Institute of Cannabis Research
COLORADO STATE UNIVERSITY–PUEBLO

Part 1. Overview Information

Funding opportunities for FY23 are contingent upon availability of appropriated funds from the State of Colorado

Funding Opportunity Title

FY23 Cannabis Research Award Opportunity

Funding Opportunity Announcement (FOA) Number

ICR-23-001

Funding Opportunity Purpose

The purpose of this Funding Opportunity Announcement (FOA) is to support projects that will significantly add to the understanding and advancement of the cannabis sciences and varied impacts of cannabis.

Key Dates

Announced Date

January 10, 2022

Application Open Date

January 24, 2022

Letter of Intent Due Date

February 21, 2022 , 5PM MST

Application Due Date

May 6, 2022by 5:00 PM (MST). Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

Scientific Merit Review

Applications will undergo the rigorous scientific merit review by a panel of peer subject matter experts as well as an internal programmatic reviewincluding Institute of Cannabis Research (ICR) members. This will require for approximately two months after the application due date.

Expected Earliest Start Date

October 1, 2022

Required Application Instructions

It is critical that applicants follow the proposal and submission instructions. Conformance to all is required and strictly enforced. **Applications that do not comply with these instructions will not be accepted under any circumstances.**

Part 2. Funding Opportunity

Section I. Description

Purpose

The purpose of this grant program is to fund observational- and hypothesis-based research to include but not limited to: scientific, medical, social science, economic, and clinical study of cannabis and other matters that have a significant impact on the state, nation, and world. Research to be supported by this opportunity is wide-ranging, and special areas of interest include the following:

- Medical and Clinical Research
- Public Health and Harm Reduction
- Pharmacology and Dosing
- Societal Impacts
- Biology, Chemistry, Physiology and Agronomy
- Economic Development and Impact

Section II. Award Information

Application Types Allowed

New

Renewal

Resubmission

Funds Available and Anticipated Number of Awards

The number of awards is contingent upon ICR appropriations and the submission of a sufficient number of meritorious applications.

Award Budget: Funding opportunities for FY23 are contingent upon availability of appropriated funds from the State of Colorado. The ICR anticipates funding 6-8 projects, and will depend on the merit, scope, and budget request of applications received. Indirect costs are limited to up to 15% of Modified Total DirectCosts. For this application cycle the ICR anticipates funding projects with differing annual budget ranges.

Proposed funding ranges (includes direct and indirect costs):
1-2 projects at $400,000-$500,000/yr for up to 3 years (likely reserved for medical and clinical projects)

2-3 projects at $150,000-$200,000/yr for up to 3 years

2-3 projects at $50,00-$100,000/yr for up to 3 years

It is incumbent upon the applicants to propose a budget that is both appropriate and well justified for the proposed project. The budget ranges included above are suggested representative ranges. Applicants may propose annual project budgets that stray outside of the suggested ranges. However, $500,000 is the maximum annual project budget allowable under this RFA.

Award Project Period

The scope of the proposed project should determine the project period and the project budget. The total project period may not exceed three years. For multi-year projects, critical annual reviews will be completed to evaluate whether significant progress is being made in meeting specific aims and warranting continuation of project funding.

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Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

- Any Colorado Institution of Higher Education and Any Research Entity Associated with Such Institutions
- Any Not-For-Profit Colorado Based Research Entity
- Any Research Entity that has a Marijuana Research and Development License (pursuant to section 44-11-408) and is Conducting the Research with a Colorado Institution of Higher Education. Contingent on the State of Colorado developing a mechanism through or by DHE.

Authorizations to Conduct Marijuana-Related Research

Under the Drug Free Schools and Communities Act, Institutions of higher education have an obligation to comply with federal drug laws as a condition of receiving grant funding or other financial assistance under any federal program. As a Schedule I substance, it remains illegal under federal law to import, manufacture, distribute, possess, or use marijuana. However, federal law provides the Food and Drug Administration (FDA) with the ability to approve research using Schedule I controlled substances. The following guidance may apply to applicants depending upon the nature of the proposed study and the type and funding status of the applicant organization. **Principal investigators should review this guidance with their organization's legal counsel to determine its applicability.**

Human Clinical Trials/Clinical Studies - Under federal law, a researcher who wishes to administer marijuana (cannabis containing > 0.3% total THC) or its component parts to human subjects must (as applicable per the study details):

- Submit an investigational New Drug application to the FDA.
- Obtain a registration from the Drug Enforcement Administration (DEA)
- Obtain approval from the appropriate Institutional Review Board (IRB)
- Receive a determination from the U.S. Department of Health and Human Services that the investigator is qualified and the proposed research has merit.
- Acquire the marijuana from the National Institute on Drug Abuse's approved source
- Follow DEA regulations and guidelines for storage and prescription.

Note: Hemp (cannabis containing < 0.3% total THC) does not fall under these restrictions

Human Observational Studies – These are studies in which subjects marijuana (cannabis containing > 0.3% total THC) or its component parts, but the researcher does NOT procure it for the subjects, the marijuana/component parts is not consumed on the institution's campus. For these types of studies, the researcher must (as applicable per the study details):

- Obtain approval from the appropriate IRB

Animal Studies - Under federal law, a researcher who wishes to use marijuana (cannabis containing > 0.3% total THC) or its component parts for research involving animals must (as applicable per the study details):

- Obtain a registration from the DEA
- Obtain approval from the appropriate institutional animal care and use committee
- Acquire the marijuana from the NIDA approved source.
- Follow DEA regulations and guidelines for storage and prescription

Note: Hemp (cannabis containing < 0.3% total THC) does not fall under these restrictions

Basic Research - Under federal law, a researcher who wishes to use marijuana (cannabis containing > 0.3% total THC) or its component parts for research that does not involve human subjects or animals, yet is directed toward greater knowledge or understanding of the fundamental aspects of marijuana must (as applicable per the study details):

- Obtain a registration from the DEA
- Acquire the marijuana from the NIDA approved source.
- Follow DEA regulations and guidelines for storage and prescription

Note: Hemp (cannabis containing < 0.3% total THC) does not fall under these restrictions

Cannabinoid Testing

- Testing of marijuana or its component parts for chemical composition and potency by a state certified Colorado laboratory or another laboratory meeting similar quality standards and qualifications is **strongly recommended** as part of clinical trials, observational studies (in which the study subjects procure their own marijuana or component parts), or animal studies involving the administration of marijuana or its component parts.
- Testing of blood, serum, or plasma levels of cannabinoids are **recommended as part of clinical studies** and should be performed by a College of American Pathologists (CAP) accredited laboratory with an appropriately sensitive, specific and validated assay using methodology such as high performance liquid chromatography-tandem mass spectrometry (LC-MS/MS).

Drug Studies

- Study drugs may be donated by pharmaceutical manufacturers; however, study results may not be used in any submission to a regulatory authority as part of a product approval, except to the extent the manufacturer is required by law or regulation to include in such a submission safety data relating to use of the study drug.
- With marijuana being a Schedule I substance, it remains illegal under federal law to import, manufacture, distribute, possess, or use marijuana. However, federal law provides the Food and Drug Administration (FDA) with the ability to approve research using Schedule I controlled substances.

Eligible Individuals (Principal Investigator(s))

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Principal Investigator(s) from an eligible organization is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are encouraged to apply.

2. Cost Sharing

This FOA does not require cost sharing, but cost sharing is encouraged.

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

Section IV. Application and Submission Information

1. Content and Form of Application Submission

Applications that are out of compliance with these instructions will not accepted for review.

Page Formatting Requirements

- 11 point font, Arial or Times New Roman
- Single spacing
- 0.5 inch margins
- Include page numbers
- All attachments must be submitted in PDF format
- Name all Files “PI Surname_DocumentName”

Page Limitations

All page limitations described in the Table of Page Limits Below:

Document Name	Page Limit	Notes
Letter of Intent	2	See details in LOI section below
Biographical Sketch	5	Use Biosketch Template; 5 page limit is per each respective biographical sketch
Project Summary or Abstract	N/A	No more than 500 words using application form field
Research Strategy including References	6	The Research Strategy must address each section clearly and concisely, and include all of the required information for the section. a. Background / Introduction to Problem / Project i. Clearly describe the issue/problem that your project proposes to address. •State primary specific goal •State secondary aim(s) ii. Summarize relevant scientific literature that clearly justifies the appropriateness of conducting a proposed research. iii. Provide complete list of references cited within text and at the end of the document. The References section at the end of the Research Strategy will not count toward the 6 page limit.
Detailed Budget	N/A	The combined total budget (direct and indirect costs) may not exceed $500,000. See proposed budget schedule under (Award Budget). Expenses need to reflect the actual needs of the proposed project. a. Please provide a detailed budget using the budget template provided. b. Do not modify the format of the spreadsheet (budget template). The budget must describe all expenses included. c. Applicants are responsible for ensuring the calculations in the budget are accurate. d. Detailed subcontractor budgets must be provided using separate copies of the same budget template. e. ICR reserves the right to deny requests for any item listed in the budget that is deemed to be unnecessary for the implementation of the project. f. Unallowable expenses: Funds from this grant may NOT be used for:

		• capital construction • building renovations (without prior approval from ICR) • lobbying g. Indirect Rate: Indirect Costs are limited at up to 15% of Modified Total Direct Costs. For applicants that do not have a federally negotiated rate agreement, please use the de minimus rate of 10%
Budget Justification	4	Applicants are required to justify each line item requested. The NIH format is suggested.
Dissemination Activities	2	The Institute of Cannabis Research grant projects are expected to yield an end product. Please describe the planned final product(s) derived from the support provided through the requested grant period. Please include all available information/details (e.g. targeted journal and expected submission timeline, funding agency and program, exhibition information, or performance timeline). All proposals must demonstrate deliverables for each year of funding. If the PI has been previously funded by the ICR please provide a summary of products delivered to date. **As a condition of accepting funding the PI(s) are required (HB19-1311) to present the results of the funded project at the ICR's annual symposium no later than the symposium occurring the year after the research project has ended.**
Career Development	N/A	A brief plan for student training/postdoc career development (500-word limit)
Facilities and Other Resources	2	List facilities and resources directly relevant to the proposed research and how use of the facilities and/or resources will benefit the overall project.
Letters of Support	N/A	Not required, but if included please include as one single PDF file.
Human Subjects and Clinical Trials Information	NA	For projects that include a clinical trial and/or human subjects please include the following as one attachment: 1. Study Protocol that includes the following elements as applicable: • Brief Summary • Eligibility Criteria • Age Limits • Subject Participation Duration • Study Timeline • Study Design • Outcome Measures • Statistical Design and Power 2. Protection of Human Subjects Plan 3. Inclusion of Women, Minorities, and Children Summary 4. Recruitment and Retention Plan 5. Data and Safety Monitoring Plan

Letter of Intent – Required.

Please include the following elements, within 2 pages maximum:

- Descriptive Title
- Applicant organization or entity name
- Name, email, telephone number of Principal Investigator
- Collaborating organization(s) or entity name(s) with names of all co-investigators
- Type of Study and/or study Design (Please refer to Part II, Section 1. for funding areas)
- Proposed duration of project (1 to 3 years)
- Approximate amount of funding being requested for the entire project (estimated total budget)
- Brief project description including Primary goal and Secondary aims
- Brief description of study methods (including analysis plans as appropriate)

- Brief description of plan for obtaining all necessary agency, IRB, and federal approvals
- Attach Biographical Sketch (not counted toward 2-page limit)
- No additional attachments will be accepted
- Please submit the LOI and Biographical Sketch in a single PDF file in the InfoReady portal by the stated deadline (see Key Dates section for details).

Please note, letters of intent will not be accepted or rejected. They will be reviewed to confirm organizations meet eligibility criteria, that project is research based and to categorize by subject matter to recruit scientific review panels. Applicants are encouraged to begin working on the full proposal as soon as they submit the letter of intent unless they are contacted by the ICR to inform them that their respective organization is not eligible to participate.

Application Deadlines and Submission: All applications must be submitted through the ICR InfoReady Portal (link can be found on the ICR website) per the Key Dates section.

Compliance Review Boards

The selected awardees will be responsible for submitting a copy of the proposal to the appropriate Review Board and confirmation of approval must be submitted to the ICR prior to the release of research funds.

- Research involving human subjects must be reviewed and approved by the Institutional Review Board (IRB, Human Subjects Committee);
- Research involving animal subjects must be reviewed and approved by the Institutional Animal Care and Use Committee (IACUC);
- Research involving recombinant DNA or hazardous materials must be reviewed and approved by the Institutional Biosafety Committee.
- PI is responsible for submission to any Other Institutional Review Boards required by their home institution.

Funding Restrictions

All ICR awards are subject to the terms and conditions, cost principles, and other considerations described in this document as well as the ICR Award Policies.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the ICR mission, all applications submitted to the ICR in support of biomedical and behavioral research are evaluated for scientific and technical merit through the ICR peer review system. Proposals will be reviewed and evaluated by a Review and Selection Committee appointed by the ICR Director with funding recommendations approved by the ICR Governing Board. Proposal evaluations will be completed using a scoring rubric.

A proposed Clinical Trial application may include study design, methods, and intervention that are not by themselves innovative but address important questions or unmet needs. Additionally, the results of the clinical trial may indicate that further clinical development of the intervention is unwarranted or lead to new avenues of scientific investigation.

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Significance

Does the project address an important scientific problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field? Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? Do the investigator(s) have appropriate experience and training? Have the investigator(s) demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise? Is there a direct and positive impact on Colorado?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

Broader Impacts

How well does the activity advance discovery and understanding while promoting teaching, training, and learning? How well does the proposed activity broaden the participation of underrepresented groups (e.g., gender, ethnicity, disability, geographic, etc.)? To what extent will it enhance the infrastructure for research and education, such as facilities, instrumentation, networks, and partnerships?

Environment

Will the results be disseminated broadly to enhance scientific and technological understanding? What may be the benefits of the proposed activity to society? Will the scientific environment in which the work will be done contribute to the probability of success? Is there institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements? Are planned analyses and statistical approach appropriate for the proposed study design and methods used to assign participants and deliver interventions?

Data Analysis

Are the procedures for data management and quality control of data adequate at clinical site(s) or at center laboratories, as applicable? Have the methods for standardization of procedures for data management to assess the effect of the intervention and quality control been addressed? Is there a plan to complete data analysis within the proposed period of the award? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

Clinical Research

If the project involves human subjects and/or ICR-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of children, justified in terms of the scientific goals and research strategy proposed? For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and

others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials. For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. When the proposed project involves human subjects and/or ICR-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of children to determine if it is justified in terms of the scientific goals and research strategy proposed.

Animal Research

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following criteria: (1) description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals. Reviewers will assess the use of chimpanzees as they would any other application proposing the use of vertebrate animals.

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Budget

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

Clinical Trials

Are the scientific rationale and need for a clinical trial to test the proposed hypothesis or intervention well supported by preliminary data, clinical and/or preclinical studies, or information in the literature or knowledge of biological mechanisms? For trials focusing on clinical or public health endpoints, is this clinical trial necessary for testing the safety, efficacy or effectiveness of an intervention that could lead to a change in clinical practice, community behaviors or health care policy? For trials focusing on mechanistic, behavioral, physiological, biochemical, or other biomedical endpoints, is this trial Clinical Trials needed to advance scientific understanding? Investigator(s)? Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? Do the investigator(s) have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project? With regard to the proposed leadership for the project, do the PD/PI(s) and key personnel have the expertise, experience, and ability to organize, manage and implement the proposed clinical trial and meet milestones and timelines? Do they have appropriate expertise in study coordination, data management and statistics? For a multicenter trial, is the organizational structure appropriate and does the application identify a core of potential center investigators and staffing for a coordinating center? Does the design/research plan include innovative elements, as appropriate, that enhance its sensitivity, potential for information or potential to advance scientific knowledge or clinical practice? Is the study design justified and appropriate to address primary and secondary outcome variable(s)/endpoints that will be clear, informative and relevant to the hypothesis being tested? Is the scientific rationale/premise of the study based on previously well-designed preclinical and/or clinical research? Given the methods used to assign participants and deliver interventions, is the study design adequately powered to answer the research question(s), test the proposed hypothesis/hypotheses, and provide interpretable results? Is the trial appropriately designed to conduct the research efficiently? Are the study populations (size, gender, age, and demographic group), proposed intervention arms/dose, and duration of the trial, appropriate and well justified? Are potential ethical issues adequately addressed? Is the process for obtaining informed consent or assent appropriate? Is the eligible population available? Are the plans for recruitment outreach, enrollment, retention, handling dropouts, missed visits, and losses to follow-up appropriate to

ensure robust data collection? Are the planned recruitment timelines feasible and is the plan to monitor accrual adequate? Has the need for randomization (or not), masking (if appropriate), controls, and inclusion/exclusion criteria been addressed? Are differences addressed, if applicable, in the intervention effect due to sex/gender and race/ethnicity? Are the plans to standardize, assure quality of, and monitor adherence to, the trial protocol and data collection or distribution guidelines appropriate? Is there a plan to obtain required study agent(s)? Does the application propose to use existing available resources, as applicable? If proposed, are the administrative, data coordinating, enrollment and laboratory/testing centers, appropriate for the trial proposed? Does the application adequately address the capability and ability to conduct the trial at the proposed site(s) or centers? Are the plans to add or drop enrollment centers, as needed, appropriate? If international site(s) is/are proposed, does the application adequately address the complexity of executing the clinical trial? If multi-sites/centers, is there evidence of the ability of the individual site or center to: (1) enroll the proposed numbers; (2) adhere to the protocol; (3) collect and transmit data in an accurate and timely fashion; and, (4) operate within the proposed organizational structure? Is the study timeline described in detail, taking into account start-up activities, the anticipated rate of enrollment, and planned follow-up assessment? Is the projected timeline feasible and well justified? Does the project incorporate efficiencies and utilize existing resources (e.g., CTSAs, practice-based research networks, electronic medical records, administrative database, or patient registries) to increase the efficiency of participant enrollment and data collection, as appropriate? Are potential challenges and corresponding solutions discussed (e.g., strategies that can be implemented in the event of enrollment shortfalls)?

1. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by the ICR.

As part of the scientific peer review, all applications:

- May undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall score.
- Will receive a written critique.

Applications will compete for available funds with all other scored applications. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

2. Anticipated Announcement and Award Dates

After the peer review of the application is completed and award decisions have been made, the award recipients will be contacted from the ICR by July 16, 2022

Section VI. Award Administration Information

1. Award Notices

A formal notification in the form of an award letter will be provided to the applicant organization for successful applications. The award letter signed an ICR Official is the authorizing document and will be sent via email to the PI and grantee's business official/AOR.

Any application awarded in response to this FOA will be subject to terms and conditions found on the ICR website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

2. Reporting

When multiple years are involved, awardees will be required to submit an Interim Progress Report (IPR) annually as outlined in the terms and conditions in the Award Letter.

A Final Progress Report (FPR) will be required within 90 days of the terminal end date of an award as outlined in the terms and conditions of the Award Letter.

Section VII. ICR Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants. All questions should be submitted to the ICR program staff at ICR@csupueblo.edu.

APPLICATION DOCUMENT CHECKLIST

[ ] Letter of Intent (previously submitted)
[ ] Biographical Sketch (ICR Template)
[ ] Project Summary or Abstract (Field completed; no more than 500 words)
[ ] Research Strategy including References (6 page limit + References)
[ ] Detailed Budget (ICR Budget Template)
[ ] Budget Justification (NIH Format Suggested)
[ ] Dissemination Activities
[ ] Career Development (If Applicable)
[ ] Facilities and Other Resources
[ ] Letters of Support (Not Required)
[ ] Human Subjects and Clinical Trials Information (If Applicable)