Licensure Requirements for Investigational New Drugs and Products

Updated 11/3/2025

This document is intended to provide guidance on Ohio Board of Pharmacy licensure requirements for entities conducting phase 2 and phase 3 clinical trials under investigational new drug applications (INDs).

For more information, please review this document, including the frequently asked questions that start on page 4. If you need additional information, the most expedient way to have your questions answered will be to e-mail the Board office by visiting: http://www.pharmacy.ohio.gov/contact.aspx

Important Definitions (ORC 4729.01)

"Investigational drug or product" means a drug or product that has successfully completed phase one of the United States Food and Drug Administration clinical trials and remains under clinical trial, but has not been approved for general use by the United States food and drug administration. "Investigational drug or product" does not include controlled substances in Schedule I, as defined in section 3719.01 of the Revised Code.

"Product," when used in reference to an investigational drug or product, means a biological product, other than a drug, that is made from a natural human, animal, or microorganism source and is intended to treat a disease or medical condition.

Licensure Requirements for Distributors of Investigational New Drugs and Products

Those engaged in the distribution of investigational new drugs and products in phase 2 or phase 3 must be licensed by the Ohio Board of Pharmacy.

If distributing non-patient specific investigational new drugs or products in phase 2 or phase 3 to entities in Ohio (ex. sending to an Ohio hospital participating in a clinical trial), you must be licensed as one of the following:

License Type	Description
Manufacturer of Dangerous Drugs	Manufactures the drug or product and ships into Ohio.
Wholesale Distributor of Dangerous Drugs	Owns the drug or product and ships into Ohio.
Outsourcing Facility	Compounds the drug or product and ships into Ohio.
Virtual Wholesale Distributor of Dangerous Drugs	Owns the drug or product but uses an Ohio licensed third-party logistics provider (3PL) to ship into Ohio.
Terminal Distributor of Dangerous Drugs – Pharmacy **Terminal Distributor of Dangerous Drugs - Non-Resident Pharmacy**	If conducting an occasional wholesale sale of a drug or product. **NOTE:** Ohio law prohibits a pharmacy from engaging in wholesale sales that exceed five per cent of the total dosage units dispensed by the pharmacy during the same calendar year (see OAC 4729:5-3-09).

IMPORTANT: Per Board resolution, the licensure requirements listed above **DO NOT APPLY** to any investigational new drugs or products that are currently in a phase 1 clinical trial. Those engaged in phase 1 clinical trials that are expected to enter phase 2 are strongly encouraged to seek Ohio Board of Pharmacy licensure to avoid any possible delays.

Licensure Requirements for Entities Conducting Phase 2 and Phase 3 Clinical Trials of Investigational New Drugs and Products

Those receiving investigational new drugs and products in phase 2 or phase 3 to dispense, personally furnish, or administer to clinical trial participants may also require a license as a terminal distributor of dangerous drugs (TDDD) from the Ohio Board of Pharmacy.

A TDDD is required if the receiving entity meets any of the following criteria:

- Is a hospital or pharmacy;
- Is a prescriber clinic or research facility that is overseen by a prescriber that **does not meet** the licensing exemptions in ORC 4729.541. More information about the licensing exemptions can be found here: www.pharmacy.ohio.gov/prescriberTDDD.

IMPORTANT: Per Board resolution, the licensure requirements listed above **DO NOT APPLY** to any investigational new drugs or products that are currently in a phase 1 clinical trial. Those engaged in phase 1 clinical trials that are expected to enter phase 2 are strongly encouraged to seek Ohio Board of Pharmacy licensure to avoid any possible delays.

Frequently Asked Questions

Q1) I am currently conducting a phase 2 or 3 clinical trial of an investigational new drug or product and my facility or my distributor is not appropriately licensed with the Ohio Board of Pharmacy. Do I need to discontinue my clinical trial?

No. The Board does not want you to discontinue any important research being conducted in the state.

To ensure no disruption to research, the Board adopted a resolution on 8/4/2025 that grants those engaged in phase 2 or 3 clinical trials of an investigational new drug or product **until February 4, 2026** to become appropriately licensed.

This means that the Board will not take any administrative action against an unlicensed entity participating in a phase 2 or 3 clinical trial of an investigational new drug or product as long as that entity becomes appropriately licensed on or before February 4, 2026.

Q2) I am conducting a research study with FDA-approved medications. Am I required to obtain licensure from the Ohio Board of Pharmacy?

Yes. FDA-approved medications fall under the definition of dangerous drugs and would require Board of Pharmacy licensure as outlined in pages 2-3 of this document.

Q3) I am conducting a research study with a Schedule I controlled substance. Am I required to obtain Board of Pharmacy licensure?

Yes. All entities engaged in any research with Schedule I controlled substances must obtain the appropriate Board of Pharmacy licensure. There are no licensing exceptions for Schedule I controlled substances.

Q4) How do I verify licensure of my facility or supplier?

Licensure may be verified using Ohio's eLicense system: www.pharmacy.ohio.gov/eLicense.

Q5) How do I apply for licensure?

Ohio Board of Pharmacy licenses must be applied for in Ohio's eLicense system: www.pharmacy.ohio.gov/eLicense.

Q6) Which license type do I apply for as a Virtual Wholesale Distributor of Dangerous Drugs?

In eLicense, select the wholesale distributor of dangerous drugs license application and then indicate that you are a virtual wholesaler within the application.

Board Resolution: Licensure of Investigational New Drug/Product Suppliers

Approved 8/4/2025

Pursuant to the definition of investigational drug or product in Section 4729.01 of the Revised Code, those engaged in the sale of investigational drugs or products that are currently in phase one of U.S. Food and Drug Administration (FDA) clinical trials are not required to obtain licensure from the Ohio Board of Pharmacy.

Those entities engaged in the sale or distribution of investigational drugs or products that are in phase two or three of FDA clinical trials are required to obtain appropriate licensure from the Ohio Board of Pharmacy in accordance with section 4729.51 of the Revised Code.

To ensure that there are no disruptions to existing phase two or three clinical trials, the Board shall exercise its enforcement discretion to provide a six-month grace period (to expire on 2/4/26) for all current suppliers of investigational new drugs or products or those conducting such trials to obtain appropriate Ohio licensure.

This enforcement discretion shall only apply to those engaged in phase two or three clinical trials and does not confer any rights or immunities to any person, applicant, or licensee that fails to comply with the Board's licensure requirements for dangerous drugs that are not investigational new drugs or products undergoing phase two or three clinical trials.

Board Resolution: Licensure Requirements for Investigational New Drug/Product Suppliers

Approved 11/3/2025

The Board hereby waives the following licensure requirements as provided in paragraphs (A)(6) and (A)(7) of section 4729:6-2-04 of the Ohio Administrative Code for applicants intending to distribute investigational drugs or products to Ohio:

- A current and valid license with the licensing authority of the state where the applicant is physically located
- Proof of the entity's valid registration with the United States food and drug administration (FDA)

The Board hereby requires all drug distributors who intend to distribute investigational drugs or products to submit a copy of valid investigational new drug applications (INDs) with their initial license application as permitted in paragraph (A)(8) of section 4729:6-2-04 of the Ohio Administrative Code.