

Consortium for Medical Marijuana Clinical Outcomes Research 2021 Request for Proposals (RFP)

Required Online LOI Submission Deadline: 5:00 PM (EST), Feb 1st, 2021

Invited Full Proposal Submission Deadline 5:00 PM (EST), April 1st, 2021

Required LOIs and invited full proposals may be submitted in response to this RFP until 5:00 PM (EST) Feb 1st, 2021 and until 5:00 PM (EST), April 1st, 2021 respectively. Applicants will be notified of the invitation to submit full proposals by Feb 15th, 2021, and awarded applicants will have one year from the notice of award (until June 30, 2022) to complete their proposed research. A letter of intent using the [online form](#) is **required** to ensure consistency of the proposed research with the research mission of the Consortium for Medical Marijuana (MMJ) Clinical Outcomes Research as defined by Florida statute, as well as to allow recruitment of external reviewers with subject matter expertise in the proposed area of inquiry.

Purpose

The Consortium for Medical Marijuana Clinical Outcomes Research is comprised of public and private university member institutions within Florida. The Consortium provides awards to support clinical and translational research related to MMJ to investigators within member institutions. The Consortium is charged by Florida statute to conduct and support *“research that contributes to the body of scientific knowledge on the effects of the medical use of marijuana and informs both policy and medical practice related to the treatment of debilitating medical conditions with marijuana”*. The statute requires *“the board to award funds to members of the consortium; requiring the board to collaborate with and authorizing the board to award funds to teaching nursing homes for certain research”*.

This award mechanism will consider fully developed research studies that generate novel evidence, as well as studies intended to facilitate the collection and/or analysis of preliminary data that will support future extramural funding applications.

Timeline

RFP Announcement	Dec 15 th , 2020
Letter of Intent Due	5:00 PM (EST), Feb 1 st , 2021
Proposal Submission Deadline	5:00 PM (EST), April 1 st , 2021
Notice of Awards	July 1 st , 2021
Award Funding Period	July 1 st , 2021 through June 30 th , 2022

NOTE: Late submissions for LOIs or Proposals will not be accepted.

Eligibility

All applicant principal investigators (PIs) must be faculty members of Consortium member institutions, which currently include:

- Florida A&M University
- Florida Atlantic University

- Florida Gulf Coast University
- Florida Memorial University
- Florida International University
- Florida State University
- University of Central Florida
- University of Florida
- University of Miami

All applicants who propose human subject/animal research must comply with their institutional IRB, IACUC, or other regulatory approvals as appropriate.

Applicants may **submit only one proposal for this RFP as the PI** and there are no restrictions regarding the number of proposals where the investigator is listed as a co-investigator.

All proposal submissions will be treated as new submissions regardless of previous participation in the consortium grants program.

Research Priorities

The following are Consortium research priorities that were derived in consultation with scientific and subject matter experts, evidence review, input from stakeholder engagement and NIH areas of programmatic interest. Proposals addressing these priorities are encouraged:

1. **Clinical Outcomes of Medical Marijuana use:** with particular emphasis on
 - a. chronic pain
 - b. anxiety/PTSD
 - c. symptomatic treatment of cancer
 - d. insomnia and sleep disorders
 - e. reduction of other medication (e.g., opioids) or substance use
 - f. effects on the developing brain
 - g. effects during pregnancy and breastfeeding
 - h. research on serious side effects including, psychosis, hyperemesis, falls, accidents, and cardiovascular events
2. **Route of Administration:** effect of dosing and routes of medical marijuana use on efficacy and safety; of particular interest are studies that evaluate effects of smoking and vaping
3. **Interactions of Medical Marijuana with other drugs/medications:**
 - a. with particular focus on medications that are commonly used by patients who seek medical marijuana treatment
 - b. impact of polysubstance, including interactions with alcohol, tobacco, benzodiazepines, and prescription and nonprescription opioids
4. **Epidemiology research** to study trends for cannabis use and cannabis use disorder (CUD), including new products, patterns of use, and reasons for use in different populations, including the impact of COVID-19
5. Research on the **human endocannabinoid system**

6. Measuring **components of medical marijuana/cannabis** (including hemp and hemp product) and contrast their clinical outcomes:
 - a. comparing different components of medical marijuana (e.g. different terpenes)
 - b. research on different potency levels of THC products (e.g. >10% vs <10% THC)
 - c. standards for measuring cannabis (including hemp and hemp product) dose, intoxication, and impairment

Review Process and Criteria

LOI Review

All applicants must submit a required letter of intent (LOI) by 5:00 PM (EST) Feb 1st, 2021, online at <https://mmjoutcomes.org/research/loi/>. The LOI will require the following information: Title of the application, PI, collaborators, research aims, proposed methods, if the proposal was submitted in a previous cycle, a translational statement describing the potential for translational research and its relationship to elucidating our understanding of MMJ clinical outcomes, an NIH style biosketch for the PI and contact information for 3 potential out-of-state reviewers. The LOI must be submitted by a PI from a member institution. Please note that late LOI submissions will not be accepted. The required Letters of Intent will be administratively reviewed and only LOIs which are aligned with the research mission of the Consortium and bear potential for translational research, will be invited for full proposal submission. All efforts will be made to notify PIs of the results of LOI review by Feb 15th, 2021.

Application Review

Each invited proposal will be reviewed by at least two subject matter experts from out-of-state institutions with no conflict of interest and serving in an ad hoc capacity. Reviewers will provide their assessment of each proposal's merit to the Consortium's governing body, the Medical Marijuana Clinical Outcomes Research Board, who will then rank proposals prior to their selection for awards. The Board is comprised of representatives from each Consortium member institution, and the Board may decide to award selected proposals for up to or less than the requested amount.

Reviewers will use standard NIH criteria to assess applications. The Medical Marijuana Clinical Outcomes Research Board will make final selections of awardees based on these assessments as well as the following criteria: scientific merit, innovation, measurable deliverables and/or milestones, potential impact, relevance to the Consortium research mission, qualifications of the PI, potential for future extramural funding, and immediate clinical and/or demonstrable translational relevance to inform medical use of marijuana. Responsiveness to the research priorities listed above will also be an important consideration in the review process.

Please note proposals with research and specific aims that differ significantly from their respective LOI will not be considered for full review.

Award Amounts

The maximum budget request is \$75,000 total cost (including indirect cost) per application, although budgets for smaller amounts are encouraged for pilot studies. Funds will be released immediately for awarded projects in consideration of the 12-month funding period consistent with the state fiscal year, once relevant approvals have been obtained. Funds may be used for any justified project expenses as detailed in the Budget Forms and Budget Justification

application section. **Indirect costs are set at 10%.** Funds must be spent by June 30, 2022 and **no-cost extensions are not permitted.**

Application Requirements

All applications must contain each component in the summary below and must be submitted according to instructions. Please use NIH formatting where not explicitly stated, meaning 11-point Arial black font with page margins set at 0.5" on all sides and text is single-spaced. The forms within are accessible via download link posted at the end of this RFP.

Application Summary

- Cover Sheet form
- Abstract
- Translational statement
- Current Consortium Awardee or Resubmission (if applicable)
- Research Plan
- Key Personnel
- NIH Biographical Sketches
- Environment/resources
- If applicable include description for protection of human subjects; Inclusion of Women, Minorities, and Children; vertebrate animals and biohazards
- Budget Justification
- Budget Worksheet
- References
- Letters of Support (from collaborators such as dispensaries are required)

Cover Sheet Form

Complete the form as provided and include as Page 1 of the application packet.

Abstract

The abstract should be limited to 250 words or less and should be contained within a single page.

Translational Statement

In one or two sentences describe the potential for translational research and its relationship to elucidating our understanding of MMJ clinical outcomes

Current Awardee or Resubmission (if applicable)

All submissions will be treated as new submissions.

- If you are a past grant awardee, please explain how the current proposal relates to the previously awarded research and what has been accomplished to-date (1-page maximum).
- If this proposal was not funded in the previous cycle, please state how you have addressed the reviewer comments in this submission (1-page maximum).

Research Plan

The research plan may be a maximum of 5 pages. The plan must contain each of the following elements: project rationale, specific aims, significance, innovation, and approach. The approach should include sufficient information regarding human subjects or animal research, where

applicable, for reviewers to assess feasibility of regulatory approval and project timeline. A timeline of the project must also be included, identifying dates for submission for regulatory approvals and progress milestones. For clinical research, the number of subjects planned to be enrolled must be stated and justified. Projects that propose prospective enrollment must include a recruitment strategy. Studies proposing research using components of marijuana (CBD, THC, CBG etc.) will be permissible. The source of marijuana/cannabis or related products must be clearly listed along with any licensure and regulatory compliance information.

Key Personnel

All key personnel must be identified via the form provided. For PIs and co-Investigators, NIH biographical sketches are required.

NIH Biographical Sketches

PIs and co-investigators listed as key personnel must include biographical sketches with applications. A sample template is provided in the application forms packet available for upload. Each key personnel on the proposal is limited to a total of 5 pages. Formatting requirements are outlined in detail at this link: <https://grants.nih.gov/grants/forms/biosketch.htm>

Environment/Resources

In one page describe the resources, facilities, and support available to the researcher.

If applicable for proposed research include section(s) for describing protection of human subjects; inclusion of Women, Minorities, and Children; vertebrate animals and biohazards

Budget Justification and Worksheet

The budget justification as well as the worksheet must include an entry for all line item costs associated with the proposed project. Cost estimates must be provided for services rendered, if applicable. The worksheet form and budget justification template are appended to this RFP announcement.

References

References should be uploaded at the end of the application and may be provided in the citation style of the applicant's choice. There is no page limit for the references section of the application.

Letters of Support

Letters of support from collaborators such as dispensaries are required. Other letters are optional but may be useful to demonstrate feasibility or relevance of the proposed work. Applicants may choose to upload a maximum of 5 letters of support for each application.

Awardee Obligations

1. **Post-Award Approval Documentation prior to Release of Funds:**
 - a. IRB approval documentation if the proposed research involves human subjects.
 - b. IACUC approval documentation if the proposed research involves animals.
 - c. Approval documentation from relevant regulatory bodies as appropriate if applicable (e.g., DEA, FDA).
2. **Progress Reports:** Under the terms of your research award for the MMJ clinical outcomes research grants program, a final report of your study progress, final results, publications, subsequent funding and other scholarly activities related to this funding is

required. In addition to an interim progress report and a final report, the awardee is required to provide an annual report of any published articles and funding updates arising from this award for a period of three (3) years after award completion.

3. **Presentation of Research Studies:** Awardees will be required to present the results of their awarded research proposal at the consortium's annual conference, Cannabis Clinical Outcomes Research Conference (CCORC).
4. **Funding Acknowledgement:** Awardees must acknowledge the State of Florida's Consortium for Medical Marijuana Clinical Outcomes Research in all resultant publications or presentations.

Submission Instructions

Email completed applications as a single PDF, including cover sheet and all attachments, to: mmj.outcomes@cop.ufl.edu . Incomplete applications or applications that do not adhere to requirements will not be reviewed. Forms are appended to this RFP announcement.

Applicant Resources and Contact

Applicants are encouraged to contact the Consortium staff for guidance regarding available resources offered by the Clinical Core. Support services for applicants may include statistical analysis, IRB preparation consulting, and support for data management.

For all questions please email: mmj.outcomes@cop.ufl.edu

Cover Sheet for Proposal to MMJ Consortium 2021 RFP

Proposal Title:

Please select PI consortium member institution affiliation:

- Florida A&M University
- Florida Atlantic University
- Florida Gulf Coast University
- Florida International University
- Florida Memorial University
- Florida State University
- University of Central Florida
- University of Florida
- University of Miami

Principal Investigator Name	
Position/Title	
Email	
Fiscal / Admin Contact (Name & Email)	

Number of participants to be enrolled (if applicable)	
Total cost of proposed work*	
Total funds requested*	

*Please use the Budget Worksheet and Justification forms to document costs.

Key Personnel

Name of Project Member	
Position/Title	
Email	
Role on Project	Principal investigator

Name of Project Member	
Position/Title	
Email	
Role on Project	

Name of Project Member	
Position/Title	
Email	
Role on Project	

Name of Project Member	
Position/Title	
Email	
Role on Project	

Name of Project Member	
Position/Title	
Email	
Role on Project	

Budget Justification (page 1 of 2)

PI Name:	
Proposal Title:	

In addition to this budget justification, applicants must complete a budget worksheet. Written cost estimates are required attachments, if applicable.

Personnel. List all Key Personnel i.e. PI, Co-I, Mentor, etc., Describe study role and amount of effort for each.

Consultants, if applicable. Describe study role.

Equipment. Major equipment is not an allowable budget item for this RFP. In order to evaluate the request for funding, provide description, purpose, total cost, useful life information and other funding sources, if applicable.

Budget Justification (page 2 of 2)

Supplies. In order to evaluate the request for funding, provide description, purpose, total cost, and funding source, if applicable.

Travel. Travel is typically not an allowable budget item for this RFP. In order to evaluate the request for funding, provide description, purpose, location, and total cost.

Other Expenses. Use this category for any expenses not described above and attach written cost estimates.

Principal Investigator (Last, First):

BUDGET WORKSHEET FOR BUDGET PERIOD

FROM
07/01/2021

THROUGH
06/30/2022

List PERSONNEL (*Applicant organization only*)
Use Calendar to Enter Months Devoted to Project
Enter Dollar Amounts Requested (*omit cents*) for Salary Requested and Fringe Benefits, if applicable

NAME	ROLE ON PROJECT	Calendar Months	INST.BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS	TOTAL
	PI					
SUBTOTALS						
CONSULTANT COSTS						
EQUIPMENT (<i>Itemize</i>)						
SUPPLIES (<i>Itemize by category</i>)						
TRAVEL						
OTHER EXPENSES (<i>Itemize by category</i>)						
CONSORTIUM/CONTRACTUAL COSTS						
SUBTOTAL DIRECT COSTS FOR BUDGET PERIOD					\$	
FACILITIES AND ADMINISTRATIVE COSTS						
TOTAL COSTS FOR BUDGET PERIOD					\$	