



RULE-MAKING ORDER

CR-103P (May 2009)
(Implements RCW 34.05.360)

Agency: Washington State Liquor and Cannabis Board

Permanent Rule Only

Effective date of rule:

Permanent Rules

31 days after filing.

Other (specify) _____ (If less than 31 days after filing, a specific finding under RCW 34.05.380(3) is required and should be stated below)

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

Yes No If Yes, explain:

Purpose: The purpose of this proposal is to implement the application process, review process, and requirements for the marijuana research license as established in RCW 69.50.372. RCW 69.50.372 gives the WSLCB authority to adopt rules related to the implementation of the marijuana research license in RCW 69.50.372(5), including application requirements and administrative provisions relating to the license. These rules are needed to fully implement and issue the license.

Citation of existing rules affected by this order:

Repealed:

Amended:

Suspended:

Statutory authority for adoption: RCW 69.50.342, 69.50.345, and 69.50.372

Other authority :

PERMANENT RULE (Including Expedited Rule Making)

Adopted under notice filed as WSR 16-23-105 on November 17, 2016 (date).

Describe any changes other than editing from proposed to adopted version: Minor adjustments were made to the proposed rules prior to requesting adoption. These changes address that research license applicants are not subject to the prioritization requirements for other marijuana licensees, and clarify that research licensees may use funds sourced from outside Washington State for research efforts.

If a preliminary cost-benefit analysis was prepared under RCW 34.05.328, a final cost-benefit analysis is available by contacting:

Name: _____ phone () _____
Address: _____ fax () _____
e-mail _____

Date adopted: January 25, 2017

NAME (TYPE OR PRINT)

Jane Rushford

SIGNATURE

TITLE

Chair

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: January 25, 2017

TIME: 10:18 AM

WSR 17-04-038

(COMPLETE REVERSE SIDE)

**Note: If any category is left blank, it will be calculated as zero.
No descriptive text.**

**Count by whole WAC sections only, from the WAC number through the history note.
A section may be counted in more than one category.**

The number of sections adopted in order to comply with:

Federal statute:	New	_____	Amended	_____	Repealed	_____
Federal rules or standards:	New	_____	Amended	_____	Repealed	_____
Recently enacted state statutes:	New	_____	Amended	_____	Repealed	_____

The number of sections adopted at the request of a nongovernmental entity:

New	_____	Amended	_____	Repealed	_____
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The number of sections adopted in the agency's own initiative:

New	<u>1</u>	Amended	_____	Repealed	_____
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The number of sections adopted in order to clarify, streamline, or reform agency procedures:

New	__	Amended	_____	Repealed	_____
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The number of sections adopted using:

Negotiated rule making:	New	_____	Amended	_____	Repealed	_____
Pilot rule making:	New	_____	Amended	_____	Repealed	_____
Other alternative rule making:	New	_____	Amended	_____	Repealed	_____

NEW SECTION

WAC 314-55-073 Marijuana research license. A marijuana research license allows a holder of the license to produce, process, and possess marijuana for the limited research purposes provided in RCW 69.50.372. The WSLCB designates a scientific reviewer (reviewer) to review research applications and make recommendations for the approval or denial of research projects and to assess licensed research activities. The following provisions are in addition to the requirements for marijuana research licensees provided in RCW 69.50.372.

(1) Eligibility and continuing requirements for research license applications, prohibitions and restrictions.

(a) Other than the restrictions listed in this subsection, any person, organization, agency, or business entity may apply for a marijuana research license.

(b) Other marijuana licensees may apply for a research license. Facilities at which the research is conducted must be wholly separate and distinct from the marijuana business, except:

(i) Licensed producers with a research license and approved research project may grow marijuana plants or possess marijuana for research purposes at the producer's licensed premises. However, all marijuana grown or possessed for research purposes or purposes other than those related to the research project must be kept wholly separated and distinct from commercial operations and must not be comingled with or diverted to marijuana grown for commercial purposes or purposes other than those related to the research project; and

(ii) Licensed processors with a research license and approved research project may possess marijuana for research purposes at the processors licensed premises. However, all marijuana possessed for research purposes must be kept wholly separated and distinct from all marijuana possessed for commercial purposes or purposes other than those related to the research project and must not be comingled with or diverted to marijuana possessed for commercial purposes or purposes other than those related to the research project. Licensed processors who do not also hold a producer license may not grow marijuana plants for the purposes of research under a research license at the processor's licensed location.

(c) Labs certified to perform quality assurance testing on marijuana and marijuana products by the WSLCB may apply for a research license. Certified labs with a research license and approved research project must ensure that all marijuana possessed for research purposes is wholly separated from and is not comingled with marijuana possessed for state required testing purposes for licensed producers or processors or marijuana possessed for any reason other than research purposes.

(d) All research license applicants and persons conducting research under the research license must be twenty-one years of age or older.

(e) All research license applicants and those persons that have managing control over an organization, agency, or business entity must pass a criminal background check and financial investigation prior to being eligible to receive a research license.

(f) Except as otherwise provided by chapter 69.50 RCW and agency rule, no applicant for a research license may possess any marijuana plants or marijuana for research purposes unless and until the re-

search project is approved and the applicant is notified that the research license is approved in writing by the WSLCB.

(g) No research licensee may conduct research unless and until the research project is approved by the reviewer and the WSLCB in writing.

(2) **Initial applications.**

(a) **Application made with business licensing services (BLS).**

(i) Applicants for a research license must apply through BLS to begin the application process for a research license.

(ii) Upon submitting an application for a research license through BLS, the applicant will receive an application letter from the WSLCB directing the applicant to submit the additional application materials directly to the WSLCB's designated scientific reviewer (reviewer).

(A) The applicant must submit complete and accurate additional application materials directly to the reviewer within thirty days of the date of the application letter from the WSLCB or by the date indicated on the application letter. It is the responsibility of the research license applicant to comply with the application requirements in this section and ensure the application is complete, accurate, and successfully submitted to the reviewer.

(B) Incomplete or incorrect additional application materials, materials that do not adhere to the content requirements in this section, or materials not received by the reviewer by 5:00 p.m. on the 30th day or the application date as indicated on the letter from the WSLCB will not be considered by the reviewer and the WSLCB will withdraw the application after receiving notice in writing from the reviewer.

(b) **Additional application materials requirements.**

(i) Application materials that do not adhere to the content requirements in this section or incomplete or incorrect applications will be withdrawn.

(ii) The applicant is responsible for ensuring that no information is included in the research plan that may compromise the applicant's ability to secure patent, trade secret, or other intellectual property protection. All application documents must be submitted by a person who has the legal authority to represent the entity if the applicant is an entity other than an individual person.

(iii) All documents must be submitted to the reviewer in a legible PDF format.

(iv) All of the following information and documents are required for each initial application:

(A) A completed cover page form, marijuana research license application form, and signature page form created by the WSLCB and available at the WSLCB's web site at www.lcb.wa.gov.

(B) A research plan limited to four pages that includes the following information:

(I) Purpose and goal(s) of the proposed research project(s);

(II) Key milestones and timelines for the research project(s);

(III) Background and preliminary studies;

(IV) Amount of marijuana to be grown, if applicable, including the justification with respect to milestone tasks;

(V) Anticipated cost of the proposed research project(s) and funding available for the work;

(VI) Key personnel and organizations, including names and roles;

(VII) Facilities, equipment, and other resources required and available for conducting the proposed research project(s).

(C) A biosketch for each individual involved in executing the proposed research project limited to two pages per individual performing technical and administrative functions essential to performing the proposed research, including proof that the individual is twenty-one years of age or older. Biosketches must be prepared using the National Institutes of Health (NIH) biographical sketch format, available at <http://grants.nih.gov/grants/forms/new-renewal-revisions.htm>.

(D) Letters of support limited to two pages per letter confirming the commitment of time and resources from external personnel or organizations if external personnel or organizations will participate in research activities under an approved research project. Letters of support are required to confirm the commitment of time and resources from personnel involved in the proposed research project(s) who are not employed at the applicant organization. Letters of support must include specific details regarding the type(s) and magnitude of the time and resources being committed to the proposed research project(s) and must be signed by individuals having the authority to make such commitments.

(E) For all project(s) involving human or animal subjects, documentation of all required institutional review board (IRB) or institutional animal care and use committee (IACUC) approvals. Documents must be provided on IRB or IACUC letterhead and be signed by authorized officials of those regulatory bodies.

(v) Documents that do not conform to the requirements in subsection (b) of this section may be withdrawn. All nonform documents must conform to the following requirements:

(A) Eight and one-half by 11-inch portrait-oriented page dimensions;

(B) Single-spaced with all margins measuring at least one inch; and

(C) At least 12-point font in Times New Roman or Arial, not proportionately reduced.

(c) Review by the WSLCB's designated scientific reviewer.

(i) If the applicant submits application materials to the reviewer by the required deadline specified by the WSLCB's application letter and the reviewer determines the additional application materials are complete and meet the document requirements specified in this section, the reviewer will proceed with reviewing the research project to evaluate whether the project complies with the provisions of RCW 69.50.372 (1) and (2).

(ii) When evaluating research projects, the reviewer must:

(A) Ensure confidentiality; and

(B) Screen members of the reviewer panel for any conflicts of interest and take appropriate measures if a conflict of interest is identified.

(iii) The reviewer will assess fees for the review of the research project proposal directly to the applicant pursuant to RCW 69.50.372(7). The reviewer will not recommend approval of an application for any research license for which an unpaid balance of fees to the reviewer is due regardless of the recommendation of the reviewer regarding the sufficiency of the research project.

(iv) If at any time during the process of review the reviewer finds that the additional application materials are not complete, the reviewer will notify the WSLCB in writing and the WSLCB will withdraw the application.

(v) The reviewer will supply a written evaluation to the WSLCB in writing after completing review of the research project. Evaluations

will provide the approval recommendation status; determination(s) of the applicable research category or categories; and, as applicable, the reasons for a "Not Approved" recommendation. The WSLCB will provide written evaluations to applicants following completion of the review process by the reviewer along with the WSLCB's approval or denial of the research license.

(d) **WSLCB requirements and licensing process.** If the reviewer indicates the application for a research license should be approved, the following requirements must be met prior to final approval of the license by the WSLCB.

(i) The WSLCB will request criminal background and financial information from the research license applicant and evaluate the applicant(s) pursuant to the standards and requirements established in WAC 314-55-020 except that research license applicants are not subject to prioritization under subsection (3) of that section;

(ii) Funding of the proposed research must be disclosed by the applicant(s) in amount, timing and source(s). Funding sources may include organizational resources and individuals and organizations that are not part of the person, organization, agency, or business entity applying for the research license. Out-of-state resources may be included, but must be identified;

(iii) The applicant(s) must adhere to the notice posting requirements under WAC 314-55-020;

(iv) The applicant must demonstrate access to and proficiency with the traceability system; and

(v) The applicant must meet facility security requirements as provided in WAC 314-55-083 prior to being granted a license.

(3) **Research license withdrawal and denials.**

(a) The WSLCB will withdraw an application if:

(i) The application or additional application materials are determined incomplete or incorrect by the WSLCB or its designated reviewer;

(ii) The additional application materials are not timely received by the reviewer as provided in this section; or

(iii) The applicant(s) request withdrawal of a research license application at any time in the application process. The applicant must request the withdrawal in writing and is responsible for any review costs due to the reviewer. The voluntary withdrawal of a research license application does not result in a hearing right.

(b) The WSLCB will deny a research license if:

(i) The scientific reviewer does not recommend approval of the license after reviewing the research proposal for compliance with this section or RCW 69.50.372;

(ii) The applicant does not meet the requirements for a license under this section or RCW 69.50.372; or

(iii) The applicant provides false or misleading information in any of the materials it submits to the WSLCB or the reviewer.

(c) If the WSLCB denies a research application for the reasons provided in (b)(iii) of this subsection or for failing to meet criminal history or administrative violations requirements under this section, the applicant(s) is prohibited from reapplying for a research license for one calendar year from the date of the WSLCB's denial of the license.

(d) A person or entity that has outstanding unpaid review fees owing to the scientific reviewer is prohibited from reapplying for a research license until all review fees are paid to the scientific reviewer.

(4) Reporting required.

(a) The WSLCB or the WSLCB's designated reviewer may require reporting by or auditing of research licensees as necessary.

(b) The WSLCB's designated reviewer must submit an annual status report of all completed and ongoing research projects for the previous year to the WSLCB by December 31st of each calendar year.

(c) The licensee must adhere to the reporting requirements in the traceability system under WAC 314-55-083.

(d) The reviewer must immediately notify the WSLCB if it receives information indicating that a research licensee is operating outside the scope of the projects approved under a research license.

(5) Adding an additional research project or changing existing approved research project process (after licensure).

(a) A research licensee is restricted to only those research activities under a research project that has been reviewed and approved by reviewer.

(b) Applications to add a new project or change an existing approved project is the same as what is required for initial application except that a new license application through BLS is not required. To apply to add a new research project or change an existing approved project, a research licensee must submit all materials to the reviewer as required under subsection (2)(b) of this section. Incomplete project applications will not be considered.

(c) The reviewer will review the application for a new research project or change to an existing approved research project pursuant to subsection (2)(c) of this section. The reviewer will supply a written evaluation to the WSLCB and the licensee in writing after completing review of the application for a new research project or a change to an existing approved research project. Evaluations will provide the approval recommendation status; determination(s) of the applicable research category or categories; and, as applicable, the reasons for a "Not Approved" recommendation.

(6) Research license renewals.

(a) Research license renewals operate on an annual basis, based on the license issuance date. A licensee must have an ongoing approved research project or an application for a new research project to be eligible for license renewal. The WSLCB will notify the licensee and reviewer ninety days prior to the license renewal date. The licensee must provide a status report to the reviewer or an application for a new research project if the licensee's ongoing approved research project will end within thirty days prior to or after the renewal date. The status report or application must be received by the reviewer within thirty days of the ninety-day renewal notice from the WSLCB or the license will not be renewed.

(b) The reviewer will notify the WSLCB in writing if the licensee meets the requirements for renewal not later than fifteen days prior to the licensee's renewal date.

(c) If the reviewer determines that the research project does not meet requirements for renewal due to lack of an ongoing project or for failure to meet the requirements of RCW 69.50.372 or this section for a proposed new project, the reviewer will recommend the WSLCB not renew the license.

(d) The WSLCB will review the licensee's violation history and criminal background check prior to renewal. If the violation history or criminal records disqualifies the licensee from eligibility for a research license under WAC 314-55-050, the WSLCB will not renew the license.

(7) **License revocation.**

(a) The WSLCB may revoke an application for the following reasons:

(i) The WSLCB has reason to believe that marijuana is being diverted from the research licensee;

(ii) The research licensee operates outside the scope of the research project(s) approved under the license issued to the licensee;

(iii) The applicant makes a misrepresentation of fact, or fails to disclose a material fact to the WSLCB during the application process or any subsequent investigation after a license has been issued;

(iv) The WSLCB finds that the licensee possesses marijuana plants, marijuana, or marijuana products that are not accounted for in the traceability system;

(v) The research licensee makes changes to their operating plan, entity structure, or location without prior approval from the WSLCB;

(vi) The research licensee fails to maintain security requirements for the licensed research facility; or

(vii) The licensee violates any provision of chapter 69.50 RCW or this chapter.

(b) A licensee may request voluntary cancellation of a license at any time. The licensee must request cancellation of a research license to the WSLCB in writing. The voluntary cancellation of a research license does not result in a hearing right.

(8) **Marijuana disposal requirements.**

(a) Licensees must dispose of marijuana as provided in WAC 314-55-097.

(b) Licensees must dispose of marijuana if the research license is discontinued for any reason. A licensee may transfer plants to another marijuana research licensee. A licensee may work with the WSLCB to dispose of marijuana or marijuana plants.

(9) An applicant or licensee may request an administrative hearing to contest the withdrawal, denial, nonrenewal, or revocation of a research license pursuant to chapter 34.05 RCW. A request for a hearing must be made in writing and received by the WSLCB no later than twenty days after the date the notification of withdrawal, denial, nonrenewal, or revocation was mailed to the applicant or licensee. Appeal requests submitted in paper form may be delivered to the WSLCB in person during normal business hours at 3000 Pacific Avenue S.E., Olympia, WA 98501, or mailed to the WSLCB. Mailed appeal requests must be addressed to: WSLCB, ATTN: Adjudicative Proceedings Coordinator, P.O. Box 43076, Olympia, WA 98504-3076 or, for certified mail, WSLCB, ATTN: Adjudicative Proceedings Coordinator, 3000 Pacific Avenue S.E., Olympia, WA 98501.