# CENTER FOR MEDICINAL CANNABIS RESEARCH (CMCR) REQUEST FOR APPLICATION

March 21, 2019

## CONTENTS


Key Dates ..... 1
Overview ..... 1
Funding Priorities ..... 2
Eligible Applicants ..... 2
Letter of Intent ..... 3
Full Application Instructions ..... 3
Prior to Funding ..... 6
Terms of the Award ..... 7
CMCR Resource Capabilities ..... 8
Contact ..... 9


### Key Dates

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| Letter of Intent Due | April 19, 2019 2 pm PST |
| Application Due | May 31, 2019 2 pm PST |
| Review | June 2019 |
| Earliest Start Date | July 1, 2019 |

### Overview

The Center for Medicinal Cannabis Research (CMCR) is seeking to fund cannabis-related studies that further enhance the understanding of the efficacy and adverse effects of cannabis and cannabinoids as pharmacological agents for the treatment of medical and psychiatric disorders, and their potential public health impacts. Two award types are available. Primary project awards will be up to $275,000 in total costs per year for up to three years. Pilot project awards will be up to $300,000 for two years (up to $165,000 in Year 1 and $135,000 in Year 2). Priority will be given to proposals addressing issues identified under Funding Priorities.

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| Primary Project Details: | Maximum duration: Three Years<br>Maximum budget: $825,000 Total Cost ($275,000 per Budget Year)<br>Detailed annual budget is required |
| Pilot Project Details: | Maximum duration: Two Years<br>Maximum budget: $300,000 Total Cost per Project (Up to $165,000 in Year 1 and up to $135,000 in Year 2)<br>Detailed annual budget is required |

## Funding Priorities

Funding priorities include studies that 1) provide proof-of-principle findings that inform future, more comprehensive studies, 2) address scientific gaps identified by authoritative reviews (e.g., 'The Health Effects of Cannabis and Cannabinoids', National Academy of Sciences, Engineering, and Medicine; 2017), or 3) represent promising new directions for research. Studies may address both beneficial and harmful effects of cannabis (e.g., effects on cognition, driving).

Examples of areas of emphasis include, but are not limited to:

- Pain, particularly potential opioid-sparing effects
- Autism spectrum disorder
- Post-traumatic stress disorder
- Early psychosis
- Anxiety
- Migraine
- Weight loss due to chronic medical conditions
- Anorexia nervosa
- Autoimmune disorders (e.g., inflammatory bowel disease)
- Sleep disorders
- Movement disorders
- Cardiovascular effects
- Public safety
- Assays/methods for detection of cannabinoids, endocannabinoids, related substances
- Basic science and animal studies with clear translational implications for human applications

Proof of principle clinical studies are encouraged, as are proposals that leverage other funding (e.g., from other grant sources, foundations, in-kind contributions of equipment or services, etc.).

## Eligible Applicants

Proposals may be submitted by any higher education or nonprofit research institution (e.g., IRS-approved non-profit 501(c) status) in the state of California. An eligible California-based institution may subcontract with organizations outside of California, but must be the lead institution.

The principal investigator must be an individual who qualifies for that status under the proposing institution's principal investigator policies. He or she must possess the necessary skills

and knowledge relevant to the proposal. The principal investigator is expected to supervise or conduct the proposed project personally and directly.

Applicants are encouraged to contact CMCR with questions regarding eligibility (CMCRgrants@ucsd.edu).

## **Letter of Intent** (2 pages maximum, plus NIH-style biographical sketch)

The principal investigator(s) must submit a letter of intent (LOI) on the proposing institution's letterhead. The LOI will be submitted via an online grant submission portal (proposalCENTRAL; https://proposalcentral.com/). To locate this grant program, search proposalCENTRAL using the term "CMCR Grants Program". The LOI should indicate the type of award requested (primary project, pilot project), the name of the principal investigator (or multiple principal investigators), the applicant organization (as well as any collaborating investigators/organizations), the approximate amount of funding being requested, and a brief summary of the proposal including the title, objectives, rationale, general description of the approach (including duration), and relevance to funding priorities. The LOI should not exceed two pages and must be accompanied by a current NIH-style biographical sketch of the principal investigator(s).

The LOI will assist the CMCR in assessing whether the proposal aligns with the stated funding priorities, and the investigator(s) possesses the requisite qualifications to conduct the research. The LOI will also help the CMCR identify scientific reviewers with expertise in the area of study to evaluate the proposed primary or pilot project. Based upon the LOI, investigators will be invited to submit a full application. Only invited proposals will be reviewed; no critique or feedback will be provided for LOIs.

## Full Application Instructions

Applications will be submitted via an online grant submission portal (proposalCENTRAL; https://proposalcentral.com/). Applicants from University of California institutions must submit with the approval of their Office of Contracts and Grants. All applications must include a Signature Page signed by the authorized signing official. The Signature Page can be found on proposalCENTRAL. Non-profit institutions must have proof of liability insurance. The submission components are described below.

### 1. Project Title and Type

Enter the title of your project. Titles are limited to 200 characters, including spaces. From the drop-down menu, select whether you are applying as a Primary Project or Pilot Project.

### 2. Identifying Information

Complete sections 4-6 in proposalCENTRAL to provide identifying information about the Principal investigator (PI), Primary Institution and Key Personnel (Co-investigators/Consultants).

### 3. **Abstract** (2,500 characters including spaces)

The abstract should summarize the proposal objectives, rationale, and approach. The abstract is not to exceed 2,500 characters including spaces, or approximately 400 words. The abstract should not contain confidential information as it may become publicly available.

### 4. **Research Proposal** (Use template found on proposalCENTRAL; individual section limits apply)

*a. Specific Aims (1 page maximum)*

List succinctly the specific objectives of the research proposed (such as to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology).

*b. Research Strategy (6 pages maximum)*

i. Background and Significance. Present the context, focus and justification of the proposal. Critically review and assess previous research relevant to the proposed project. Highlight deficiencies in current knowledge or understanding, describe how the proposed work will address these gaps, and provide references to the intellectual foundations for the justification of the proposal.

ii. Innovation. Describe how the application challenges or seeks to shift current research or clinical practice by using novel concepts, approaches, methods, or interventions. Address how the concepts, approaches, methods, or interventions are novel to the field of research or novel in a broad sense. Delineate any refinements or improvements to existing methods, or note any new application of concepts, approaches, methods, or interventions that are being proposed.

iii. Methods. Identify the specific research activities proposed, and describe how they will advance scholarship in the field. As appropriate, include their applicability to interdisciplinary research, or areas of potential strategic importance to expanding knowledge of the basic, clinical and public health sciences relevant to cannabis and cannabinoids. The narrative should describe plans for obtaining extramural support for related research activities beyond the award period.

*c. Drug Administration Detail (1 page maximum)*

If cannabis- or cannabinoid-based medicine is to be administered to human subjects, describe the product to be used in this study including its source, mode of administration, dosing and rationale for the selected dose. Identify any safety concerns based on pre-clinical or clinical data. Federal regulations require that all cannabinoid products used in human research have prior approval by the US Food and Drug Administration (FDA). At the time of this RFA, this stipulation means that any whole plant cannabis material must either be obtained from the US National Institute on Drug Abuse (via their Drug Supply Program) or from a manufacturer whose product is approved by the FDA/DEA.

*d. Statistical Analysis (1 page maximum)*

Describe the plan for analyzing data to address the specific aims. Include a power analysis to justify the proposed sample size.

*e. Timeline (1 page maximum)*

Identify the research timeline, benchmarks, and milestones, and justify how the proposed time period and requested budget will accomplish these milestones.

*f. Potential Problems and Proposed Solutions (1 page maximum)*

Identify problems that may be interfere with the ability to carry out the project as proposed and solutions or alternative strategies.

*g. Investigative Team (1 page maximum)*

Describe the investigative team's background, expertise, suitability, and contribution to the proposed research project. If the investigators are established, but new to research in cannabis, describe their record of accomplishments, and how the investigators will apply this background to the present research, including how this expansion of interests will advance the field.

*h. Environment (1 page maximum)*

Describe how the scientific environment in which the work will be done will contribute to the probability of success. Define the institutional support, equipment and other physical resources available to the investigators and how this environment will contribute to the project proposed. As applicable note how the project will benefit from any unique features of the scientific environment, participant populations, or collaborative arrangements. Discuss the strategy for leveraging additional research funds (if any). If cannabis or cannabinoid is to be administered to human subjects, describe your institution's process for meeting the regulatory requirements for storing and dispensing Schedule I controlled substances.

*i. Literature Cited (no maximum)*

Provide a bibliography for references cited in the text.

**5. Organization Assurances (Human Subjects and Vertebrate Animals)**

Complete the Organization Assurances section regarding human subjects and vertebrate animals.

*a. Human Subjects (Use template provided; no page limit applies)*

If applicable, complete a human subjects section using the Human Subjects template based on NIH guidelines. No page limit applies. Do not use the human subjects section to circumvent the page limits outlined above for the Research Plan. If human subjects are not involved in the proposed research, use this template to explain why the proposed work is not considered human subjects research. For studies involving human subjects and that meet the NIH definition of a clinical trial, state that the investigator agrees to post the trial on clinicaltrials.gov. Indicate the plan for obtaining the appropriate regulatory approvals (i.e., Drug Enforcement Administration, Food and Drug Administration, Research Advisory Panel of California, the applicant's Institutional Review Board).

*b. Vertebrate Animals (Use template provided; no page limit applies)*

Complete a vertebrate animals section using the Vertebrate Animals template based on NIH guidelines. No page limit applies. Do not use the vertebrate animals section to circumvent the page limits outlined above for the Research Plan. If vertebrate animals are not involved in the proposed research, state "not applicable."

**6. Biographical Sketch** (5 page limit for each key personnel)

Complete and upload an NIH-style biographical sketch for the each of the key personnel using the NIH guidelines (https://grants.nih.gov/grants/forms/biosketch.htm). Each biographical sketch should not exceed five pages.

**7. Consortium or Cooperative Agreements/Relationships (if applicable).**

Subawards/Consortium Agreements are allowable expenses for this program, pending prior approval by the CMCR. Sites may request IDC in accordance with standards outlined in this RFA. The Prime applicant may request IDC reclamation on subawards up to $25,000 of Modified Total Direct Costs.

**8. Budget and Budget Justification**

Enter proposed project costs directly into proposalCENTRAL for each project period. Prepare and upload a corresponding budget justification using the template found on proposalCENTRAL.

*Maximum direct costs*

For the Primary Grant Program, the maximum total cost is $825,000 ($275,000 per year for up to three years).

For the Pilot Grant Program, the maximum total cost is $300,000 for two years (up to $165,000 in Year 1 and $135,000 in Year 2).

*Allowable costs*

Allowable expenses include salaries and fringe benefits for professional and support personnel, consultant and contractual costs, supplies and expenses, equipment, and travel. However, award funds may not be used to increase or supplement total approved compensation for institutional personnel (e.g., a University faculty member who is already 100% full-time equivalent/FTE cannot be supported with these funds unless partial FTE release is granted). Nine-month appointees may request summer salaries. Funds for anticipated range adjustments and employee benefits must be included in the personnel budget.

Students. Funding is not allowed for student stipends and fees.

Equipment is defined as non-expendable, tangible, personal property, which has an acquisition cost of $5,000 or more, is free standing and has a normal life expectancy of one year or more. Upon termination of an award, all materials and equipment purchased with award funds become the property of the department or equivalent administrative unit concerned.

Indirect Costs. Applications from University of California institutions will be eligible for 30% indirect costs. Non-University of California institutions will be eligible for indirect costs up to 30% of total direct costs, minus equipment, or at the rate established for the institution through a U.S. Department of Health and Human Services (DHHS) indirect cost negotiated rate agreement (or other similarly established rate), whichever is lower. Indirect costs should be calculated at the lower rate, and shown on the budget. A copy of the institution's DHHS rate agreement, or alternate rate agreement, must be included with the proposal. Non-University of California institutions without an established DHHS indirect cost negotiated rate agreement (or other similarly established rate) will be allowed to request 30% indirect costs based on the modified total direct costs. Indirect costs should be calculated and shown on the budget worksheet(s).

Indirect cost reclamation for Non-University of California institutions with subawards are limited to the first $25,000 of the total subaward. University of California institutions with subawards to other University of California institutions will not be eligible for subaward indirect cost reclamation.

Travel. Travel is allowed as needed in order to conduct the study (e.g., if there are multiple sites), for a presentation at a scientific meeting, and presentation of study updates and results at the annual CMCR Symposium (typically in San Diego). Principal investigators should budget travel for this annual, one-day CMCR event.

## Prior to Funding

Prior to funding, prospective awardees are expected to:

- Provide evidence of Institutional Review Board approval
- Provide updated human subjects, animal subjects, and biohazard assurances as applicable
- Modify titles and abstracts, if requested
- Submit revised budgets, if required
- Address issues of scientific overlap and time commitment
- Demonstrate completion of all institutional, State and Federal regulatory approvals

- Work with the CMCR DMIS group to develop a mechanism for efficient submission of study data to the CMCR Research Repository

Investigators may request up to $50,000 in advance funding in order to support the staff needed to address the above requirements. Such funding will be subject to CMCR approval.

## Terms of the Award

The CMCR will adhere to relevant University of California, State and Federal policies. Investigators will be expected to comply with these standards as well as the specific terms described below. On-going funding will be dependent upon compliance.

*Reporting*

Awardees are expected to account in a timely manner for the expenditure of grant funds and for the performance of work as agreed upon. The Institutional Officials' and Principal Investigator's signatures on the Verifications page of the application signify that the individuals are aware of the conditions for receiving a grant from the University of California and agree to comply with all applicable University of California Policies and Procedures, including the following:

- Use of award funds only as approved
- Timely submission of semi-annual progress reports and a final scientific report
- Timely submission of semi-annual and final fiscal reports. Based on progress during the first year, the reporting period may be reduced to annually.
- Timely submission of study data to the CMCR Research Repository (minimally every 6 months)

*Carry-forward funding*

Awardees will receive funding on an annual basis. Carry-forward of unexpended funds is allowable, pending prior approval by the CMCR.

*Presentation at annual CMCR Symposium*

Awardees may be asked to present an update on their studies and findings annually at the CMCR Symposium.

*Use of standardized forms across studies*

As appropriate, awardees will be asked to collect certain data using standardized CMCR data collection forms. This approach will allow de-identified data to be pooled across studies and analyzed in aggregate.

*Development of a Cannabis Research Repository*

One of the goals of the CMCR is to facilitate research beneficial to public health by developing sample (e.g. plasma) and data repositories that may ultimately help California address scientific issues that may not have been part of a study's initial aims. Awardees will be expected to submit de-identified data and samples generated by the study for storage and potential distribution via a structured data/sample request and review mechanism. To assist investigators, the CMCR Data Management and Information Systems staff will meet with awardees to establish mechanisms of data management that facilitate this process, which may range from data exports to investigators using the integrated CMCR Data Management System. On-going funding will be dependent upon compliance with this requirement.

*Acknowledgment of the CMCR*

Recipients of CMCR funding will be expected to acknowledge the CMCR in any presentation or publication of data resulting from the funded study.

## Policy Regarding Scientific Misconduct

The CMCR adheres to the policies and procedures employed by the National Institutes of Health (NIH), including those that apply to scientific misconduct. The DHHS Office of Research Integrity is responsible for implementing DHHS regulations regarding scientific misconduct in research conducted with NIH and other support from the U.S. Public Health Service.

The administrative actions imposed by DHHS include the following: correction of the scientific literature; special plan of supervision to ensure integrity of the scientific research; certification of the accuracy of the scientific data; certification of the accuracy of sources and contributions for scientific ideas and writings; prohibition against service on PHS advisory committees or as a consultant; and debarment from receipt of federal funds. These actions are for specified durations, depending on the nature and the seriousness of the misconduct.

Applicants for, or recipients of, grants from the CMCR must promptly inform the CMCR Director of an administrative action for scientific misconduct that is imposed by DHHS by providing a copy of the final notice of the administrative action (i.e., after the disposition of an appeal), either at the time of application or within thirty days of the imposition of the administrative action. In general, the CMCR will apply the same administrative action. For example, if DHHS has debarred an investigator from applying for or receiving NIH awards for a specified period of time, that investigator would also be excluded from applying for or receiving awards from the CMCR. To take another example, if an investigator has entered into a voluntary agreement with DHHS for special oversight and supervision of the investigator's grant applications, research and publications, that agreement would apply to that investigator's grant applications with, or awards from, the CMCR.

Grant applicants or recipients may request that DHHS administrative actions be waived or modified with respect to a grant application or award from CMCR. In such cases, the applicant must present a justification for the request.

## CMCR Resource Capabilities

The CMCR offers resources that can be leveraged to efficiently provide support for cannabis research. Applicants are encouraged to contact the CMCR regarding ways in which the CMCR might facilitate proposed studies. CMCR resources include:

- Regulatory Expertise: Navigation through federal and state regulatory pathways; guidance regarding IRB applications.
- Clinical Research Expertise: Guidance regarding study design, outcome selection, specimen collection (e.g., lumbar punctures), cross-study standardization to allow for combined data analysis across larger pools of participants.
- Data Management and Information Systems: State-of-the-art web-based data management and reporting systems, and both the hardware and software for collaborative research and communication. Where applicable, data collection can be integrated and standardized across studies to facilitate big data analysis.
- Specimen Collection, Processing and Storage: Expertise in collecting and processing blood, spinal fluid, oral fluid, urine, stool and breath. Samples collected in associated studies can be stored in the CMCR specimen repository, which

features 24-hour temperature monitoring and a custom web-based inventory system, allowing samples to be identified and retrieved quickly for analysis.

- Toxicology Services: The CMCR toxicology laboratory utilizes mass-spectrometry to measure the concentration of cannabis metabolites and endocannabinoids in human samples and tissues, and potentially cannabinoids within cannabis products.
- Facilities and Equipment: The CMCR has specially-designed facilities for the administration of cannabis (e.g., negative pressure rooms), for simulated driving, and for performing clinical exams and cognitive testing.

## Contact

For assistance with your proposal contact CMCRgrants@ucsd.edu.