Consortium for Medical Marijuana Clinical Outcomes Research Funding Opportunity Announcement: Request for Applications (RFA)

Submission Deadline: October 16, 2019

Applications can be submitted in response to this RFA until 5:00PM on October 16, 2019. Applicants will be notified of the funding decision by December 1, 2019, and funded applicants will have a period of 8 months from the notice of award (until July 31, 2020) to complete their projects. **A letter of intent must be submitted to mmj.outcomes@cop.ufl.edu by October 1, 2019**, 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 medical marijuana to investigators within member institutions. The Consortium is charged by Florida statute to conduct and support research that will contribute to the body of scientific knowledge on the effects of the medical use of marijuana to inform policy and clinical practice related to the treatment of debilitating medical conditions with marijuana.

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

RFA Announcement	September 16, 2019
Letter of Intent Due	October 1, 2019
Application Deadline	October 16, 2019
Notice of Awards	December 1, 2019
Award Funding Period	December 1, 2019 through July 31, 2020

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 research must be in compliance with their institutional IRB investigator qualifications. Where applicable, investigators **are required to demonstrate project IRB, IACUC, or other regulatory approval as appropriate, following notice of award. It is recommended that applicants seek regulatory approvals prior to receiving the notice of award to ensure no delay in project start.**

Applicants may submit more than one application for this RFA as the PI and there are no restrictions regarding the number of applications where the investigator is listed as a co-investigator.

Review Process and Criteria

All applicants must submit a letter of intent by <u>October 1, 2019</u> to <u>mmj.outcomes@cop.ufl.edu</u> containing a broad description of the proposed study and subject area of inquiry. The letter may be a maximum of 1 page in length. The purpose of the letter is for the Consortium to identify relevant expert reviewers and it should be noted that **applicants will not receive feedback on the letter of intent.**

Each application will be reviewed by at least two subject matter experts from out of state institutions and serving in an ad hoc capacity. Reviewers will provide comments and recommendations on the application's merit to the Consortium's governing body, the Medical Marijuana Research Board, who will then rank applications prior to selection of applications for awards. The Board is comprised of representatives from each Consortium member institution, and the Board may decide to award selected applications up to or less than the requested amount.

Reviewers will be asked to use standard NIH criteria to assess applications. The Medical Marijuana 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 charge, qualifications of the PI, potential for future extramural funding, and immediate clinical and/or demonstrable translational relevance to inform medical use of marijuana.

Award Amounts

The maximum budget request is $75,000 total 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 8-month funding period once relevant regulatory 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 July 31, 2020 and **no-cost extensions are not permitted**. Investigators are encouraged to apply for funding in the next 2020-2021 funding cycle to continue their work.

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 RFA.

Application Summary
- Cover Sheet form
- Abstract
- Research Plan
- Key Personnel
- NIH Biographical Sketches
- Budget Justification
- Budget Worksheet
- References
- Letters of Support (optional)

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.

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 or animal subjects research, where applicable, for reviewers to assess feasibility of IRB 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. Projects that propose prospective enrollment must include a recruitment strategy.

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

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 RFA announcement. Upon the launch of the Consortium website, these documents will also be available for download at: www.mmjoutcomes.org

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

Applicants may choose to upload a maximum of 5 letters of support for each application. Letters are not required but may be useful to demonstrate feasibility or relevance of the proposed work.

Awardee Obligations

1. **Post-Award Approval Documentation**:
   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:** For at least 2 years following award receipt, awardees will submit a progress report via email. These reports should be a maximum of 3 pages and include: project progress and/or results, all publications resulting from this project, and all extramural applications submitted and funded resulting from this project. Reports should be submitted to: mmj.outcomes@cop.ufl.edu.
3. **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 RFA announcement.

Applicant Resources and Contact

Applicants are encouraged to contact the Consortium 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 Consortium Funding Award: Fall 2019

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

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 RFA. In order to evaluate the request for funding, provide description, purpose, total cost, useful life information and other funding sources, if applicable.

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 RFA. 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 12/01/2019	THROUGH 07/31/2020

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 *(Itemize)*						
SUPPLIES *(Itemize by category)*						
TRAVEL						
OTHER EXPENSES *(Itemize by category)*						

CONSORTIUM/CONTRACTUAL COSTS	DIRECT COSTS	
SUBTOTAL DIRECT COSTS FOR BUDGET PERIOD		$
CONSORTIUM/CONTRACTUAL COSTS	FACILITIES AND ADMINISTRATIVE COSTS	
TOTAL DIRECT COSTS FOR BUDGET PERIOD*		$

Reminder: 10% indirects will count towards the award maximum amount of $75,000.