

UC Office of the President

State of California Agencies

Title

UC Comments on California Department of Cannabis Control Proposed Regulation specific to the Medicinal and Adult-Use Commercial Cannabis Regulations issued on March 4, 2022

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OFFICE OF THE VICE PRESIDENT – RESEARCH AND INNOVATION

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April 19, 2022

Ms. Kaila Fayne
Department of Cannabis Control
Legal Affairs Division
2920 Kilgore Road
Rancho Cordova, CA 95670
E-mail: publiccomment@cannabis.ca.gov

RE: Department of Cannabis Control Proposed Regulation specific to the Medicinal and Adult-Use Commercial Cannabis Regulations issued on March 4, 2022

Dear Ms. Fayne:

I write on behalf of the University of California (UC) system regarding the Notice of Proposed Rulemaking specific to the consolidated Medicinal and Adult-Use Commercial Cannabis Regulations at California Code of Regulations Title 4, Division 19 (Regulation) issued by the Department of Cannabis Control (DCC) on March 4, 2022 (Notice).

The UC system has more than 800 research centers, institutes, laboratories, and programs that span 10 campuses, 6 medical schools, a Division of Agriculture and Natural Resources, and 3 affiliated U.S. Department of Energy national laboratories. UC has established an unparalleled reputation for first class research and innovation on a global scale and the 2nd most Nobel Prizes of any university system in the world. Specific to cannabis research, UC serves as the scientific frontrunner investigating and publishing impactful cannabis research in clinical, molecular-chemical, economic, societal, and agricultural disciplines. UC's notable cannabis research centers extend throughout the State of California:

- UC Berkeley – Cannabis Research Center
- UC Davis – Cannabis and Hemp Research Center
- UC Irvine – Center for the Study of Cannabis
- UCLA - Cannabis Research Initiative
- UC Merced – UC Nicotine and Cannabis Policy Center
- UC Riverside – Cannabis and Hemp Agricultural Research and Regulation Center
- UC Santa Cruz – Cannabis & Hemp Initiative for Interdisciplinary Plant Studies
- UC San Francisco – Center for Tobacco Control Research and Education
- UC San Diego – Center for Medicinal Cannabis Research

Given UC's extensive research experience in this area, UC welcomes the opportunity to comment on Chapter 13 (Other Provisions) of the Regulation. In order to align the Regulation with standard research administration practices, including those codified within the California Education Code, and to optimize the quality of research conducted with DCC resources, UC strongly recommends, in descending order of importance, the following seven changes to the Regulations.

1) Clarify that DCC uses a peer review process to assess scientific merit of proposed projects.

Applicable Regulation Number: §17902. Selection Process and Criteria.

Comment: Section 17902(c) of the Regulation identifies criteria that DCC will use to select eligible proposals for funding. Section 17902(c)(2) includes considerations for the scientific and technical merit of proposed projects by stating the following: “[t]he extent to which the proposed project is designed to achieve measurable outcomes, and the clarity of the measures for success, including, for research-based objectives, the scientific and technical merit of the proposed project as evaluated by relevant experts.” Typically, considerations of scientific merit are conducted by peer reviewers practiced in the scrutiny of research design and methodology. Experienced, academic peers are uniquely qualified to measure the potential contributions and impact on the field of proposed research; risks involved in conducting the study; as well as the adequacy and appropriateness of requested resources. Peer reviewers provide broad and diverse scientific perspectives, and ensure their impartiality (and oftentimes anonymity) during the review process. A transparent scientific review process ensures that publicly accountable governmental funders expend resources only on projects most likely to advance science and address societal challenges in line with the agency’s mission and ethical standards.

Suggested Change: While the Regulations state that relevant experts will evaluate proposed projects, the language should clarify that DCC will use a peer review process. As such, we strongly suggest the following revision to Section 17902(c)(2):

- (c) The Department will make a selection for funding based on criteria including, but not limited to:
- (2) The extent to which the proposed project is designed to achieve measurable outcomes, and the clarity of the measures for success, including, for research-based objectives, the scientific and technical merit of the proposed project as evaluated by relevant experts as part of a peer review process.

2) Provide justification to applicants not selected for DCC research funding.

Applicable Regulation Number: §17902. Selection Process and Criteria.

Comment: There may be many reasons why an application is not selected for funding, and not all high quality applications can be supported. Providing an unsuccessful applicant with constructive feedback can add further transparency around funding recommendations. Providing such feedback will advance DCC’s mission by (a) encouraging higher quality applications from such applicants under future calls, and (b) enforcing and highlighting for applicants the eligibility and scoring criteria established by DCC.

Suggested Change: DCC should provide constructive critiques to unfunded applicants. We recommend adding the following language to Section 17902:

(e) Applicants not selected for funding will be notified. The Department will endeavor to provide denied applicants with constructive feedback from peer reviewers explaining the reason as why the proposal was not funded.

3) Acknowledge DCC, UC and CSU’s obligation to use the California Model Agreement for funding agreements as required by California Education Code §67325 et seq.

Applicable Regulation Number: §17903. Release of Funds.

Comment: [California Education Code §67325 et seq.](#) requires state agencies to use a standard agreement template, the California Model Agreement (CMA), when contracting with, or issuing grants to, a UC or California State University (CSU) campus. The CMA contains a set of boilerplate terms called the University Terms and Conditions (UTC) negotiated, on behalf of state agencies, by the Department of General Services,

and by UC Office of the President and the CSU Chancellors Office.¹ Additional terms specific for DCC awards can be included in Exhibit G of the CMA without violating the California Education Code.

Suggested Change: We propose the Regulation acknowledge the requirement to use the CMA for agreements between DCC and UC or CSU campuses. A suggested insertion, placed at Section 17903(a), is:

(a) The Department shall not cause funds to be disbursed until the recipient has executed a Grant Agreement and any other required documents. The California Model Agreement will be used for any dispersal of funds to University of California or California State University campuses in accordance with California Education Code Section 67325 et seq.

4) Clarify records subject to retention and align retention period with standard research administration expectations.

Applicable Regulation Number: § 17905. Research Records.

Comment: Section 17905 of the Regulation requires grantees maintain “*research and financial data necessary to substantiate the purposes for which the funds were spent, for the duration of the funding, and for a period of seven years after completion of the research project.*” The University agrees that **records** are necessary to substantiate the responsible expenditure of DCC funds by grantees in accordance with approved project objectives; however, the term “data” has a broader meaning within the research context. Research records, on the other hand, are documents and information related to the administrative, financial, and human resource management of research. The Regulation could be strengthened by clarifying the records to be retained and adjusting the retention period to align with the majority of sponsor and university practices.

Suggested Change: Revise Section 17905 as follows:

Recipients shall retain all research and financial ~~data~~ records pertaining to the performance of a project funded under this Act and necessary to substantiate the purposes for which the funds were spent for the duration of the funding, and for a period of ~~seven~~ six years after completion of the research project. Recipients shall provide such documentation to the Department upon request.

5) Replace the word “staff” with “key personnel”.

Applicable Regulation Numbers: §17902. Selection Process and Criteria and §17904. Reports to the Department.

Comment: UC suggests that the word “staff” be replaced with “key personnel” at Section 17902(c)(4) and Section 17904(b)(5). Most research universities employ centralized research administrators, typically referred to as staff, who perform institution-wide duties supporting the university’s research portfolio (for example, extramural accounting analysts, payroll analysts, contract and grant proposal review analysts, compliance analysts, etc.). In contrast, key personnel contribute to the scientific development or execution of a project in a substantive, measurable way.² University staff who might be tangentially involved in the administration of a campus’s research portfolio do not directly control the design, conduct and reporting of the project. In addition, it is customary in university research to report changes in project key personnel to the sponsor.

¹ The UTC is also called Exhibit C in the CMA. More about the CMA, including the applicable templates, can be found [here](#).

² The National Institutes of Health defines “[Senior/Key Personnel](#)” as “The PD/PI and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant. Typically these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level may be considered senior/key personnel if their involvement meets this definition.”

Suggested Change: Revise 17902(c)(4) and Section 17904(b)(5) as follows:

17902(c)(4) Qualifications of the ~~staff~~ key personnel who will be assigned or working on the proposed project.
17904(b)(5) Any changes to the information provided in the proposal, including, but not limited to, change in ~~staff~~ key personnel.

6) Resolve typo.

Applicable Regulation Number: §17901. Request for Proposals

Comment: The word “notify” is misspelled at Section 17901(a).

Suggested Change: We recommend the following correction:

(a) A Request for Proposal (RFP) is the document issued by the Department to ~~notifiy~~ notify all eligible fund recipients of the following, at a minimum:

7) Utilize RGPO’s Grantmaking Expertise and Resources Available to DCC.

Comment: We want to note that UC Office of the President includes a Research Grants Program Office (RGPO) that administers a diverse range of research programs, helps identify and foster the highest quality research, shares resources and best practices across programs, supports researchers in managing UCOP-administered grants, and helps to measure and communicate the impact of research at UC and throughout California. RGPO has an extensive grant-making portfolio exceeding \$100 million per year, including Proposition 56 funds dedicated to studying the consequences and benefits of cannabis use. RGPO’s existing infrastructure, including a broad base of peer reviewers, and expertise in managing a complex array of interdisciplinary research grants programs ensures unbiased, open competitions for all California-based investigators. We strongly encourage DCC to explore partnering with RGPO for the administration and management of DCC’s award program.

UC greatly appreciates DCC’s continued efforts to meet the concerns of public institutes of higher education while developing regulations for medical and adult-use cannabis in California. We look forward to developing a lasting collaboration with DCC while pursuing academic research beneficial to all stakeholders within the State of California and beyond. For your convenience, a copy of Chapter 13 of the Regulation illustrating UC’s recommended edits is appended hereto.

We welcome any opportunity to further discuss the comments of this letter. If you have any questions concerning our comments, please contact Agnes Balla, Research Policy Manager, at agnes.balla@ucop.edu.

Sincerely,



Deborah Motton, Ph.D.

Executive Director

Research Policy Analysis and Coordination

University of California, Office of the President

Appendix 1

Chapter 13. Other Provisions with UC suggested edits as tracked changes (strike through deletions and underlined additions)

Chapter 13. Other Provisions

Article 1. Research Funding

§17900. Eligibility.

(a) Only public universities in California shall be eligible to be selected to receive funds disbursed pursuant to Revenue and Taxation Code section 34019(b).

(b) Subject to available funding, the amounts to be disbursed to the university or universities will not exceed the sum of ten million dollars (\$10,000,000) for each fiscal year, ending with the 2028-2029 fiscal year.

Authority: Section 26013, Business and Professions Code. Reference: Section 34019, Revenue and Taxation Code.

§17901. Request for Proposals.

(a) A Request for Proposal (RFP) is the document issued by the Department to ~~notify~~ notify all eligible fund recipients of the following, at a minimum:

- (1) The funding available for research related to the Act or this division;
- (2) Disbursement of funds to eligible applicants through a review and selection process, including the criteria that will be used for review and selection;
- (3) The specified timeframes for the proposal review and selection process, including the deadline for submission of proposals;
- (4) Proposal requirements, including necessary documentation;
- (5) Any priorities or restrictions imposed upon the use of the funds;
- (6) The governing statutes and regulations; and
- (7) The name, address, and telephone number of a contact person within the Department who can provide further information regarding the process for submission of proposals.

Authority: Section 26013, Business and Professions Code. Reference: Section 34019, Revenue and Taxation Code.

§17902. Selection Process and Criteria.

(a) The selection process shall involve eligible proposals timely received by the Department, in response to an applicable RFP, or similar notice.

(b) The Department will consider only one proposal per applicant for a given research project. Applicants may submit more than one proposal if the proposals are for separate and distinct research projects or activities.

(c) The Department will make a selection for funding based on criteria including, but not limited to:

- (1) The extent to which the proposed project is designed to achieve objectives specified in Revenue and Taxation Code section 34019(b).
- (2) The extent to which the proposed project is designed to achieve measurable outcomes, and the clarity of the measures for success, including, for research-based objectives, the scientific and technical merit of the proposed project as evaluated by relevant experts as part of a peer review process.
- (3) The extent to which the proposed project is feasible, demonstrated by:
 - (A) A timeline for project completion, including readiness; and
 - (B) Budget detail.
- (4) Qualifications of the ~~staff~~ key personnel who will be assigned to or working on the proposed project.
- (5) Any other criteria to determine the proposed project's efficacy in evaluating the implementation and effect of the Act.

(d) Applicants selected for funding will be notified of the selection and amount of funding in writing.

(e) Applicants not selected for funding will be notified. The Department will endeavor to provide denied applicants with constructive feedback from peer reviewers explaining the reason as why the proposal was not funded.

~~(e)~~ (f) The Department's selection decision is final and not subject to appeal.

Authority: Section 26013, Business and Professions Code. Reference: Section 34019, Revenue and Taxation Code.

§17903. Release of Funds.

(a) The Department shall not cause funds to be disbursed until the recipient has executed a Grant Agreement and any other required documents. The California Model Agreement will be used for any dispersal of funds to University of California or California State University campuses in accordance with California Education Code Section 67325 et seq.

(b) Selected recipients shall receive a single disbursement of funds for the duration of the research project.

(c) Funds released to the recipient that will be used for the purchase of any equipment related to the research project shall, at a minimum, meet the following conditions:

(1) Prior to the purchase of any equipment, the recipient shall obtain written approval from the Department.

(2) Receipts or other documentation for the purchase of any equipment shall be provided to the Department immediately upon purchase and request and retained pursuant to section 17904.

(d) Any funds that are not used prior to the completion of the research project shall be forfeited.

Authority: Section 26013, Business and Professions Code. Reference: Section 34019, Revenue and Taxation Code.

§17904. Reports to the Department.

(a) The recipient of funds shall provide regular performance reports to the Department in the following manner, unless otherwise specified in the Grant Agreement:

(1) At monthly intervals for research projects with an estimated completion time not exceeding one year.

(2) At quarterly intervals for research projects with an estimated completion time exceeding one year.

(b) Performance reports shall include, at a minimum:

(1) A detailed, estimated time schedule of completion for the research project;

(2) A description of any measurable outcomes, results achieved, or other completed objectives of the research project;

(3) A description of remaining work to be completed;

(4) A summary of expenditures of the funds and statement of whether the research project is meeting the proposed budget. If not, the reasons for any discrepancies and a list of actions that will be taken to ensure completion of the research project; and

(5) Any changes to the information provided in the proposal, including, but not limited to, change in ~~staff~~ key personnel.

Authority: Section 26013, Business and Professions Code. Reference: Section 34019, Revenue and Taxation Code.

§17905. Research Records.

Recipients shall retain all research and financial ~~data~~ records pertaining to the performance of a project funded under this Act and necessary to substantiate the purposes for which the funds were spent for the duration of the funding, and for a period of seven ~~seven~~ six years after completion of the research project. Recipients shall provide such documentation to the Department upon request.

Authority: Section 26013, Business and Professions Code. Reference: Section 26160, Business and Professions Code; and Section 34019, Revenue and Taxation Code.