Consortium for Medical Marijuana Clinical Outcomes Research
2025 Request for Proposals (RFP)

Required Online LOI Submission Deadline: 11:59 PM (EST), Feb 3rd, 2025

Invited Full Proposal Submission Deadline 11:59 PM (EST), April 3rd, 2025

A required Letter of Intent (LOI) and invited full proposals may be submitted in response to this RFP until 11:59 PM (EST) on Feb 3, 2025 and April 3, 2025, respectively. Applicants will be notified of the invitation to submit full proposals by Feb 24, 2025, and after review, awards will be announced, with a July 1, 2025 start date. A LOI 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. For pilot grants, there needs to be a clearly delineated plan for securing future funding. The Consortium discourages applications that repeat previous research projects with unclear justification for innovation.

Timeline

RFP Announcement	Oct 31, 2024
Online Letter of Intent Deadline	11:59 PM (EST), Feb 3, 2025
Invited Proposal Submission Deadline	11:59 PM (EST), April 3, 2025
Notice of Awards	July 1, 2025
Award Funding Period	Level 1 July 1, 2025 through June 30, 2026 Level 2 July 1, 2025 through June 30, 2027*

*dependent on continued state support, and internal board review of progress made towards year 1 goals

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
- Nova Southeastern University

There is no restriction on the affiliation of the Co-investigators. 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.

Grant awardees are eligible to apply again after one year from their Consortium grant end date. In case of a no-cost extension, the end date of the no-cost extension will be considered the grant end date.

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, NIH areas of programmatic interest, and the research priorities proposed by National Academies. Priority will be given to human subjects research, but preclinical translational research with strong rationale for clinical applicability will also be considered.

Proposals addressing these priorities are highly encouraged:

1. ***Clinical Outcomes of Medical Marijuana Use:*** with priority granted to studies investigating efficacy and safety in humans, for the treatment of qualifying conditions listed for medical marijuana use in Florida (see qualifying conditions list at: https://knowthefactsmmj.com/patients/), or within populations critical to monitor, including:
    a. pregnant people (and exposed infants);
    b. youth and young adults (with emphasis on the impacts on developing brain);
    c. veterans (PTSD, mental health);
    d. older adults and adults with chronic conditions.

2. ***Effect of Medical Marijuana Use in Reducing Opioid Dependence:*** human subjects research on the effectiveness of MMJ as an analgesic/adjuvant in pain management and reduction in opioid use.

3. ***Routes 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.

4. ***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 use, including interactions with alcohol, tobacco, benzodiazepines, and prescription and nonprescription opioids

5. ***Public health outcomes of cannabis laws and regulations:*** studies on how state and local cannabis regulations, such as those related to licensing, zoning, product types, product additives, advertising, product labeling, and pricing influence:
    a. public health outcomes, including health service use, disparities in treatment access, and health equity and
    b. research outcomes, including limitations or other effects on ability to conduct research

6. ***Evaluating Components of Medical Marijuana/Cannabis*** 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 dose, intoxication, and impairment
    d. health effects of emerging synthetic and semisynthetic cannabinoids and high-concentration products.

7. ***Mitigation of the risks of cannabis use*** by evaluating risk-mitigation strategies for cannabis use and their effectiveness in reducing problematic use and minimizing harm.

Review Process and Criteria

LOI Review

All applicants must submit a required online LOI by 11:59 PM (EST) Feb 3, 2025. The LOI will require the following information: Title of proposed research, funding level applied to, PI and collaborators names and their affiliations, research aims, proposed methods, if the proposal was submitted in a previous cycle, clinical relevance of proposed research, an NIH style biosketch for the PI, and name and contact information for 3 potential out-of-state reviewers. The LOI must be submitted by a PI from a member institution. **The required LOIs will be reviewed and only LOIs that align with the research mission of the Consortium, demonstrate innovation and have direct clinical applicability, will be invited for full proposal submission.** Priority for funding will be given to human subjects research. All efforts will be made to notify PIs of the results of LOI review by Feb 24, 2025.

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: relevance to the Consortium research mission, potential for future extramural funding, immediate clinical and/or demonstrable translational relevance to inform medical use of marijuana, as well as responsiveness to the research priorities listed above. Please note proposals with research and specific aims that differ significantly from their respective LOI will not be considered for full review.

Funding Levels

Two levels of research funding will be available for the 2025 grants cycle:

- Level 1: Proposals with a one-year research plan, will be funded for $75,000 each.

- Level 2: Proposals with a two-year research proposal plan, will be funded for $130,000 each ($65,000/year), with second year funding dependent upon state support and an internal board review of progress made towards year 1 goals. Proposals with a clinical focus will be prioritized for level 2 funding.

Applicants can apply to only one of the above two funding categories. The total budget request should include Facilities and Administrative (F&A) costs, and budgets for smaller amounts are encouraged for pilot studies. Funds will be released immediately for awarded projects in consideration of the 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 and Budget Justification sections. **F&A costs will be allowed to a maximum of 10% of total budget, to be allocated based on the discretion of the individual institutions.** Funds must be spent by end of award date and no-cost extensions are discouraged.

Application Requirements

All applications must contain each component in the order listed 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. There are pdf fillable forms at the end of this RFP.

Application Summary

- Cover Sheet form
- Abstract
- Clinical Relevance
- 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, if applicable)

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.

Clinical Relevance
In one or two sentences describe the clinical relevance and how it elucidates 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. Clear distinction should be made between Co-Is and consultants.

NIH Biographical Sketches
Biographical sketches for PIs and co-investigators listed as key personnel must be included. Each biosketch is limited to a total of 5 pages. Formatting requirements are outlined in detail at: 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 templates are included at the end of the RFP and must include an entry for all line item costs associated with the proposed project. Cost estimates must be provided for services rendered, if applicable. PI salaries must adhere to the NIH salary cap.

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, if applicable. 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.

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 for the MMJ clinical outcomes research grant award, an interim progress report, and a final report, which includes results, publications, subsequent funding and other scholarly activities related to this funding is required. The awardee is required to provide an annual update of any published articles and extra mural funding 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 at the consortium's annual conference, Cannabis Clinical Outcomes Research Conference (CCORC) and agree to showcase their research on Consortium platforms.
4. **Funding Acknowledgement in all resultant publications or presentations:** Cite the Consortium for Medical Marijuana Clinical Outcomes Research as the funding source and include the disclaimer as follows:
    "Dr. XXX received funding from the Year Research Grants Program of the Consortium for Medical Marijuana Clinical Outcomes Research which is funded through State of Florida appropriations. Any published findings and conclusions are those of the authors and do not necessarily represent the official position of the Consortium for Medical Marijuana Clinical Outcomes Research."
    Upon publication (of any type), provide a courtesy copy of any published reports or research results to the Consortium for Medical Marijuana Clinical Outcomes Research.

Submission Instructions

Email completed applications as a single PDF, including cover sheet and all attachments, to: mmj.outcomes@cop.ufl.edu by April 3rd, 2025. Incomplete applications or applications that do

not adhere to requirements will not be reviewed. Forms are included in 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 2025 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
- ☐ Nova Southeastern University

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

Number of participants to be enrolled (if applicable)	
Total direct costs*	
Total funds requested (direct costs plus Facilities and Administrative costs)*	

*Please read RFP Budget section for details and use the Budget Worksheet and Justification forms to document costs.

Key Personnel

List *consultants* as senior/*key personnel* only if they will contribute substantively and measurably to the scientific development or execution of a project.

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, staff 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. In order to evaluate the request for funding, provide description, purpose, location, and total cost. Travel to the Consortium's annual conference may be requested.

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 07/01/2025	THROUGH 06/30/2026

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	
SUPPLIES	
TRAVEL	
OTHER EXPENSES *(Itemize by category)*	
CONSORTIUM/CONTRACTUAL COSTS	
SUBTOTAL DIRECT COSTS FOR BUDGET PERIOD	**$**
FACILITIES AND ADMINISTRATIVE COSTS	
TOTAL COSTS FOR BUDGET PERIOD	**$**

***For a Level 2 proposal use second sheet for year 2 budget (7/1/2026-6/30/2027)**