

Psilocybin Laboratory License Application Guide for Applications Submitted by Mail

PUBLIC HEALTH DIVISION
CENTER FOR HEALTH PROTECTION
Oregon Psilocybin Services (OPS)
<http://oregon.gov/psilocybin>

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Introduction

The purpose of this guide is to provide additional support to applicants submitting a psilocybin laboratory license application **BY MAIL**. The most current version of this guide and the online application guide can be found on the web at [Oregon Psilocybin Services \(OPS\) – Laboratory License webpage](#). Applicants must read, understand, and agree to adhere to the Oregon Psilocybin Services statutes and administrative rules, outlined in [Oregon Revised Statute \(ORS\) Chapter 475A](#), [Oregon Administrative Rules \(OAR\) Division 333, Chapter 333](#), as well as any other applicable statutes or laws.

The [Oregon Psilocybin Services – Training Program, Licensing, and Compliance system \(TLC\)](#) is an online platform where applicants can apply for psilocybin licenses, worker permits, and training program curriculum approval. Please visit <https://psilocybin.oregon.gov> to complete the application online. If you are unable to complete the application packet online, you may print, complete, and mail the application packet and pay the application fee following the instructions provided in the remittance form at the end of this application. Printable application forms may be found [here](#).

Everyone has a right to know about and use Oregon Health Authority (OHA) programs and services. OHA provides free help. If you need these written materials in other languages, braille, large print, or other formats, please contact:

OHA.Psilocybin@oha.oregon.gov
(971) 673-0322

For all other questions and concerns regarding licenses and permits, please contact:

Licensing.Psilocybin@oha.oregon.gov
(971) 673-0304

DISCLAIMER: Psilocybin remains a schedule I drug under the federal Controlled Substances Act. Applicants are responsible for making their own determinations regarding the legal risks associated with participating in this program. The information provided in the application materials, including applicant and instructor names, is subject to disclosure under Oregon's public records laws.

Laboratory License Application Packet Checklist

The paper application packet contains a checklist to assist in planning and ensuring the application is complete. Please complete the checklist to ensure you have all the necessary items.

- Completed and signed laboratory license application
- Copy of the front and back of a valid, unexpired government-issued photo identification for **each individual applicant**. Applicants must be age 21 or older. Accepted identification includes:
 - Passport;
 - Driver license, whether issued by the State of Oregon or by another state of the United States;
 - Identification card issued under ORS 807.400;
 - United States military identification card;
 - An identification card issued by a federally recognized Indian tribe with photo, name, and date of birth; or
 - Any other identification card issued by a state or territory that bears a picture of the person, the name of the person, the person's date of birth and a physical description of the person.
- Copies of Individual and Legal Entity Applicant Information forms for **each applicant**
- Copy of ORELAP Endorsement
- Copy of the Premises Plan including boundaries and camera plan
- Copy of the Social Equity Plan
- Copy of the Authorized Individuals form
- \$500 Non-refundable license application fee with payment remittance form (payment must clear before application will be reviewed)

Getting Started with a Mailed Application

The paper version of the laboratory license application packet is 13 pages and contains the following:

- Application introduction and checklist
- Main application form
- License application fee payment remittance form
- License application supplemental for additional applicants

Please be sure to complete each section of the application and ensure all information is entered correctly. Incorrect entry of contact information may result in delayed application processing.

Laboratory Information

Please provide the following information:

- Named Licensee **(required)**
 - The named licensee is an individual or entity who is listed on the license certificate.
- Website **(optional)**
- Registered Business Information **(required)**
 - The application asks if the laboratory is registered as a business with the Oregon Secretary of State. If yes, please provide the SOS business registry number.
 - If no, the application asks if the laboratory is registered as a business in another state, US territory, or freely associated state. If yes, please provide the business registry number.
 - US territories: American Samoa, the Commonwealth of the Northern Mariana Islands (CNMI), Guam, Puerto Rico, US Virgin Islands
 - Freely associated states: the Federated States of Micronesia, the Republic of the Marshall Islands, Republic of Palau
 - Review and initial the statement indicating you understand and agree licensees that are required to be registered with the Oregon Secretary of State must register prior to receiving a license and maintain registration **(required)**
- Physical Address **(required)**
- Mailing Address **(required)**
 - Provide a brief description of the premises including any information to assist OPS with planning for and travelling to a site inspection

Previous License or Permit

If the named licensee has ever applied for or received any other licenses from Oregon Psilocybin services, please provide this information within the application.

Applicant Information

An application for a psilocybin laboratory license must identify all individuals and legal entities who qualify as applicants as described in [OAR 333-333-1010](#) and [OAR 333-333-4030](#). Applicants are responsible for ensuring all individuals and legal entities who meet the definition of an applicant are identified.

Applicants are individuals or legal entities who:

- Hold or control an interest of more than 20 percent in the entity proposed to be licensed;
- Are entitled to receive 20 percent or more of revenue, profits or proceeds from the entity proposed to be licensed; or
- Are entitled to exercise control over the entity proposed to be licensed

If a legal entity is an applicant, the following individuals within the legal entity are also applicants:

- If an applicant is a limited partnership, each general partner in the limited partnership
- If an applicant is a limited liability company, each manager and managing member of the limited liability company
- If the applicant is a for-profit corporation, each principal officer of the corporation
- If the applicant is a non-profit entity, each principal officer of the entity
- Any individual within the legal entity who meets the definition of applicant in OAR 333-333-1010

All applicants must be identified in the application. If an individual within a legal entity is identified as an applicant, please be sure include them as an individual applicant.

Designated Primary Point of Contact

One applicant must be designated as the Primary Point of Contact for communication. The Primary Point of Contact is responsible for ensuring all persons identified as licensees or applicants are aware of relevant communications, including but not limited to notices issued under ORS Chapter 183.

Please indicate which individual **or** legal entity applicant is designated as the Point of Contact by selecting **only one** checkbox under the Point of Contact Columns in the application

Individual Applicant Information Form

Each individual applicant must complete an Individual Applicant Information Form. Applicants are responsible for completing and ensuring all individual applicant information forms are included with the mailed application.

Individual applicant information forms can be found on the [Oregon Psilocybin Services – Apply for a Laboratory License webpage](#).

Each individual applicant must complete and sign their own applicant information form.

Within this form, an individual applicant will provide the following information:

- Indicate which type of license the individual applicant is associated with: manufacturer, laboratory, or service center **(required)**
- Provide the Laboratory Named Licensee listed on the application. **(required)**
- Provide the name(s) of the legal entity applicants the individual may be associated with **(required is applicable)**
- Legal Name **(required)**
- Preferred Name **(optional)**
- Prior Names and Aliases **(required)**
 - This information is used for the purposes of the background check
- Date of Birth **(required)**
- Social Security Number **(required if you have one)**
 - If you do not have a social security number, you may still be licensed or permitted by Oregon Psilocybin Services
 - As part of your application for an initial or renewal license, Federal and State laws require you to provide your Social Security Number (SSN), if you have one, to Oregon Psilocybin Services for child support enforcement purposes (42 USC § 666(a)(13) & ORS 25.785). If you are an applicant or licensee and have an SSN but fail to provide your SSN, Oregon Psilocybin Services may refuse to process your application. Your SSN will be used only for child support enforcement

purposes unless you confirm your agreement that OPS can use it for administrative purposes as well

- In the application, we ask for **voluntary** consent to use your social security number, if you have one, to confirm your identity during the criminal records check. We will not deny you any rights, benefits, or privileges otherwise provided by law if you do not consent to use of your SSN for these administrative purposes

- Check the appropriate box next to the social security field indicating whether you consent or do not consent

(required)

- Primary Phone Number **(required)**
- Alternate Phone Number **(optional)**
- Primary Email Address **(required)**
- Preferred Language **(optional)**
- Preferred Pronouns **(optional)**
- Physical Address **(required)**
- Mailing Address **(required)**
- Residential History Outside of Oregon in the Past 5 Years **(required if applicable)**
 - This information is used for the purposes of the background check

Previous License or Permit

If the individual applicant has ever applied for or received any other licenses or permit from Oregon Psilocybin Services, please provide this information within the form.

Worker Permit

An individual who is a licensee or a licensee representative must have a valid worker permit if the individual participates in:

- The provision of psilocybin services at a licensed premises
- The possession, manufacturing, securing, or selling of psilocybin products at a licensed premises
- The recording of the possession, manufacturing, securing, or selling of psilocybin products at a licensed premises
- The verification of any document described in ORS 475A.445

Please review the worker permit application and application guide by visiting the [Oregon Psilocybin Services \(OPS\) – Worker Permit webpage](#). Individuals may apply for a worker permit online by visiting [Oregon Psilocybin Services – Training Program, Licensing, and Compliance system \(TLC\)](#). If an individual applicant does not want or is unable to apply online, the worker permit application may be submitted with the laboratory license application or mailed separately.

Important note: An individual person identified as a license applicant is not required to undergo a criminal background check and fitness determination if that person has completed a criminal background check and fitness determination in connection with another license application **within 30 days of their current license application**.

[Legal Entity Applicant Information Form](#)

Each legal entity applicant must complete a Legal Entity Applicant Information form. Applicants are responsible for completing and ensuring all legal entity applicant information forms are included with the mailed application. The Legal Entity Applicant Information form can be found on the [Oregon Psilocybin Services – Apply for a Laboratory License webpage](#).

Within this form, the legal entity will provide the following information:

- Indicate which type of license the legal entity applicant is associated with: manufacturer, laboratory, or service center **(required)**
- Provide the Laboratory Named Licensee listed on the application. **(required)**
- Legal Entity Name
- Registered Business Information **(required if applicable)**
 - The application asks if the laboratory is registered as a business with the Oregon Secretary of State. If yes, please provide the SOS business registry number.
 - If no, the application asks if the laboratory is registered to do business in another state, US territory, or freely associated state. If yes, please provide the business registry number.
 - US territories: American Samoa, the Commonwealth of the Northern Mariana Islands (CNMI), Guam, Puerto Rico, US Virgin Islands

- Freely associated states: the Federated States of Micronesia, the Republic of the Marshall Islands, Republic of Palau
- Review and initial the statement indicating you understand and agree licensees that are required to be registered with the Oregon Secretary of State must register prior to receiving a license and maintain registration **(required)**
- Primary phone number **(required)**
- Alternate phone number **(optional)**
- Primary email address **(required)**
- Preferred language **(optional)**
- Headquarters/Main Office Address **(required)**
- Physical Address **(required)**
- Mailing Address **(required)**

Previous License or Permit

If the legal entity applicant has ever applied for or received any other licenses or permit from Oregon Psilocybin Services, please provide this information within the form.

Financial Interests

Applicants and licensees must create and maintain complete lists of all individuals and legal entities that hold a financial interest in a laboratory, including contact information for each individual or entity and a description of their financial interest. Applicants and licensees must provide the information required to Oregon Psilocybin Services within 15 calendar days of the written request for such information.

If a legal entity holds a financial interest, the following individuals within the legal entity also hold a financial interest:

- For limited partnerships, each general partner in the limited partnership
- For limited liability companies, each manager and managing member of the limited liability company
- For for-profit corporations, each principal officer of the corporation
- For non-profit entities, each principal officer of the entity

The legal entity applicant must initial the following statement indicating they understand and agree:

- I have read, understand, and agree to adhere to the financial interest requirements outlined in ORS 475A and OAR Chapter 333, Division 333

Associated Individual Applicants

The following individuals within the legal entity are also applicants:

- If an applicant is a limited partnership, each general partner in the limited partnership
- If an applicant is a limited liability company, each manager and managing member of the limited liability company.
- If the applicant is a for-profit corporation, each principal officer of the corporation
- If the applicant is a non-profit entity, each principal officer of the entity
- Any individual within the legal entity who meets the definition of applicant in OAR 333-333-1010

The legal entity applicant must provide the names and dates of birth of all individuals who meet the definition of an applicant. Those individuals must complete an Individual Applicant Information Form. Within the application, a table is provided to enter several applicants. If more space is needed, a supplemental applicant form is included at the end of the application.

Oregon Environmental Laboratory Accreditation Program (ORELAP) Accreditation

Laboratories must be accredited by the Oregon Environmental Laboratory Accreditation Program (ORELAP) prior to applying for a psilocybin laboratory license. For more information about accreditation by ORELAP please visit: [Resources for Laboratories Seeking Accreditation for Psilocybin](#)

Applicants must submit a copy of the ORELAP accreditation with the laboratory license application.

Important Notes:

- A laboratory licensee may not perform any required psilocybin sampling or testing using any sampling or testing methods or equipment not permitted under the laboratory's accreditation through the Oregon Environmental Laboratory Accreditation Program

- A laboratory licensee may not perform any required psilocybin sampling or testing for any licensed psilocybin manufacturer in which the laboratory licensee has a financial interest
- Nothing in OAR Chapter 333, Division 333 prohibits laboratory licensees from possessing *psilocybe cubensis* for purposes of method validation and testing

Premises Plan

Laboratory license applicants must submit a premises plan as part of the application. A premises plan must include:

- A map or sketch of the proposed license premises, including the boundaries of the licensed premises relative to its location
- Identification of any unlicensed areas within the building where the licensed premises is located including suite numbers (if applicable)
- Identification of any residence or other unlicensed structures located on the same tax lot as the premises proposed to be licensed
- A scaled floor plan identifying all points of ingress and egress
- Identification of camera locations
 - A licensed premises must have camera coverage for:
 - All points of ingress and egress to and from indoor areas of the licensed premises
 - All areas where psilocybin products are stored or produced
 - All areas where psilocybin waste is required to be stored, destroyed, or rendered unusable as required by OAR 333-333-8000
- Identification of limited access areas
- Identification of areas where psilocybin products will be stored within the licensed premises.

Social Equity Plan

Applicants must submit a social equity plan with their application. An applicant may determine the format and structure of the social equity plan while meeting the requirements in [OAR 333-333-4020](#) which describes the following:

Social equity plans must include a description of the following:

- Application of diversity, equity, justice and inclusion principles to the licensee's internal practices and policies.
- Objective performance measures that the licensee will use to evaluate their social equity plan.

Important Reminders

- An applicant for license renewal must provide documentation of the evaluation of implementation of their social equity plan based on the objective performance measures required in social equity plans.
- Licensees must provide written notice, in a form and manner prescribed by the Authority, of any material changes to their social equity plan within 60 days of making the change.

Authorized Individuals of the Named Licensee Form

Manufacturer, service center, and laboratory license applicants must submit the Authorized Individuals form which identifies the individual applicants authorized to make decisions on behalf of the Named Licensee. At least one individual must be identified.

Applicants must use the Authorized Individuals of the Named Licensee form which may be found on the [Oregon Psilocybin Services \(OPS\) – Manufacturer License webpage](#).

Fee Information and Submitting the Application

Non-Refundable Application Fee: \$500 USD

The laboratory license has an application fee of \$500 USD and will not be reviewed until the application fee payment has been received and cleared. The application fee remittance form within the application provides instructions on how to submit the application fee payment. If an applicant fails to pay the application fee within 90 calendar days of submitting the application, the application is considered incomplete and will be closed.

Non-Refundable Laboratory Annual License Fee: \$10,000 USD

If the laboratory license application is approved, pending license fee payment and clearance, you will receive a request to pay the annual

licensing fee. At that time, we will provide a licensing fee remittance form to submit with your annual license fee payment.

A license will not be issued until the license fee is paid and cleared. A licensee may not operate until the effective date of licensure.

If an applicant fails to pay the license fee within 180 calendar days of being notified of the license being approved, pending license fee payment and clearance, the application is considered incomplete and will be closed.

Fee Payment Clearance

An application will not be reviewed until the application fee payment has been received and cleared. A license will not be issued until the license fee is paid and cleared. A licensee may not operate until the effective date of licensure.

Please note personal and business checks will be held for 21 days to ensure payment clearance.

Remittance Form and Submitting the Application

An application fee payment remittance form is included in the application packet. Please include the remittance form with the application fee payment. Once an application has been approved, pending fee payment and clearance, we will provide an annual licensing fee remittance form to submit with your license fee payment. Please include the remittance form with the license fee payment.

OPS accepts the following payment methods for mailed applications:

- Money Order
- Cashier's Check
- Personal/Business Check
 - Personal and business checks will be held for 21 days to ensure payment clearance
- Cash (**Please Do Not Mail Cash**)

Money orders and checks are payable to: **Oregon Psilocybin Services**

Applicants can mail the application packet, money order or check, and remittance form to the following address:

Oregon Health Authority - Public Health Division
Fiscal Services
RE: OPS
PO Box 14260
Portland, OR 97293-0260

In-person payment with a money order or check:

To make an in-person fee payment with a money order or check, proceed to Cashier's Office on the second floor of the Portland State Office Building at:

800 NE Oregon St, Suite 200
Portland, OR 97232
Hours: 9am to 4pm, Mon to Fri

Additional instructions: The Cashier's Office window is located on the second floor next to the Vital Health Statistics window. If security asks if you have an appointment, you may let them know you are dropping off a payment for Oregon Psilocybin Services at the Cashier's Office window which does not require an appointment. Please include the remittance form with the payment and provide the application, if not already submitted by mail.

To make cash payment arrangements or for payment questions, please contact:

Licensing.Psilocybin@oha.oregon.gov or (971) 673-0304

Background Checks

Individual applicants for a laboratory license are required to pass a criminal background check to be issued a license. Within the Individual Applicant Information form, individual applicants will be asked to provide information required to initiate the background check process. The following information in the form will be used to initiate the background check:

- Legal name
- Prior names and aliases
- Date of birth
- Social security number

- We ask for **voluntary** consent to use your social security number, if you have one, to confirm your identity during the criminal records check. We will not deny you any rights, benefits, or privileges otherwise provided by law if you do not consent to use of your SSN for these administrative purposes
- Physical address
- Mailing address (if different)
- Phone number
- Email
- Residential history outside of Oregon in the past five years

Do not submit fingerprints until Oregon Psilocybin Services requests that you do so.

Once we initiate a criminal background check, the individual applicant will receive an electronic letter by email that explains how to schedule an appointment with a [FieldPrint](#) vendor. FieldPrint vendors are private contractors and are not associated with a government agency. Visit [this link](#) to find the nearest FieldPrint vendor.

For more detailed information on background checks, please review the [OPS - Overview of the Background Check Process](#) document.

Application Review

OPS will review applications once the application fee payment is paid and cleared. It may take OPS several weeks to review applications and it will be reviewed in the order received. Thank you for your patience.

Incomplete and Insufficient Applications

An application is considered **incomplete** if the application is missing required information (e.g., the application fee has not been paid or the applicant did not submit fingerprints). If the application is incomplete, we will notify you by email to give you an opportunity to make your application complete. You have 90 days from the initial date you are notified to complete your application. If you fail to do so, the application will be closed.

An application is considered **insufficient** if the complete application or site inspection does not meet requirements outlined in statute or rule. If the

application is insufficient, we will notify you by email to give you an opportunity to meet requirements. You will have 90 days from the initial date you are notified to meet requirements, or your application will be denied.

Application Approval and Proof of License

Once the application has been approved (after the license fee is paid and cleared), we will notify you by email that the annual license is approved. The Point of Contact will be emailed a proof of license which will include the laboratory named licensee, license ID number, address, license effective date, license expiration date, and a QR code which can be scanned to verify license status. Please note, the public facing license verification look-up and QR code **will only** confirm a license ID number, effective date, and expiration date.

As outlined in [OAR 333-333-4120](#), laboratory licensees must display a proof of licensure in a prominent place on the licensed premises. **A licensee may not operate until the effective date of licensure.**

Notification of Changes

Please review all rules for Notification of Changes as described in [OAR 333-333-4200](#). An applicant or licensee must notify OPS in writing within 10 business days of the changes described in rule. Please notify the OPS Licensing Team of these changes by emailing the licensing team at licensing.psilocybin@oha.oregon.gov.

Changes which need to be reported by laboratory license applicants and licensed laboratories include:

- Adding or removing an individual or legal entity who qualifies as an applicant under OAR 333-333-1010 or OAR 333-333-4030
- A change in contact information for any person listed as an applicant or licensee.
- Any closure of the licensed premises lasting more than 30 days.
- Any conviction for any misdemeanor or felony committed by an individual listed as an applicant or licensee.
 - When notifying the OPS licensing team of changes to conviction history, please only include the following information:
 - Legal Name

- Laboratory License ID Number
- A statement notifying OPS of a change to criminal history conviction
 - Please **DO NOT** provide any conviction details in the notification to OPS
- A criminal background check is required if we learn that an individual has been convicted of a crime after their license has been issued.
- Any arrest for conduct that occurred on the licensed premises.
- Any theft of psilocybin products or cash from the licensed premises.

Frequently Asked Questions (FAQs)

How do I know when my application and payment have been received?

Once OPS receives your application, application fee payment, and remittance form OPS will send you a confirmation email.

Is the \$500 application fee refundable?

No. The application fee is nonrefundable.

Is the annual license fee refundable?

No. The annual license fee is nonrefundable.

How long will it take OPS to review applications?

OPS will review applications once the application fee payment is paid and cleared. Due to limitations in predicting application volume, it may take OPS several weeks to review applications. Thank you for your patience.

How do I know the status of my application?

Due to limitations in predicting application volume, it may take OPS several weeks to review applications.

If you have questions about the status of your application, please contact:

Licensing.Psilocybin@oha.oregon.gov

(971) 673-0304

OPS sent me a notice that the application is incomplete or insufficient. What do I do now?

If the application is incomplete, you have 90 days from the initial date you are notified to complete your application. If you fail to do so, the application will be closed. If the application is insufficient, you will have 90 days from the initial date you are notified to meet requirements, or your application will be denied. You may also request withdraw of the application at any time by notifying OPS. Please note, the application fee is nonrefundable.

What happens if my application is closed? What happens if it is denied?

If the application is closed, you may reapply and pay the nonrefundable application fee. If OPS denies an application, OPS will provide notice of the denial in writing and you have a right to a hearing under [ORS chapter 183](#).

Can I withdraw my application?

You may request withdraw your application by contacting OPS. Please note, the application fee is nonrefundable.

Licensing.Psilocybin@oha.oregon.gov
(971) 673-0304

How long is the license valid?

The laboratory license term is one year from the effective date. OPS is currently developing the application renewal process for laboratory licenses.

How do I know what the TLC ID number assigned to my license is?

Please contact OPS for assistance:

Licensing.Psilocybin@oha.oregon.gov
(971) 673-0304

Who do I contact about general questions regarding license and permit questions?

Please contact OPS for assistance:

Licensing.Psilocybin@oha.oregon.gov
(971) 673-0304