



Notice of Permanent Rules for the Marijuana Research License

This explanatory statement concerns the Washington State Liquor Control Board's adoption of rules for the Marijuana Research License.

The Administrative Procedure Act (RCW 34.05.325(6)) requires agencies to complete a concise explanatory statement before filing adopted rules with the Office of the Code Reviser. This statement must be provided to anyone who gave comment about the proposed rulemaking.

The Liquor and Cannabis Board appreciates your involvement in the rule making process. If you have questions, please contact Joanna Eide, Policy and Rules Coordinator, at (360) 664-1622 or e-mail at rules@lcb.wa.gov.

Background and reasons for adopting this rule.

Rule changes are needed to implement the marijuana research license established by RCW 69.50.372. Changes to RCW 69.50.372 were passed during the 2016 legislative session making it possible for the WSLCB to proceed with implementing the new license. 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 requirement and administrative provisions relating to the license. These rules are needed to be able to fully implement and issue the license.

Summary of public comments received on this rule proposal.

CR-101 – filed August 24, 2016, as WSR 16-17-149.

CR 102 – filed November 17, 2016, as WSR 16-23-105.

Public Hearing held December 28, 2016.

Written Comments Received:

Below is a summary of the comments received as part of this rulemaking.

- 1. Concerns about the residency requirements for applicants and holders of a marijuana research license. Does this include corporations headquartered outside of Washington State, but with facilities that are licensed to do business within Washington? If yes, then we interpret section the law to require the manager and research personnel of that facility to have resided in the state for at least three months prior to applying for a research license.**



WSLCB response: Thank you for your comments. Washington state residency requirements apply to applicants for a marijuana research license. It is a 6 month residency requirement and applies to the applicant and holder of the license, including members of a business or organization entity.

Was the comment reflected in the final rule? The residency requirements for marijuana licensees, including research licensees, are provided in statute and cannot be changed through rulemaking. As such, the rule language was not changed.

- 2. Comments were received regarding the inability to transfer marijuana plants back into the regulated market. Currently, there is no legal means to transfer new genetic material into the regulated market. It would be a shame if there couldn't be some way to allow discoveries/technologies that come out of the research system to bear fruit in the industry. Allow the transfer of immature plant material between research and producer licenses to facilitate access to research discoveries.**

WSLCB response: Thank you for your comments. The prohibition on transfer of material by research licensees to anyone other than a research licensee is included in statute and cannot be changed through rulemaking. RCW 69.50.372(3) says “[a] marijuana research licensee may only sell marijuana grown or within its operation to other marijuana research licensees. The liquor and cannabis board may revoke a marijuana research license for violations of this subsection.” If the Legislature changes the law surrounding plant or material transfers from a research licensee into the regulated market, the WSLCB will adjust rule requirements accordingly.

Was this comment reflected in the final rule? No. Since the prohibition is included in statute, it cannot be changed through rulemaking.

- 3. What are the mechanisms for researchers to acquire marijuana? RCW mentions it will be donated. This could place limitations on access to quality material if producers are only willing to donate material that is very old or suspected to fail microbial or pesticide analysis. Please allow researchers to purchase on the existing traceable wholesale market from producers and processors. Researchers should not be allowed to sell cannabis material at an excessive price that cannot be justified by research costs and a science faculty-level wage for time spent. I agree with the limitation of selling only to other research licensees and UW/WSU, however, I recommend to expand that to allow sale from researchers to certified testing labs. The purpose is to foster scientific collaboration and cross access specialized equipment.**

WSLCB response: The WSLCB is seeking amendments to RCW 69.50.372 by the Legislature in the 2017 Legislative Session to allow for research licensees to source



Washington State Liquor and Cannabis Board

material from both producers and processors. Currently, the statute only mentions processors. Certified labs cannot sell or donate product to research licensees as state law requires that excess material left over from quality assurance testing be returned to the licensee or destroyed.

Was this comment reflected in the final rule? No. The WSLCB is seeking statutory changes that may allow for changes to rule language in the future.

- 4. What are the limits for project timelines? Is there a simple method to renew projects for continuing research? The process is often cumbersome in academia and there is the opportunity to make this a lightweight process to better accelerate research.**

WSLCB response: No project timeline limits are included in statute or rule. The scientific reviewer will evaluate the projects on an individual basis and determine whether the project timeline meets the requirements of RCW 69.50.372 and WSLCB rules.

Was this comment reflected in the final rule? No changes to language are necessary to address this comment at this time.

- 5. Is this license subject to the same public space proximity restrictions? If possible, making the research license exempt from location restrictions would broaden access to many more scientists, many of whom maintain personal labs of high caliber.**

WSLCB response: Research licensees are subject to the same requirements as other marijuana licensees established in RCW 69.50.331 and WSLCB rule.

Was this comment reflected in the final rule? No. Since the requirement is included in statute, it cannot be changed through rulemaking.

- 6. Flexibility in funding sources should be included in the rules to clarify that out of state funds may be used by research licensees for research conducted under the license.**

WSLCB response: Thank you for your comments.

Was this comment reflected in the final rule? Yes. Clarifying changes to language were made regarding funding sources in the rules to accommodate comment requests and ensure that no additional prohibitions other than what is provided in statute apply regarding funding sources.

- 7. Section (1)(c) requires labs applying for a marijuana research license to clearly separate research materials from marijuana that is being tested according to LCB purity and potency requirements. To clarify organizational eligibility**



Washington State
Liquor and Cannabis Board

concerns, we suggest adding a new section ahead of the current 1()(d) and 1)(e) that define personnel requirements.

WSLCB response: The rules do not prohibit the scenario you describe.

Was this comment reflected in the final rule? No. No changes were needed to accommodate this comment.

8. **By requiring licensee applicants to delineate the scope of their project/investigation, it assumes a track of investigation that may yield unexpected breakthroughs and new avenues of opportunity. From the perspective of privately funded research, Research and Development (R&D) almost always takes unexpected twists and turns. R&D is the process of answering a series of unanswered questions. We are very supportive of the efforts to create a Cannabis Research License. Our one concern is the requirement to “know” what the research project may result in. We recommend the LCB include and/or allow flexibility in the R&D investigation process. Undoubtedly new insights will pop up that may provide new pathways of opportunity, and the State can foster this development by allowing entities some latitude in their investigation process.**

WSLCB response: Current marijuana licensees may conduct their own R&D without the need for a research license. Project proposals are required under RCW 69.50.372 for applications for marijuana research licenses, which cannot be changed through rulemaking. However, there would not be a prohibition for research licensees to ignore findings and research licensees would be able to submit a new research proposal for review to add to their efforts under their research license if approved. The research licenses were created to generate data that is needed regarding cannabis and it is not the WSLCB's understanding that the research licenses were created for R&D purposes. Additionally, research proposals do not have to “know” what the result may be, but must have a goal in mind. The scientific reviewer will review each research project proposal and determine whether it meets the requirements in RCW 69.50.372 and agency rule requirements. It is possible that some degree of flexibility may be acceptable in proposals, and the scientific reviewer will be tasked with that assessment.

Was this comment reflected in the final rule? The requirements were unchanged from the CR-102 filing.

9. **I'm very glad this subject is being addressed. Research is necessary for scientific credibility and also for innovation. I'm also very glad that the reviewer looks for conflict of interest. Be ruthlessly scrutinizing. Scrutiny makes for credible research. The applicant should be notified immediately by email if minor issues not related to content, like their application's format or font, are incorrect, so they can correct it. They should also be encouraged to**



Washington State Liquor and Cannabis Board

have their application proofread to avoid any unnecessary "bumps in the road."

WSLCB response: Thank you for your comments. The rules are proposed in order to implement the license as created under state law and adjusted by the Legislature during the 2016 legislative session allowing the WSLCB the flexibility in selecting a scientific reviewer and proceed with creating the license. The rule requirements for the applications are very clear so as to fully communicate requirements to an applicant, including font size, etc. As far as encouraging proofreading, that is something that we can do outside rule requirements.

Was this comment reflected in the final rule? No changes to rule language were needed to accommodate this comment.

10. Please create a marijuana research license so that there can be scientific data to back up the claims made about medical marijuana.

WSLCB response: Thank you for your comments. The WSLCB is currently in the rulemaking process to implement the marijuana research license under RCW 69.50.372. You can find more information about the proposed rules on our Proposed Rules webpage, here: <http://lcb.wa.gov/rules/proposed-rules>.

Was this comment reflected in the final rule? No changes to rule language were needed to accommodate this comment.

11. Regarding required "barrier" between research operations and commercial enterprises: It would be beneficial to provide further clarification regarding what constitutes a "barrier". Does this mean a firewall? A plastic partition? Does the barrier need to be secured by doors and locks? We suggest keeping this simple with plastic partition.

WSLCB response: Thank you for your comments. Each operation will be different, and we did not include specific requirements for ensuring that marijuana is not comingled. Each layout will be assessed as part of the license application process and will be considered on a case-by-case basis to address each different instance as they will vary.

Was this comment reflected in the final rule? No changes were needed to rule language to address this comment.

12. "All research license applicants and persons conducting research under the research license must be 21 years of age or older." Comment: It seems this provision is unnecessarily broad in restriction, and would be especially problematic at research universities. Given that not all roles in a research project will involve direct contact with the cannabis plant, it may be useful to include language that provides for interns or students to participate in



Washington State
Liquor and Cannabis Board

research that does not require them to come in contact with flowers or flowering plants.

WSLCB response: RCW 69.50.331 requires that all applicants, licensees, and employees of licensees be 21 years of age or older. Rulemaking cannot change requirements established in statute.

Was this comment reflected in the final rule? The requirements were unchanged from the CR-102 filing. Rulemaking cannot change requirements established in statute.

13. **"No applicant for a research license may possess any marijuana plants or marijuana unless and until the research project is approved and the applicant is notified that the research license is approved in writing by the WSLCB."**
Comment: This paragraph could be interpreted to mean that adults over the age of 21 who participate in research projects would be prohibited from possessing cannabis for personal or medical use.

WSLCB response: Thank you for your comments. We agree that the language was somewhat broad and may have that unintended interpretation.

Was this comment reflected in the final rule? Rule language was adjusted to include caveats for "except as otherwise allowable under laws and rules."

14. **"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)."**
Comment: It will be very important to allow applicants an opportunity to make positive or negative recommendations on prospective reviewers, insofar as some reviewers may pose conflicts or competitive concerns that only applicants may be aware of.

WSLCB response: The scientific reviewer will have to have proper procedures in place to identify and solve for conflicts of interest.

Was this comment reflected in the final rule? Rule language already requires the scientific reviewer to have procedures for identifying and solving for any conflicts of interest.

15. **The fact that applicants must pay for the costs of review would invite major conflict of interest. It sets up a model where reviewers are essentially government consultants, and would perform as arbiters of the process with little restriction or oversight. The potential for abuse here is high. Review costs should defined, fixed, and affordable. For example, they can be part of a nominal application fee of between \$500 and \$1000. This would ensure that research groups are not unduly burdened with arbitrarily-high fees before they**



Washington State
Liquor and Cannabis Board

have a chance to conduct any research. Similarly fees for reviewers should be fixed. Reviewers of federal research grants and local programs like the former LSDF received stipends ~\$400/day for reviews. Suggest looking at other models and determining a standard, flat rate determined by the assigning agency.

WSLCB response: Thank you for your comments. RCW 69.50.372 requires that applicants pay for the costs of review directly to the scientific reviewer, which cannot be changed through rulemaking. The WSLCB is currently soliciting bids for third-party scientific reviewers and will be assessing costs as part of the bidding process.

Was this comment reflected in the final rule? No changes to rule language are necessary to accommodate this comment. The WSLCB is currently soliciting bids for third-party scientific reviewers and will be assessing costs as part of the bidding process.

- 16. The confidentiality requirements in the rule appear unenforceable. Recommend more strict language that a reviewer be subject to enforceable non-disclosure. Also recommend that all application materials be exempt from public disclosure.**

WSLCB response: Thank you for your comments. The WSLCB feels that the rule language addresses confidentiality. Exemptions from disclosure are included in RCW 42.56.270 for proprietary financial, commercial, operations, and technical and research information and data submitted to or obtained by the liquor and cannabis board in applications for marijuana research licenses under RCW 69.50.372, or in reports submitted by marijuana research licensees in accordance with rules adopted by the liquor and cannabis board under RCW 69.50.372. Exemption from public disclosure for research licensee reports is provided in RCW 42.56.620. There is also direction in the rules to ensure that applicants do not include information that would undermine the applicant's ability to secure patent, trade secret, or other intellectual property protection.

Was this comment reflected in the final rule? No changes to rule language are necessary to accommodate this comment.

- 17. Paragraph (3)(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.” Comment: Recommend that applications should have a reasonable application fee to offset costs and eliminate excessive fees, which seems about the only way an issue regarding delinquent payments may arise.**

WSLCB response: RCW 69.50.372(7) sets application and renewal fees and also requires that the scientific reviewer be paid directly for costs of review. (7) The application fee for a marijuana research license is two hundred fifty dollars. The



Washington State Liquor and Cannabis Board

annual fee for issuance and renewal of a marijuana research license is one thousand dollars. The applicant must pay the cost of the review process directly to the scientific reviewer as designated by the liquor and cannabis board. It would be improper to allow a research licensee to renew a license or receive approval for an additional project if the licensee has outstanding review costs owing.

Was this comment reflected in the final rule? No. The WSLCB chose to maintain the language as proposed.

- 18. Paragraph (9) “An applicant or licensee may request an administrative hearing...” Comment: Recommend developing a process to request a review of a denied project. As written, rule only provides an option to request a hearing if license is revoked.**

WSLCB response: Administrative hearings are the appropriate mechanism for an applicant or licensee to appeal a decision by the WSLCB and is standard practice and requirements as provided in chapter 34.05 RCW.

Was this comment reflected in the final rule? No. The WSLCB chose to maintain the language as proposed.

- 19. Some research projects will involve investment in seed varieties and large-scale, living plant repositories. Recommend provisions that would allow materials to be transferred or preserved in the event that a research project seeks continuation, expansion, or relocation.**

WSLCB response: This is accommodated in the procedures in the rules.

Was this comment reflected in the final rule? No. No change to language is needed to accommodate this comment.

- 20. Many plant samples must be immediately transferred to laboratory or other facilities after samples are taken. Standard quarantine rules for plants would be problematic in these instances. Recommend allowances for immediate transfer of non-narcotic tissue, root, soil and other samples with conditions that minimize possibilities of diversion.**

WSLCB response: The 24-hour wait time requirement prior to transferring will apply the same as for other marijuana licensees.

Was this comment reflected in the final rule? No. The WSLCB chose to maintain the language as proposed.

- 21. I think the best part of WAC 314-55-073 is that research will not be limited to a few entities but instead anyone can suggest and then conduct an approved research study: a free market approach to research can only lead to greater**



Washington State
Liquor and Cannabis Board

discovery. My only concern is the broadness of how RCW 69.50.372 defines "scientific reviewer." Particularly, I would like to see the law be more specific on how scientific reviewers will be assigned to each submitted research project. I think some thought needs to be put into, and the law eventually amended, to assure that no bias exist in approving or disapproving suggested studies.

WSLCB response: The WSLCB is currently soliciting bids for third-party scientific reviewers and will be assessing the reviewer processes.

Was this comment reflected in the final rule? No. This comment can be addressed through the selection of a scientific reviewer if necessary.

22. Sourcing of Marijuana and Marijuana Extracts: we believe it is important that the rules are very clear on the procedures in which a Lab can source materials for testing. While we agree that Labs should be able to grow their own material we also believe that they should be able to freely source materials from licensed entities throughout the state (complying with all existing laws governing the wholesale distribution of marijuana, including but not limited to the use of BioTrack). The reason for this is that our researchers would like to have access to a vast array of plant genetics and do not want to have to become specialist in the growing and extraction of marijuana.

WSLCB response: There are no restrictions in the rule language regarding variety of sourcing material. The statute has a limitation (technicality) that material can only be sourced from licensed processors (RCW 69.50.372). We are looking to allow for both licensed producers and processors to be able to supply material (along with other research licensees) in agency request legislation that we are bringing to the Legislature in the 2017 session. Part of the idea behind establishing this state research license was to allow for a greater variety of strains for research.

Was this comment reflected in the final rule? No changes to rule language were needed to accommodate this comment.

23. Stream Lining the Clinical Investigation Process: we are hopeful that the State recognizes that the goal of a Lab will be able to create and analyze products that will be useful for humanity (particularly for people suffering from various ailments). As such we urge that the clinical trial aspect of any law be geared to more, not less, testing. As such we think that, as in almost all research areas, that the Lab, working within the parameters of Washington Law and the standards of scientific research, should be the entity that designs and approves research studies. Of course, in any medical studies an Institutional Review Board (IRB) would be incorporated into the process.

WSLCB response: The scientific reviewer will evaluate the clinical investigation process proposed under each project and make recommendations to the WSLCB.



Was this comment reflected in the final rule? No changes to rule language were needed to accommodate this comment.

24. Patient Population: we would like to see in the law clear guidelines on: a) who we can use as test subjects (i.e. would minors be allowed in the patient population); b) the rules governing the relationship between a Lab and medical facilities and professionals; c) whether or not we can give our test subjects products for free; and, d) the procedures for how we physically provide the products to patients (do they have to be picked up in person or can they be mailed, can multiple doses be provided, etc.).

WSLCB response: Each research project will be developed and proposed on an individual basis, and reviewed by the scientific reviewer in a similar fashion. Whether there is more or less testing will depend on the individual project, and the assessment of the scientific reviewer in determining whether a license should be granted and a project be approved. The other points you raise, b through d, would likely be addressed through the review of the research proposal. It would also be important to assess whether there are other legal prohibitions outside of chapter 69.50 RCW and chapter 314-55 WAC against some of the activities you mention.

Was this comment reflected in the final rule? No changes to rule language were needed to accommodate this comment.

25. Cooperation and Reporting of Findings: while this is ultimately a business endeavor we are also excited about forging forward in an unexplored area that promises great potential discoveries. As such, we believe cooperation and a central depository of information is crucial for Washington State and the United States to become the leader in marijuana research. As such, we recommend that the State create an optional, but strongly encouraged, central depository for all research studies to be published. In addition, a system that encourages the use of government resources, such as State Universities, would benefit the process and jump start progress in this field.

WSLCB response: The idea you have wouldn't be prohibited. It sounds like something that licensees would be able to get together and do themselves if they wish to do so without any need for action on the part of the WSLCB.

Was this comment reflected in the final rule? No changes to rule language were needed to accommodate this comment.

Public Hearing Comments:

No public testimony was offered. Once clarifying question was raised about the transfer of plants: how research licensees may obtain material and whether and to whom



Washington State Liquor and Cannabis Board

research licensees may transfer marijuana or marijuana plants. WSLCB staff provided a response consistent with the comments raised in this Concise Explanatory Statement.

WAC Changes from Proposed Rules (CR-102) to the Rules as Adopted:

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. The WSLCB also made changes to language regarding the possession of marijuana to ensure no conflicts with personal possession of marijuana (discussed in comments above).