Board of Pharmacy (or "BOP"). (See 21 C.F.R. §§ 1308.11 – 1308.15; R.C. § 3719.41; OAC §4729-11-92; OAC § 4729-11-03.) **Such schedules are amended periodically and this definition shall change accordingly.** The Office of General Counsel can provide the most recent state and federal schedules upon request.
- A Controlled Substance Research Project (or CSRP) is any research project that involves the manufacture, procurement, possession, dispensation, or administration of a Controlled Substance.
- A Controlled Substance Researcher (or CSR) is a University student, faculty member, or employee who is engaged, in any capacity, in research involving the manufacture, procurement, possession, dispensation, or administration of a Controlled Substance.

- A Controlled Substance Research Team (or CSRT) is the group consisting of the CSRs involved in a particular research project that involves the manufacture, procurement, possession, dispensation, or administration of a Controlled Substance.
- The Controlled Substances Workgroup or Workgroup is a committee composed of a representative of the University's: (1) Office of the Provost; (2) Office of General Counsel (or "OGC"); (3) Department of Public Safety (or "DPS"); (4) Department of Environmental Health and Safety (or "EHS"); and (5) Office of Research and Sponsored Programs (or "RSP").

XXXX.3 Legal Compliance

All CSR shall comply with all applicable laws and regulations. Failure to comply with this policy, or with applicable laws and regulations, may result in disciplinary action, which can include termination of employment or student dismissal. Non-compliance may also result in the imposition of civil and criminal penalties, including imprisonment, by federal, state, and local authorities.

For a given CSRP, the Chief is responsible for understanding, monitoring, and enforcing compliance. The processes and procedures for ensuring and enforcing such compliance shall be promulgated by EHS. Such processes and procedures may be amended at any time, and as needed, by EHS. They may be found here: <https://policy.wright.edu/policy/13301-environmental-health-and-safety>.

XXXX.4 Approval Process

Any University student, faculty member, or employee seeking to begin a CSRP shall prepare a written proposal and submit it for review and consideration by the Workgroup. At a minimum, a CSRP proposal shall include:

- A description of the project, including a statement of why Controlled Substances are necessary for the research, how Controlled Substances will be incorporated into the research, and an estimate of the type and quantity of Controlled Substances that will be used in the project;
- Biographies or CVs of each individual who will have access to Controlled Substances, and nomination of a CSR to serve as the project Chief;
- A description of the site, including specific building and room numbers, where Controlled Substances will be stored or used, along with a summary of all existing physical security measures.
- A summary of funding sources and amounts.

Proposals shall be submitted to RSP in a manner consistent with its requirements for all research proposals. RSP shall distribute a copy of each such proposal to the Workgroup's members. A representative of DPS shall then confer with a CSR on all measures of physical security. Once such security review is complete, DPS shall notify RSP, which shall then convene a meeting of the Workgroup to review the proposal.

The Workgroup shall approve or disapprove of the proposal based on the University's ability to accommodate the research safely and in compliance with applicable laws and regulations. The Workgroup

may impose limitations on the CSRP, and may also condition approval of the proposal. No CSRP may proceed to a stage where Controlled Substances are manufactured, procured, possessed, dispensed, or administered unless and until the Workgroup has given its approval.

After the Workgroup approves of a CSRP, the CSRT will equip and secure its research facilities according to applicable laws and regulations. Funding for any physical facility upgrades or improvements shall be included in the CSRP's budget.

XXXX.5 Background Checks and Drug Screening

The Workgroup may request a background investigation for any CSR at any time for any reason. Such investigation may include, but is not limited to, a criminal background check, a drug test, or both. The Workgroup shall have sole discretion in determining the scope of such investigation, and the cost of such investigation shall be accounted for in the CSRP's budget. A CSR is not required to permit or subject themselves to a Workgroup-directed background investigation; however, the Workgroup will not approve a CSR's participation (or continued participation) in a CSRP if the CSR refuses to promptly submit to a background investigation.

The Workgroup may refuse to authorize any CSR's participation in a CSRP, or remove such CSR from such CSRP, if its investigation shows such CSR has:

- Committed or been convicted of any crime related to or involving a Controlled Substance;
- Committed or been found culpable or liable for any violations of laws, rules, regulations, policies, processes, or procedures applicable to CSRPs;
- Abused, misused, or been addicted to or dependent upon any Controlled Substance or alcohol without a medical explanation; or
- A history of acts or omissions which demonstrates they are neither reliable nor trustworthy enough to participate in a CSRP.

Prior to removing a CSR from a CSRP, the Workgroup shall provide the CSR with written notice as to the basis of their removal and provide them with an opportunity to provide a reasonable explanation for the result and why they should not be removed from the CSRP. The Workgroup is not required to provide such notice or opportunity if it is not authorizing CSR from beginning to participate in a CSRP.

XXXX.6 Security and Storage

Minimum physical security, safety, and storage requirements are set by the BOP and the DEA. The University (through the Workgroup) may require additional security and storage requirements. CSRs must anticipate the costs of physical security and storage compliance, and budget for those costs while planning a CSRP.

In addition to minimum physical security, safety, and storage requirements, CSRs shall ensure that:

- Every room in which Controlled Substances are stored, and every room in which materials and equipment used in the manufacture of Controlled Substances (other than common reagents and

laboratory equipment) are stored, shall be locked at all times. Access to such rooms will be limited to CSRs whose duties require it. Any room in which Controlled Substances are manufactured, or where bulk quantities of Controlled Substances will be stored, may not be shared with other researchers or research projects unrelated to the CSRP.

- Guests shall only be permitted in extraordinary circumstances for purposes related to the CSRP (e.g. escorting test subjects). Guests shall be accompanied at all times by a CSR with access privileges, and bulk quantities of Controlled Substances will be securely locked away during any such visits.
- Physical security shall include, but may not be limited to, sturdy locks on all doors and windows to rooms where Controlled Substances will be manufactured, stored, or used in any quantity. Electronic intrusion detection and 24/7 central station monitoring are generally required, except where there will be an especially small quantity of Controlled Substances on-hand, or where there is a particularly low risk of criminal activity.
- CSRP research facilities may be used at any time by CSRs, but bulk quantities of Controlled Substances may only be handled between 8:00 AM and 5:00 PM, Monday through Friday, unless the CSR has made other arrangements in writing with DPS.
- When not in use, Controlled Substances shall be secured behind a double-lock system. This may include a locked cabinet or safe within a locked room. Cabinets and safes shall be affixed to a wall or floor unless the size of the cabinet or safe is sufficiently large to make removal impractical.
- Bulk quantities of Controlled Substances and Schedule II order forms shall be accessible only to the Chief and, if the Chief wishes, a maximum of one other CSR designated by the Chief in writing. No other person shall have access to such bulk quantities or order forms, except for emergency personnel, such as DPS or EHS.
- Certified, operating chemical hoods shall be installed if the CSRP involves Controlled Substances that are susceptible to airborne distribution (e.g. granular fentanyl). In such cases, the Workgroup may require that research facilities be placed on a separate or filtered ventilation system to protect the rest of the building from potential contamination. All requests to modify existing rooms to install such chemical hoods shall be made to the University's Facilities Department and be made consistent with such department's requirements.
- Appropriate antidotes (e.g., Narcan, if a CSRP involves opiates) shall be kept on-hand in a quantity to be determined by the University Police (or the Fairborn Fire Department). The Chief shall ensure that CSRs are trained to identify the symptoms of possible overdose or exposure to any Controlled Substances used in the CSRP, and if applicable, to administer the appropriate antidote.
- Research facilities will be equipped with suitable personal protective equipment.

XXXX.7 Deliveries & Transportation

The Chief shall be responsible for coordinating the delivery of any Controlled Substance with its manufacturer or distributor. Such Controlled Substance shall be delivered in nondescript packaging

directly to the University's central dock with instructions that such package shall be held for the Chief to pick up only.

When picking up Controlled Substances, the Chief shall be accompanied by at least one other CSR. All Controlled Substances shall be transported from the dock to the CSRP research facilities directly, and shall be promptly inventoried and secured upon arrival.

The Chief shall arrange for armed escorts if Controlled Substance deliveries are frequent, occur at regular or predictable intervals, are of a significant quantity, or where other factors increase the risk of interception/theft. The Chief shall contact and coordinate with DPS for such armed escorts. Armed escorts are optional in other circumstances, but encouraged.

The Chief shall notify the Workgroup, DPS, the BOP, and the DEA immediately if they discover that any Controlled Substance is lost, stolen, or tampered with in transit. The Chief shall arrange for alternate delivery methods if there are incidents with multiple shipments using a particular carrier.

Controlled Substances shall not be transported or shipped off-campus without the prior written authorization of the Workgroup.

XXXX.8 Disposal

The Chief shall coordinate is responsible for coordinating the disposal of any unused, expired, unwanted, or partially consumed Controlled Substances. Disposal costs should be factored into any CSRP budget, which may include, but is not limited to, the engagement of a DEA-approved reverse distributor. EHS is not a DEA-approved reverse distributor, and is not permitted to collect, store, or dispose of Controlled Substances.

The Chief shall not transfer Controlled Substances to the CSR of any other CSRT or CSRP without obtaining prior written authorization from the Workgroup, the DEA, and the BOP. CSRs are prohibited from sharing, lending, transferring, or donating Controlled Substances between CSRPs.

XXXX.9 Licensing and Registration

After the Workgroup approves of a CSRP, the CSRT will equip and secure its research facilities according to applicable laws and regulations. Generally, funding for any physical facility upgrades or improvements must be provided through the CSRP's budget.

The Chief shall apply for BOP licensure and DEA registration after the research facilities are equipped and secured. Generally, a BOP license is required before DEA will process an application for registration. Once the facility is licensed by BOP and the Chief is registered with DEA, the Chief is responsible for maintaining the license and registration in good standing for as long as Controlled Substances are manufactured, procured, possessed, dispensed, or administered.

At the conclusion of a CSRP, the Chief is responsible for coordinating the disposal of all Controlled Substances in accordance with applicable laws and regulations, and for resigning or otherwise terminating the BOP license and DEA registration.

XXXX.10 Delegation of Tasks

The Chief shall be ultimately responsible for any loss, theft, misuse, or diversion of Controlled Substances manufactured or procured using their credentials. In accordance with applicable laws and regulations, the Chief may sometimes delegate tasks, but not responsibilities, to other CSRs. The Chief shall not delegate the following:

- Picking-up deliveries of Controlled Substances;
- Conducting audits of Controlled Substances on-hand at least quarterly and recording the results;
- Maintaining their licenses and registrations in good standing;
- Reporting suspected loss, theft, or diversion of Controlled Substances to DPS, the BOP, and DEA;
- Maintaining correct records as required by law; and
- Monitoring and enforcing this policy.

At the Chief's discretion, the Chief may designate a maximum of one CSR to have access to bulk quantities of Controlled Substances and Schedule II order forms. At the Chief's discretion, any other CSR may be given access to non-bulk quantities of Controlled Substances if such access is required for performance of that CSR's duties.

XXXX.11 Required Reporting

All CSRs shall promptly notify the Workgroup of:

- Any theft, loss, misuse, or diversion of any Controlled Substance;
- Abuse, misuse, addiction to, or dependence on any substance by any CSR;
- The arrest, citation, charging, or conviction of any CSR for any offense other than a minor misdemeanor traffic offenses;
- The death, resignation, or withdrawal of any CSR;
- Any basis to suspect or believe that a CSR is neither reliable nor trustworthy enough to participate in a CSRP; or
- Any potential or perceived violations of laws, rules, regulations, policies, processes, or procedures applicable to CSRs.

XXXX.12 Non-owned Controlled Substances

Any person who discovers Controlled Substances whose responsible owner is unknown or no longer associated with the University shall notify DPS. DPS shall then notify the BOP and the DEA regarding such substances and comply with such authorities regarding the safekeeping, security, or disposal of the same.

XXXX.13 Audits and Recordkeeping

The Chief is responsible for Controlled Substance recordkeeping. Records shall include those required to be kept by BOP and DEA, and those records that are required to be kept by the Workgroup. Records will be maintained in good order, and in close proximity to Controlled Substances to which they apply.

State and federal agencies may have authority to audit all drugs and records. Audits may occur without prior notice, and at any time. The Workgroup may require its own audit of any Controlled Substances records used in the CSRP.

No later than January 31 of each year, the Chief shall prepare a short report summarizing the status of the CSRP, the amount of Controlled Substances on-hand, any change in members of the CSR team, any incidents (including diversions, losses, thefts, etc.) involving Controlled Substances, and a timeline for the CSRP.