# Pharmacy Pilot or Research Projects

**Updated 8/20/2024**

To be used ONLY by a licensee seeking Board approval of a pilot or research project for innovative system applications in the practice of pharmacy that are not currently permitted under Board of Pharmacy rules (see OAC 4729:5-3-20).

**IMPORTANT:** In reviewing projects, the Board shall only consider projects that expand pharmaceutical care services that contribute to positive patient outcomes.

To be considered, a licensee must submit to the Board a petition for approval, using the form starting on page 3 of this document that contains the following information:

1) **Responsible pharmacist.** Name, address, telephone number, and the license number of the pharmacist responsible for overseeing the project.
2) **Location of project.** Name, address, and telephone number of each specific location and, if a location is a pharmacy, the pharmacy's terminal distributor of dangerous drugs license number where the proposed project will be conducted.
3) **Project summary.** A detailed summary of the proposed project that includes the following information:
    a) The goals, hypothesis, and objectives of the proposed project.
    b) A full explanation of the project and how it will be conducted.
    c) The time frame for the project including the proposed start date and length of the project. The time frame may not exceed eighteen months from the proposed start date of the project.
    d) Background information or literature review to support the proposed project.
    e) The rule or rules to be waived in order to implement the project, an explanation of why such a waiver would not be a detriment to the public, to include procedures to be used during the project to ensure that the public health and safety are not compromised as a result of the waiver, and a request to waive the rule or rules.

Upon complete submission, projects will undergo an initial review by Board staff. If the petition is incomplete or fails to meet the Board's outlined purpose, staff shall return the petition to the requestor with a letter explaining the reason the petition is being returned. A petition that has been returned pursuant to this paragraph may be amended or supplemented as necessary and submitted for reconsideration. A petition that is deemed appropriate and complete shall move on the Board member review process.

After initial staff review, two members of the Board, appointed by the Board President, will conduct a review, and make a recommendation to the full board. Board members conducting a review may request additional documentation and information from the petitioner as part of this review process.

Following the Board member review, the Board will consider the project request at a regularly scheduled meeting of the Board. Upon review, the Board will either approve or deny the petition.

The Board is not permitted to approve any such project if the proposal might jeopardize public health or welfare. If the Board approves the petition, the approval:

a) Will be specific for the project requested, with any modifications the Board deems necessary for patient safety;

b) Will approve the project for a specific time period; and

c) May include conditions or qualifications applicable to the project, including limited waivers of applicable/related rules.

The Board will make reasonable efforts to determine the initial approval or denial of a submission within 90 days of a completed submission.

**IMPORTANT:** All documents pertaining to the application, project, and reports are considered a public record under section 149.43 of the Revised Code and will be provided upon request, without notice to the project's petitioners and/or responsible person. For more information on this, see the notice on page 4 of this document.

For further reference, please see rule 4729:5-3-20 of the Ohio Administrative Code.

# Pharmacy Pilot Research Project Request Form

**Instructions:** *The completed form, along with all supporting materials, must be submitted electronically via email to: compliance@pharmacy.ohio.gov.*

**Part 1 – Responsible Pharmacist Information –** *Pharmacist responsible for overseeing the proposed project*

| **Name of Responsible Pharmacist** | | |
|---|---|---|
| **Address** | **City** | **Zip Code** |
| **Phone Number** | **Email Address** | **Ohio License Number of Responsible Pharmacist** |

**Part 2 – Location of Pilot/Research Project** – *If more than one location is requested, include additional locations in an attachment submitted with this form*

| **Name** | | |
|---|---|---|
| **Address** | **City** | **Zip Code** |
| **Phone Number** | **Is the location a pharmacy?** Yes ◯ No ◯ | **License Number** *(if applicable)* |
| **Will this project include additional locations?** *(If yes, include additional locations as an attachment to this form)* Yes ◯ No ◯ | | |

**Part 3 – Project Summary**

Please include a detailed summary with the submission of this form that includes the following information (submissions must be in either Adobe PDF or Microsoft Word format):

1. The goals, hypothesis, and objectives of the proposed project.
2. A full explanation of the project and how it will be conducted.
3. The time frame for the project including the proposed start date and length of the project. The time frame may not exceed eighteen months from the proposed start date of the project.
4. Background information or literature review to support the proposed project.
5. The rule or rules to be waived to implement the project, an explanation of why such a waiver would not be a detriment to the public, to include procedures to be used during the project to ensure that the public health and safety are not compromised as a result of the waiver, and a request to waive the rule or rules.

**IMPORTANT:** Each part of your project summary should be clearly labeled. Headers should clearly indicate which part of the of the project summary the licensee is addressing. Submissions that do not comply with this format may be returned.

***NOTICE ABOUT OHIO PUBLIC RECORDS LAW***

All documents pertaining to the application, project, and reports are considered a public record under section 149.43 of the Revised Code and will be provided upon request, without notice to the project's petitioners and/or responsible person.

Petitioners asserting that some or all of an application contains information exempt from disclosure under Ohio law shall comply with the following:

- Submit a memorandum identifying the content not subject to disclosure under section 149.43 of the Revised Code, including supporting legal authority for each assertion.
- Submit a redacted version of the materials that the applicant agrees may be released without prior notice to the applicant.

**Part 4 – Attestation** – *To be signed by the responsible pharmacist listed in Part 1 of this form. A digital signature may be used.*

| |
|---|
| I DECLARE UNDER PENALTIES OF FALSIFICATION AS SET FORTH IN CHAPTERS 2921. AND 4729. OF THE OHIO REVISED CODE THAT THE ANSWERS PROVIDED ON THIS FORM AND ALL ACCOMPANYING MATERIALS ARE **TRUE, CORRECT, AND COMPLETE.**<br><br>I FURTHER ATTEST THAT I UNDERSTAND THE PROVISIONS OF OHIO'S PUBLIC RECORDS LAW AS SET FORTH IN SECTION 149.43 OF THE REVISED CODE AND RULE 4729:5-3-20 OF THE ADMINISTRATIVE CODE. |

| **Signature of Responsible Pharmacist** | **Date Signed** |
|---|---|
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***The completed form, along with all supporting materials, must be submitted electronically via email to: compliance@pharmacy.ohio.gov.***