Consortium for Medical Marijuana Clinical Outcomes Research

ANNUAL REPORT | 2019-2020

February 2020

Prepared by the Consortium for Medical Marijuana
Clinical Outcomes Research

For more information about the Consortium visit: www.mmjoutcomes.org

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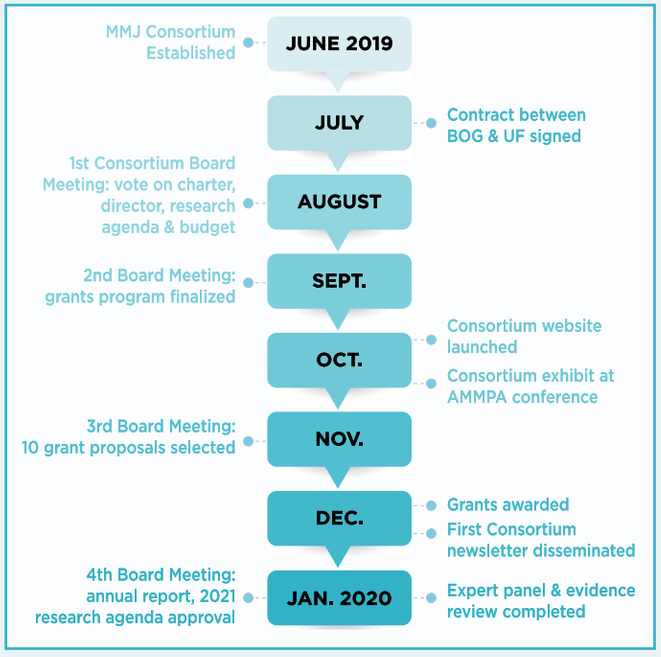
EXECUTIVE SUMMARY

Beginning with the Compassionate Use Act passed in 2014 and followed by several amendments, Florida law allows the use of marijuana for the treatment of certain debilitating conditions. Persons seeking Medical Marijuana (MMJ) may suffer from serious health conditions and symptoms, many of which are not responsive to approved medications. While MMJ could potentially improve health outcomes, there are also significant safety concerns related to cognitive effects, risk for accidents, interactions with other medications, psychosis, and addiction. Moreover, MMJ varies significantly in terms of its specific components and mode of administration (including smoking and vaping), but little is known about how MMJ improves clinical outcomes and what components, doses and delivery methods provide the optimal risk-benefit profile. There is a substantial need to understand how MMJ impacts health and safety outcomes. But due to the complex federal and state legal restrictions for both MMJ use and MMJ research, the development of evidence on the safety and effectiveness of medical marijuana is lagging far behind the rapid uptake.

To address the need for rigorous evidence on the safety and effectiveness of medical marijuana, the state legislature introduced Section 1004.4351, Florida Statutes, to establish the Consortium of Medical Marijuana Clinical Outcomes Research to conduct, disseminate and support rigorous scientific research on the clinical effects of medical marijuana. In July 2019, the Florida State University System Board of Governors, following a competitive request for proposals, designated the University of Florida as the lead university of the Consortium. Eight additional universities have joined the Consortium to-date, each with one designee to form the Medical Marijuana Research Board.



Timeline of Activities of the Consortium for Medical Marijuana Clinical Outcomes Research, 2019-2020.

At its first board meeting in August 2019, the board adopted a charter, the 2020 Consortium research program, a budget, and elected Consortium leadership.

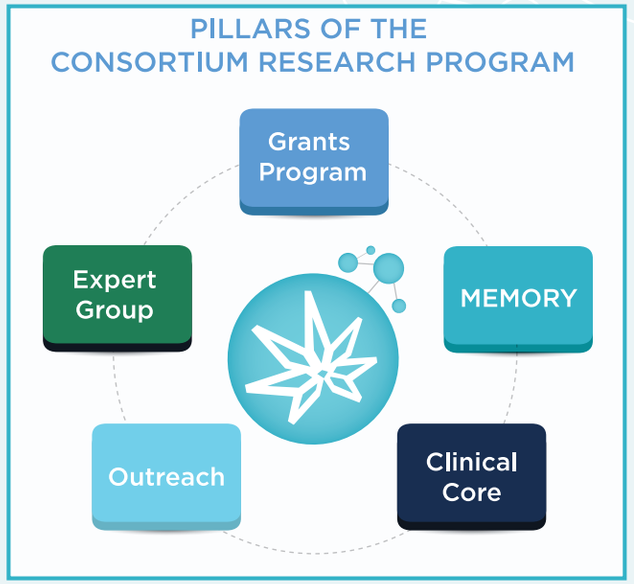
The charter defines the Consortium purpose as **"creating an effective medical marijuana clinical outcomes research program which would mobilize the scientific and medical resources that presently exist in the state to determine the appropriate and best use of marijuana to treat illness."** Consortium responsibilities as defined in the charter and consistent with statute include:

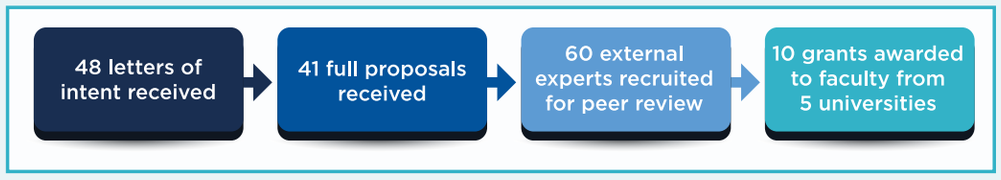
- Conduct rigorous scientific research
- Disseminate research
- Guide policy for the adoption of a statewide policy on ordering and dosing practices for the medical use of marijuana.

Two board meetings followed in fall 2019, which focused on expediting the Consortium Grants Program launch to optimize research investments in the current fiscal year. The fourth board meeting in January 2020 reviewed Consortium accomplishments to be summarized in this report and established the research plan for 2020-2021.

CONSORTIUM RESEARCH PROGRAM

The Consortium research program rests on five pillars aimed at supporting the Consortium mission to foster medical marijuana clinical outcomes research including: a **Grants Program**, a new and unique research data repository known as the **ME**dical **M**arijuana Clinical Outcomes **R**epositor**Y** (**MEMORY**), a **Clinical Research Core**, a S**cientific Expert Group** and an **Outreach** program. All five pillars have been established and worked towards completing specific goals proposed by the Consortium director and endorsed by the board in August 2019. Our proposal for the Consortium 2020-2021 research plan builds on the same research program structure. Following is a brief overview of the purpose of each pillar and activities to-date.





The Consortium Grants Program was launched in September 2019 with the release of its first request for proposals (RFP). The Grants Program received tremendous enthusiasm documented by 41 proposals submitted by investigators from all 9 Consortium universities within only one month after RFP release. Submitted proposals were routed for review to 60 ad-hoc out-of-state faculty reviewers with demonstrated expertise in the respective research area. The board selected 10 proposals for funding from 5 of the Consortium member institutions. Proposed research in these funded proposals included 4 clinical and 5 translational studies, as well as one product safety study. Disease conditions addressed in the clinical/translational proposals included brain and muscle injury, drug resistant cancers, chronic spinal cord injury pain, PTSD related sleep disturbances, chemotherapy-induced pain, as well as migraine-like pain, negative emotion and photophobia. Progress reports including preliminary research findings are scheduled for May 2020.

MEMORY is designed to establish the infrastructure for real-world MMJ clinical outcomes evaluations similar to those employed by the US Food and Drug Administration (FDA). Specifically, the Consortium aims to link the Office of Medical Marijuana Use (OMMU) MMJ registry data with other clinical databases commonly used for outcomes research to create a robust research-ready repository available in de-identified fashion to all Consortium members. Linkage of detailed MMJ dispensing information with clinical outcomes data allows controlled studies on MMJ effectiveness and safety and establishes an active surveillance platform that can detect emerging safety signals that may be associated with a particular MMJ product as recently experienced with certain vaping products. The initial request for data has been rejected by the Office of Medical Marijuana Use (OMMU), and legal departments at the Department of Health (DoH) and the University of Florida (UF) are now attempting to resolve the differences between interpretations of the statutory requirements for DoH to share OMMU registry data with the Consortium.

The Clinical Research Core was established to complement MEMORY, which facilitates *retrospective* studies of routinely collected data, thus maximizing sample size and the ability to examine long-term outcomes or rare safety events. The Clinical Research Core aims to provide infrastructure support for *prospective* studies (including randomized controlled trials) involving collection of new data, which may include detail on patient reported outcomes or other experiences related to MMJ use. To facilitate such studies, the Clinical Core is working with patients, providers, trainees, and industry partners. To facilitate patient recruitment, the Consortium has begun to assemble a group of MMJ Provider Partners. A patient recruitment platform on the Consortium website will be launched in spring 2020. The clinical research core is also responsible for connecting researchers to the broad range of services and support infrastructure made available by the Clinical and Translational Science Institutes (CTSIs) at UF, the University of Miami and Florida State University, which have pledged their support for the Consortium.

The Consortium Outreach Program includes a website launched in October 2019 and available at *https://mmjoutcomes.org/*, a quarterly newsletter with its first issue disseminated in December 2019, an exhibit at the American Medical Marijuana Provider Association (AMMPA) annual meeting in October 2019 and a state-wide MMJ provider survey to be launched in March 2020.

Finally, the **Consortium Scientific Expert Group** was formed in November 2019 to support Consortium researchers and to inform the 2021 Consortium research agenda. The expert group includes clinical and translational scientists who have expertise across the full breadth of rapidly expanding clinical treatment scenarios and the evolving evidence on MMJ outcomes (desirable and undesirable). Experts in pharmacology and medicinal chemistry are included to inform clinical studies, as well as faculty in law and policy to help with interpreting legal issues and suggest changes and evaluations of policy.

The scientific expert panel has met several times in late 2019 to advise on the 2020-2021 Consortium research priorities. The expert group's work was supported by a broad literature mapping review aimed at highlighting evidence gaps in our understanding of the clinical outcomes of medical use of marijuana. Based on these expert group recommendations, preliminary stakeholder feedback solicited at the AMMPA meeting, and the Consortium research mission, the board has prioritized the following areas for its 2020-2021 research agenda:

- **Clinical Outcomes:** with particular emphasis on chronic pain, anxiety and symptomatic treatment of cancer
- **Route of Administration:** effect of dosing and routes on efficacy and safety; of particular interest will be studies that evaluate effects of smoking and vaping
- **Interactions of MMJ with other drugs:** with particular focus on those medications that are expected to be prevalent in patients who seek medical marijuana

CONSORTIUM RESEARCH PLAN 2020-2021

Since its inception in July 2019, the Consortium has made great strides towards facilitating and conducting research that will inform clinical care and policy about the medical use of marijuana to improve public health. To build on these initial efforts, we propose continued development of the five Consortium research program pillars that were established last year: the Grant program, MEMORY, the Clinical Core, Outreach and Scientific Expert Group Activities. The specific goals and plans for each pillar have been updated and are described below.

Assuming a consistent budget, the following describes the proposed Consortium Research Plan for fiscal year 2021.

- In light of the impressive response to the Consortium's **grants program**, the board proposes to continue this effort without major changes in the coming fiscal year. The application process will start March 1, 2020 with the goal to make awards by July 1 once the Consortium budget is released, which will allow a full 12-months funding period and enhance the scope of studies that can be completed. The most noteworthy modification of the first grants cycle is the introduction of a focus on specific research priorities that have been endorsed by the board as described above.

- Plans for **MEMORY** development remain unchanged for fiscal year 2021 with the key focus on establishing data sharing processes and procedures with OMMU. To facilitate rapid detection of emerging safety signals as exemplified with the recent concern about marijuana vaping products and severe lung disease, the Consortium considers two aspects of MEMORY as they relate to DoH data transmission particularly critical: access to data that details the specific marijuana product that licensed patients purchased from dispensaries; and frequent updates of data (as stipulated in the statute on a quarterly basis). As envisioned, MEMORY can then support controlled studies on medical marijuana effectiveness and safety and active surveillance for emerging safety issues among MMJ users.

- Goals for the **Clinical Core** will include an expansion of the Consortium infrastructure to support patient recruitment into prospective research studies. This will include development of policies and procedures to engage patients and research partners (providers and industry) who have expressed interest in collaboration and pilot work to establish a prospective statewide cohort of MMJ users to be conducted at one or more MMJ provider practices and/or dispensaries in Florida. The Clinical Core will also work on guidance for investigators on regulatory issues involving use of medical marijuana in research studies.

- The Consortium is planning to increase its **Outreach** through the first Consortium Symposium on Medical Marijuana Clinical Outcomes Research. This will be a research-centric meeting, though open to patients and providers, to share research findings and stimulate research collaborations throughout the state and nationally. The Consortium will make a particular effort to reach out to lawmakers and regulators to facilitate discussions on evidence-based policy to enhance both research on and the clinical use of medical marijuana.

- Two new activities that complement Consortium outreach activities will be launched by the **Scientific Expert Group**, including publication of emerging evidence reviews and patient/provider info sheets. Emerging evidence reviews will scan the medical literature and highlight new and clinically relevant findings. The Consortium will further develop patient and provider information sheets, available at the Consortium website, on two important topics: use of medical marijuana for treatment of anxiety, and interactions of medical marijuana with prescription drugs. The purpose of these info sheet is to provide unbiased, evidence-based and up-to-date information for important topics on medical marijuana clinical outcomes.

The Consortium board and staff look forward to continuing this critical work in fiscal year 2020-2021 to ensure the Florida Medical Marijuana program meets its primary intent to improve the health of Florida citizens.

INTRODUCTION

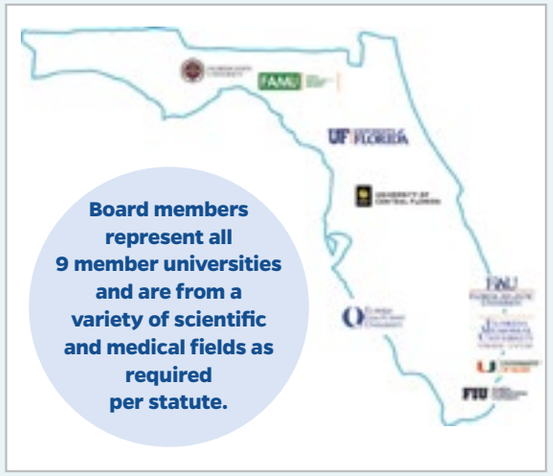
Beginning with the Compassionate Use Act passed in 2014 and followed by several amendments, Florida law allows the use of marijuana for the treatment of certain debilitating conditions. Persons seeking Medical Marijuana (MMJ) may suffer from serious health conditions and symptoms, many of which are not responsive to approved medications. While MMJ could potentially improve health outcomes, there are also significant safety concerns related to cognitive effects, risk for accidents, interactions with other medications, psychosis, and addiction. Moreover, MMJ varies significantly in terms of its specific components and mode of administration (including smoking and vaping), but little is known about how MMJ improves clinical outcomes and what components, doses and delivery methods provide the optimal risk-benefit profile. There is a substantial and urgent need to understand how MMJ impacts health and safety outcomes to guide both policy and clinical decision-making. But due to the complex federal and state legal restrictions for both MMJ use and MMJ research, the development of evidence on the safety and effectiveness of medical marijuana is lagging far behind the rapid uptake. As of January 2020, 302,891 persons were actively registered with the Florida Office for Medical Marijuana Use (OMMU), and over 79,000,000 mgs of medical marijuana (MMJ) and low-tetrahydrocannabinol (THC) cannabis were dispensed in just the first week of January.

To address the above need for rigorous evidence on the safety and effectiveness of medical marijuana for the various patient populations who are seeking licensure for use, the state legislature introduced Section 1004.4351, Florida Statutes, to establish the Consortium of Medical Marijuana Clinical Outcomes Research to conduct, disseminate and support rigorous scientific research and to disseminate such research. In July 2019, the Florida State University System Board of Governors, following a competitive request for proposals, designated the University of Florida as the lead university of the Consortium. Eight additional universities have joined the Consortium to-date, each with one designee to form the Medical Marijuana Research Board. The Board has appointed Dr. Almut G Winterstein, RPh, PHD, FISPE, Professor and Chair of Pharmaceutical Outcomes and Policy and Director of the Center for Drug Evaluation and Safety (CoDES) at the University of Florida as its director. Dr. Winterstein also serves as the principal investigator of the contract with the Board of Governors.

Pursuant to statute, which requires “a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives on research projects, research findings, community outreach initiatives, and future plans for the consortium,” the Consortium of Medical Marijuana Clinical Outcomes Research presents this Annual Report.

CONSORTIUM LEADERSHIP AND ADMINISTRATIVE STRUCTURE

The Consortium for Medical Marijuana Clinical Outcomes Research Board



The Consortium of Medical Marijuana Clinical Outcomes Research is open to all public and private universities in Florida. The Consortium is directed by the Medical Marijuana Research Board, which is composed of representatives from each participating university, including the Florida Agricultural and Mechanical University (FAMU), Florida Atlantic University (FAU), Florida Gulf Coast University (FGCU), Florida International University (FIU), Florida Memorial University (FMU). Florida State University (FSU), the University of Central Florida (UCF), the University of Florida (UF), and the University of Miami (UM).

Medical Marijuana Research Board – photo from the August board meeting from left to right: Dr. Robert Cook, UF, Consortium Associate Director; Dr. Dalton Dietrich, UM; Dr. Cynthia Hughes Harris, FAMU; Dr. Martha S. Rosenthal FGCU; Dr. Roger Fillingim, UF, Chair, Research Board; Dr. Daniel C. Flynn, FAU, Vice-Chair Research Board; Dr. Almut Winterstein, UF, Consortium Director; Dr. Timothy A. Gilberston, UCF

A new leadership team, establishment of the Consortium charter and adoption of the Consortium research program including a grants program to conduct medical marijuana clinical outcomes research highlighted the inaugural Consortium board meeting on Aug. 19th, 2019 in Gainesville. Roger Fillingim, Ph.D., a distinguished professor in the UF College of Dentistry and director for the Center for Pain Research and Intervention Center of Excellence, was elected board chair, while Daniel Flynn, Ph.D., vice president for research at Florida Atlantic University was elected vice chair. Profiles of all Board Members are included as part of Appendix A.

The charter defines the Consortium purpose as **"creating an effective medical marijuana clinical outcomes research program which would mobilize the scientific and medical resources that presently exist in the state to determine the appropriate and best use of marijuana to treat illness"**. Consortium responsibilities as defined in the charter and consistent with statute include:

- Conduct rigorous scientific research
- Disseminate research
- Guide policy for the adoption of a statewide policy on ordering and dosing practices for the medical use of marijuana.

BOARD MEETINGS

To expedite Consortium progress, the board has met four times between August 2019 and January 2020, including two face-to-face meetings on August 19, 2019 at the University of Florida campus in Gainesville and on January 17, 2020 on the University of Central Florida campus in Orlando. Key accomplishments and decisions at the board meetings are summarized in the following section and complete meeting minutes are available at the Consortium website at *https://mmjoutcomes.org/board-meetings/*.

AUGUST 19, 2019

- In the inaugural board meeting Senior Vice President for Health Affairs, University of Florida and President of UF Health Dr. Nelson welcomed Board Members and stated the commitment of UF to support and foster the Consortium's efforts in conducting and disseminating medical marijuana clinical outcomes research.
- David Lewis, Assistant Counsel, Office of the Vice President and General Counsel, University of Florida, presented an overview of Florida Sunshine and Public Records Laws
- The Board voted unanimously in favor of Dr. Roger Fillingim beginning his term as Chair and Dr. Daniel Flynn beginning his term as Vice Chair. Dr. Almut Winterstein was appointed as the Consortium Director and Dr. Robert Cook as the Associate Director.
- The board adopted Charter and Bylaws for the Consortium and approved the annual research plan and budget presented by Dr. Winterstein.

SEPTEMBER 13, 2019

- This web-based meeting was devoted to development of the Grants Program Funding Opportunity Announcement. The request for applications (RFA) was approved by the board for distribution.

NOVEMBER 25, 2019

- The board convened via another web-based meeting to finalize the selection of research proposals for funding. The consortium received 41 proposals, which were reviewed by ad-hoc out-of-state faculty reviewers with demonstrated expertise in the respective research area. Based on reviewer scores and further board deliberation considering the Consortium research mission, the Board awarded a total of $653,990 for 10 research proposals from 5 universities.
- The Consortium's new communications specialist and program coordinator were introduced to the board.

JANUARY 17, 2020

The board convened a meeting at the UCF Lake Nona campus to review the contents of the Consortium Annual Report and to review and vote on the 2021 Research Plan.

- Research Priority Recommendations were reviewed and endorsed for the upcoming grants program cycle to focus proposals on the most pressing knowledge gaps involving clinical and policy decision-making on the medical use of marijuana.
- The board agreed on several procedural changes in the grants program application process
- The draft of the Annual Report for the Consortium was presented, and all board members expressed appreciation of the accomplishments of the Consortium.
- The Research Plan for fiscal year (FY) 2021 was presented and all Board Members voted in its favor.
- Ideas for an annual Consortium conference were shared, with discussions to be continued at the next Board meeting

CONSORTIUM ADMINISTRATIVE STRUCTURE

Pursuant to statute, the board appointed Almut G. Winterstein, RPh, PhD, FISPE, Professor and Dr. Robert and Barbara Chair in Pharmaceutical Outcomes and Policy and Director of the Center for Drug Evaluations and Safety (CoDES) at UF as its director (*Figure 1*). Leveraging her 20-year experience in directing research on drug outcomes in real-world populations and her 6-year tenure as chair of the FDA Drug Safety and Risk Management Advisory Committee, Dr. Winterstein leads the development of MEMORY, the Consortium research data repository, administers the grants program, and has assumed responsibility for Consortium administration and support of the Board as defined by statute.

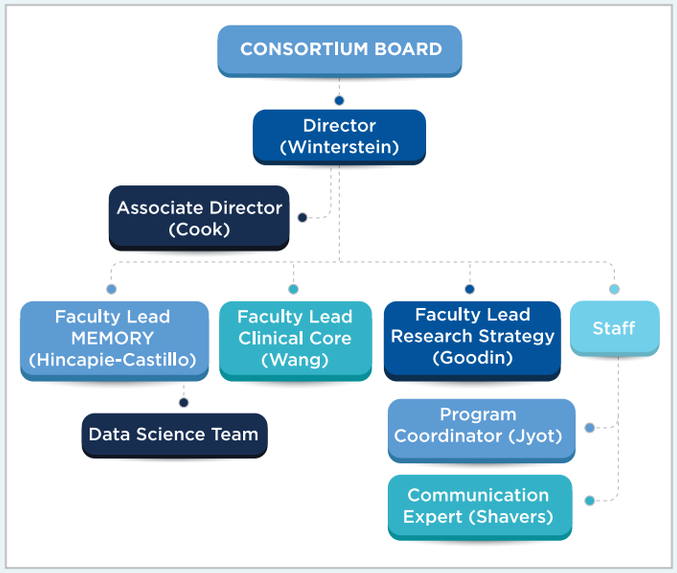


FIGURE 1. CONSORTIUM ADMINISTRATIVE STRUCTURE

She is supported by Dr. Robert Cook, MD, MPH, professor of Epidemiology and Internal Medicine and director of the Southern HIV and Alcohol Research Consortium (SHARC) Center for Translational HIV Research. Dr. Cook has assumed responsibility for developing the Clinical Research Core, leads the statewide MMJ Provider Partners Group, and oversees Consortium outreach activities. They are supported by a faculty lead for the data science team charged with the development of MEMORY, a faculty lead for development of the clinical research core and a faculty lead who directs development of the Consortium research strategy including maintenance of a national scientific expert group. Program staff include a program coordinator to support day-to-day operations, and a communication expert who leads outreach activities, in addition to a data science team. The Consortium staff is further supported by various administrative entities within UF. Profiles of all Consortium staff are available in Appendix B.

RESEARCH PROGRAM

Central to the Consortium is its mission to foster clinical outcomes research on MMJ across the state. Five pillars constitute the Consortium Research Program: a **Grants Program**, new and unique data repository known as the **ME**dical **M**arijuana Clinical **O**utcomes **R**epositor**Y** (**MEMORY)**, a **Clinical Research Core**, **Outreach** activities and a **Scientific Expert Group** (*Figure 2*). Consistent with its charter, the Consortium has engaged scientists and researchers with relevant research programs to participate in the Consortium and foster research collaborations to accelerate the development of evidence on MMJ clinical outcomes. Outreach has been realized through a comprehensive communication plan including a website and a newsletter, which is enhanced through exhibits at state-wide meetings and a MMJ provider survey. The Consortium has engaged and plans to maintain a **Scientific Expert Group** of researchers representing the breadths of research methodology and clinical and policy expertise relevant to MMJ research, charged with advising the research agenda to be established annually by the Consortium and to provide expertise to researchers. The Consortium director has assumed a variety of administrative functions.

The following sections provide a brief description of each of the Consortium functions and a detailed progress report. *It should be noted that this annual report is provided based on the first seven months of the Consortium's existence. Thus, several goals set forth for this current fiscal year are pending completion until the end of the Consortium's budget year in June 2020.*

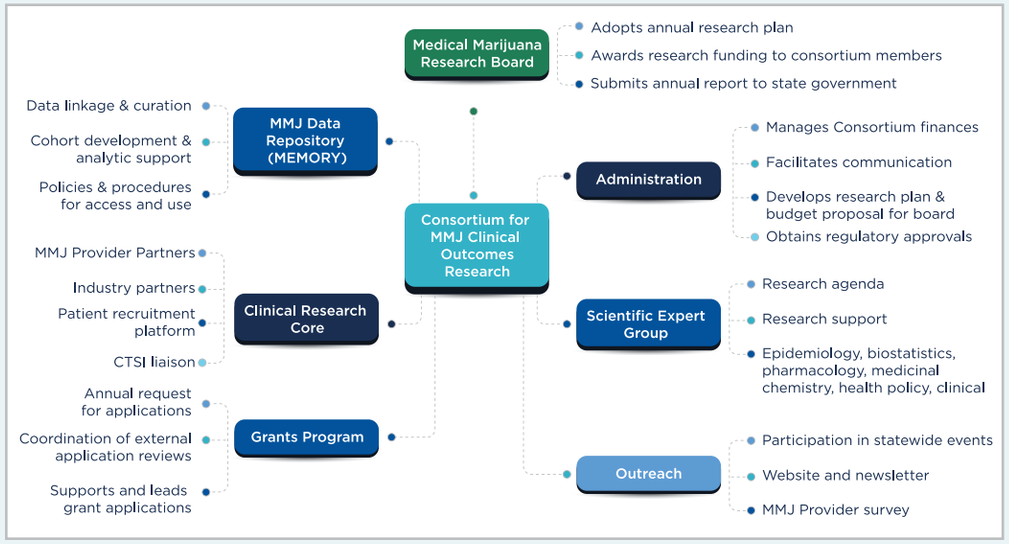


FIGURE 2. CONSORTIUM OF MEDICAL MARIJUANA CLINICAL OUTCOMES RESEARCH: ORGANIZATIONAL STRUCTURE 2020

The Medical Marijuana Research Board consists of one member from each participating university in the Consortium. The Consortium headquarters, based at UF, houses three cores (MEMORY, Clinical Research Core, and Grants Program), supported by an administrative team, a Scientific Expert Group, and Communications and Outreach support. This infrastructure will support research that is funded directly by the Consortium as well as other sources including NIH.

GRANTS PROGRAM

Each year, the Consortium intends to offer the Consortium MMJ Clinical Outcomes Research Grants Program, open to all members of the Consortium and teaching nursing homes. The research focus of the grants program is prioritized based on statutory guidance and the annual Consortium research agenda at the beginning of the fiscal year to ensure optimal fund utility. Applications are reviewed by external reviewers, recruited from out-of-state research units, using NIH review criteria. Final grant awards are made by the board based on study quality, impact and relevance to the Consortium research priorities. Calls for proposals are disseminated by each board member within their university systems and through the Consortium website and newsletter.

In September 2019, the Consortium released its first Request for Applications (RFA) for investigators at the different consortium member institutions (2019 RFA at https://mmjoutcomes.org/grants-program/). Because Consortium funding cannot be carried over across fiscal years, priority was given to rapid turn-around, resulting in recruitment of peer reviewers and completion of peer review activities within only one month. Awards were made early December, only three months after the Consortium board had approved its research program and budget.

The Consortium Grants Program received tremendous enthusiasm documented by 48 Letters of Intent (LOI) and by 41 proposals submitted by investigators from all nine participating universities. Submitted proposals were routed for review to 60 ad-hoc out-of-state faculty reviewers with demonstrated expertise in the respective research area (refer to Appendix C for a list of reviewers). Each application was reviewed by at least two subject matter experts. The Medical Marijuana Research Board made final selections of awardees based on scientific merit, innovation, 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. The following ten awards were made in the 2019 cycle of the Medical Marijuana Clinical Outcomes Research Grants Program.

Summary of 2019 Awarded Research Projects

The ten proposals selected for funding were received from five of the Consortium member institutions including, Florida Agricultural and Mechanical University (FAMU), Florida Atlantic University (FAU), Florida Gulf Coast University (FGCU), the University of Florida (UF), and the University of Miami (UM). Proposed research in these funded proposals included 4 clinical and 5 translational studies, as well as one product safety study with focus on heavy metals and microplastic contaminants in CBD oil. Disease conditions addressed in the clinical/translational proposals included brain and muscle injury, drug resistant cancers, chronic spinal cord injury pain, PTSD related sleep disturbances, chemotherapy-induced pain, as well as migraine-like pain, negative emotion and photophobia. These conditions reflect some of the current indications requiring additional research mentioned in the statutory requirements for the Consortium and the 2020-2021 research priorities adopted by the Consortium board.

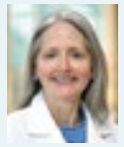
Grants Program - Year 1 Activities: planned and progress to-date	
GOALS	**ACHIEVEMENT TO-DATE**
Develop and disseminate RFP	Completed
Identify external (out-of-state) subject matter experts for external review	Completed
Organize board review and selection of awardees	Completed
Manage allocations (via subcontracts) including regulatory approvals and obtain progress reports	All contracts awarded and progress reports scheduled for May 2020

Summary Awarded Projects...continued

PI: PAUL BORSA, PH.D.
University of Florida
Research proposal titled **"Efficacy of a controlled short-term trial of CBD ingestion on reducing symptomatic response and facilitating recovery after induced muscle injury"**

PROJECT NARRATIVE: Many physically-active Americans have reported pain relieving effects of cannabidiol (CBD) that can reduce or eliminate use of nonsteroidal anti-inflammatory drugs (NSAIDs) for activity-related pain with minimal to no side effects. Long-term use of over the counter (OTC) medications, including NSAIDs, can pose a significant health risk, coupled with the rise in dependence on opioid medications has resulted in the deaths of tens of thousands of Americans annually. Currently its biological and therapeutic effects have not been explained, and clinical research in humans regarding its effectiveness is urgently needed.

ANTICIPATED IMPACT: There is a large consumer base for CBD products in the US that will be expanding exponentially in the next few years. If CBD is found to be effective for managing musculoskeletal pain and anxiety, the impact for clinical and policy decision-making could be far-reaching.



PI: HELEN BRAMLETT, PH.D.
University of Miami
Research proposal titled **"Therapeutic dosing of a cannabinoid (CBD) after mild and moderate brain injury for translation to the clinic"**

PROJECT NARRATIVE: The prevalence of Traumatic Brain Injury (TBI) and concussion is on the rise, but research and treatments are still very much in the early stages. Cannabinoids (CBD) have been shown to have not only an anti-inflammatory effect but also modulation of neuronal activity as well as an antioxidant. Our lab has developed a method to reliably administer oral CBD which will accelerate the research on this class of drug and drug products by dissolving CBD in peanut oil and assess efficacy for translation to the clinic.

ANTICIPATED IMPACT: Because CBD is an excellent candidate for therapeutic development based on preliminary data and lack of untoward psychoactive sequelae, this preclinical study will contribute to the generation of new knowledge on the use of medical marijuana and clinical practice for treating TBI and other neurological disorders.

PI: JOSHUA BROWN, PHARM.D., PH.D., M.S. **University of Florida**
Research proposal titled **"Characterizing community and physician-level factors associated with medical marijuana prescriber registration and patient access"**

PROJECT NARRATIVE: This project will assess the ecological and external factors that influence clinical outcomes for patients who access medical cannabis. Community-level factors, such as access to care and indicators of community health, as well as physician-level factors, such as high-risk prescribing practices, physician specialty and availability of cannabis-licensed physicians, are likely to vary geographically throughout Florida. We hypothesize that these county-level and physician-level factors vary among physicians authorized in Florida's medical marijuana program and are correlated with availability of physicians and dispensaries throughout communities in Florida.

ANTICIPATED IMPACT: This study will provide evidence on whether community and physician-level factors influence access to medical marijuana. We aim to understand what interventions may be needed to ensure that all state residents have access to medical cannabis and high-value care from licensed physicians.

PI: ANDREA CIPPITELLI, PH.D.
Florida Atlantic University
Research proposal titled **"Cannabidiol: A potential treatment for migraine-like pain, negative emotion and photophobia"**

PROJECT NARRATIVE: Migraine is extremely common, but the disease is poorly understood, leading to challenges in therapeutics development. Cannabidiol (CBD) holds beneficial effects in multiple neurological diseases, and its use is favorable due to its active, but not addictive nature. The mechanism of action of CBD within the cell alludes that it may be beneficial for managing migraine based on our understanding of the disease, and by modeling this in our lab it could provide a valuable treatment alternative for patients with migraine seeking relief.

ANTICIPATED IMPACT: By testing verified CBD from a reputable source in a controlled lab setting and modeling migraine pathology, a debilitating disease lacking successful treatment options, we will be able to evaluate CBD's role in relieving symptoms caused by migraine.

PI: GREGORY McMANUS, PH.D.
Florida Gulf Coast University
Research proposal titled **"Rapid identification and quantification of heavy metals and microplastics in CBD oil."**

PROJECT NARRATIVE: Cannabis has shown great promise for the treatment of many medical conditions. There are, however, substantial uncertainties surrounding the nature and content of contaminants in cannabis plants. This project aims to develop reliable, rapid, efficient, inexpensive techniques for the determination of key contaminants within the cannabis plant and to accelerate research in this promising industry to ensure consumer/patient safety.

ANTICIPATED IMPACT: This project intends to provide a better understanding of the contaminants present in medicinal products derived from the cannabis plant. Ensuring that these medicinal products are free of toxins is essential for public health.

PI: MANDIP SINGH SACHDEVA, PH.D. **Florida Agricultural & Mechanical University.**
Research proposal titled **"Hyaluronic acid functionalized, Cannabidiol-loaded Mesenchymal Stem Cells (MSC)-Derived Exosomes for Drug Resistant Cancers"**

PROJECT NARRATIVE: The objective of this proposal is to formulate hyaluronic acid (HA) functionalized

mesenchymal cells (MSC) derived exosomes which will serve as an ideal delivery platform not only for increasing the bioavailability and anticancer effects of Cannabidiol (CBD) but also for overcoming resistance of docetaxel (DTX) in MDA-MB-231 (i.e., CB1, CB2, and CD44 receptors expressing) triple negative breast cancer cells.

ANTICIPATED IMPACT: This project will allow us to develop a formulation of exosomes containing CBD which will have possible superior pharmacodynamic effects. Further, the stabilized formulation of HA coated CBD exosomes will then be evaluated in 3D culture systems to suggest their translational potential for future in vivo studies.

PI: JACQUELINE SAGEN, PH.D., M.B.A. **University of Miami**
Research proposal titled **"Evaluation of medical marijuana for the treatment of chronic spinal cord injury pain using a rat central neuropathic pain model"**

PROJECT NARRATIVE: Although the most frequently reported use of medical marijuana is for pain relief, there have thus far been a paucity of preclinical studies evaluating the effects of Cannabis components in chronic pain models, in particular for debilitating neuropathic pain resulting from injury to the nervous system such as spinal cord injury (SCI). Thus, the goal of this study is to rigorously evaluate the effects of the two major but mechanistically distinct Cannabis components, CBD and THC and their combination, on alleviating chronic pain following spinal cord injury using a preclinical rodent model. Analgesic dose-ranging, side effects, and effects on reducing opioid use will be tested to provide the foundation for further development of medical marijuana in the treatment of chronic neuropathic pain.

ANTICIPATED IMPACT: There is a compelling need for improved treatment options for chronic pain patients through the identification of new and potent therapeutics. Despite promising anecdotal reports, solid preclinical evidence supporting the use of cannabis-derived compounds for management of chronic pain following spinal cord injury is lacking, and progress in the field has been hampered by legal restrictions. The study will address this knowledge gap to provide the necessary preclinical evidence for guiding policy decision-making on the medical use of marijuana for the clinical management of chronic pain.

PI: KRISHNA VADDIPARTI, PH.D., M.P.E., M.S.W. **University of Florida**
Research proposal titled **"A feasibility study of real-time monitoring of Posttraumatic Stress Disorder related sleep disturbances and other symptoms among patients on medical marijuana"**

PROJECT NARRATIVE: Posttraumatic Stress Disorder (PTSD) is a debilitating disorder experienced by a subgroup of individuals following a life-threatening trauma, such as sexual and physical assault, natural disasters, and military combat. In the US several states have passed laws permitting the medical use of marijuana by individuals with PTSD but, at this point we lack evidence on the appropriateness of marijuana as a therapy for PTSD. The goal of this pilot grant is to recruit and retain patients with PTSD on medical marijuana in a prospective study and examine in real-time how medical marijuana affects PTSD related sleep disturbances and recovery from PTSD symptoms and distress.

ANTICIPATED IMPACT: This pilot study will generate necessary evidence about the feasibility of conducting a prospective, real-time assessment of sleep problems, PTSD symptoms and mood among persons on medical marijuana for their PTSD symptoms. Such feasibility data is crucial at this juncture to inform large studies to investigate the long-term clinical impact of treating PTSD symptoms with medical marijuana.

PI: JENNY L. WILKERSON, PH.D.
University of Florida
Research proposal titled **"Marijuana-derived terpenes for the treatment of chemotherapy-induced pain"**

PROJECT NARRATIVE: Paclitaxel, commonly used to treat breast and lung cancers, produces persistent and debilitating side effects such as chemotherapy induced peripheral neuropathy (CIPN) and impairments in mood. Marijuana contains a multitude of non-psychoactive compounds (i.e., terpenes, minor cannabinoids) which may hold therapeutic promise in the treatment of pathological pain. This research will examine if a subset of terpenes found in marijuana: γ-terpinene, α-terpineol, β-caryophyllene, and minor cannabinoids: cannabichromene (CBC) and cannabinol (CBN), reduce CIPN in an experimental mouse model.

ANTICIPATED IMPACT: This research will provide a foundation for understanding the pharmacology and mechanisms of minor cannabinoids/ terpenes as a function of their effects in a model of neuropathic pain. This research will produce timely data that will help inform public policy regarding the potential of the components of marijuana to produce analgesia, with a major anticipated relevance to neuropathic pain. Additionally, of clinical impact, this research may lead to the development of new therapeutics to treat neuropathic pain that lack abuse potential.

PI: ALI M. YURASEK, PH.D.
University of Florida
Research proposal titled **"The Relationship between State Medical Marijuana Laws, Substance Use and Mental Health Disorder Diagnoses, and Associated Health Care Costs"**

PROJECT NARRATIVE: The influence of medical marijuana laws on changes in substance use or mental health diagnoses or treatment related health costs remains unclear. To date, no studies have examined substance use and mental health diagnoses and treatment utilization trends in states with and without medical marijuana laws. This project will examine these relationships using novel measurement and analytical techniques.

ANTICIPATED IMPACT: Completion of this project will provide policy-related information about the influence of medical marijuana laws on health care utilization for substance use and mental health diagnoses. Findings will inform both health care policy and state-specific medical marijuana policy and implementation

MMJ CLINICAL OUTCOMES RESEARCH DATA REPOSITORY (MEMORY)

Unlike medications that have undergone rigorous testing, only a small number of controlled studies are available for MMJ. In addition to a rigorous approval process, the Food and Drug Administration (FDA) can require the drug manufacturer to conduct additional studies after drug approval to address safety concerns. Such studies use oftentimes controlled observational designs, where experiences of real-world populations are evaluated. MEMORY will establish the infrastructure for real-world MMJ clinical outcomes evaluations similar to those employed by the FDA. Specifically, the Consortium aims to link the Office of Medical Marijuana Use (OMMU) MMJ dispensing data with other clinical databases commonly used for outcomes research to create a robust research-ready repository. The planned linkages will optimize detail on MMJ use (type, dose, route, originating plant from the OMMU registry) and detail on patient health history, other treatments and outcomes (from linked clinical encounter data), and facilitate controlled longitudinal studies on safety and effectiveness outcomes. Data will be stored in a secure computing environment that has been approved for storage of sensitive information. Pending relevant approvals, the Consortium plans to make a de-identified version of the repository available to Consortium researchers, thus providing state-wide infrastructure for real-world clinical outcomes research.

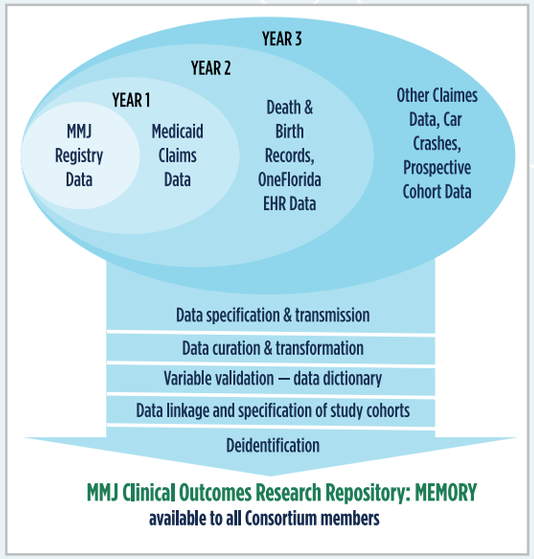


FIGURE 3. MEMORY DEVELOPMENT PROCESS

Core tasks to develop MEMORY include:

a) data acquisition, curation and linkage, resulting in a well-documented longitudinal database of patients who initiated MMJ and adequate control groups who have not (yet) initiated MMJ,
b) provision of adequate study cohort data for researchers along with analytical support, and
c) the development and implementation of policies and procedures to access and use the data.

Development of MEMORY will follow sequential steps over several years, resulting in a consistently expanding wealth of clinical outcomes research data made available to Consortium researchers (*Figure 3. MEMORY development process*). Pending successful data linkage, the Consortium will provide descriptive analyses of the data that characterize socio-demographic and clinical conditions (indications, comorbidities and co-medications) of MMJ users throughout the growth of the Florida Medical Marijuana Program to understand utilization pattern and prioritize research needs.

Due to differences in the interpretation of the statutory requirements for DoH to share OMMU registry data with the Consortium, no data has been received to-date. The legal departments of the Department of Health (DoH) and the University of Florida (UF) are now attempting to resolve the differences between interpretations of the statutory requirements for DoH to share OMMU registry data with the Consortium.

MMJ Data Repository (MEMORY) — Year 1 Activities: planned and progress to-date	
GOALS	**ACHIEVEMENTS TO-DATE**
Establish process and procedures for data flow, relevant institutional approvals and data user agreements, and security standards	IRB approval obtained; processes and procedures proposal completed; DUA with DoH/OMMU pending; data transfer from OMMU pending
Convert OMMU data into research-ready format	
Link OMMU data to Medicaid clinical encounter and pharmacy claims data	
Communicate information about MEMORY via the Consortium website and other means	
Pending successful data linkage, provide descriptive analyses of the data that characterize socio-demographic and clinical conditions throughout the growth of the MMJ program to understand utilization pattern and prioritize research needs	

CLINICAL RESEARCH CORE

To complement MEMORY, which facilitates *retrospective* studies of routinely collected data, thus maximizing sample size and the ability to examine long-term outcomes or rare safety events, the clinical research core is designed to provide infrastructure support for *prospective* studies (including randomized controlled trials) involving collection of new data such as patient-reported outcomes. To facilitate patient recruitment, the Consortium has begun to assemble a group of **MMJ Provider Partners**. Provider partners are physicians throughout the state who are willing to recruit patients for specific research studies or help to inform the Board about the most pressing clinical outcomes research needs. MMJ Provider Partners will contribute to a robust **patient recruitment platform** established by the Consortium and to be initiated on the Consortium website in spring 2020.

The clinical research core has begun to connect researchers to the broad range of services and support infrastructure made available by the **Clinical and Translational Science Institutes** (CTSIs) at UF, the University of Miami and Florida State University. Depending on study needs, such support can include assistance with recruitment, data collection or analysis or storage of specimen (biorepositories), or access to laboratory experts who can analyze MMJ products. For example, one Consortium grants awardee has been connected to CTSI services to facilitate FDA IND application for research on cannabidiol. All three CTSIs have pledged their support for the Consortium.

The clinical research core will also help to connect potential **industry and business partner**s to researchers. Initial meetings with industry partners have commenced and discussed data sharing and other agreements to facilitate collaborations for Consortium researchers.

Clinical Research Core - Year 1 Activities: planned and progress to-date	
GOALS	**ACHIEVEMENTS TO-DATE**
Conduct provider survey on research needs	Pilot with convenience sample at AMMPA conference completed
Establish directory of research partners (providers, patients, industry)	In progress
Create patient recruitment platform and procedures	In progress
Facilitate access to clinical research services for pilot studies	In progress

OUTREACH

The Consortium's outreach activities are directed to patients, providers, researchers and industry to maximize participation in research. In March 2020, the Consortium will launch its **MMJ Provider Survey** to gather providers' need for answers to support treatment decisions such as specific considerations for dose or route in light of certain patient comorbidities or comedications or concerns about safety issues among patients with certain risk factors. The survey has been pilot-tested at the Annual Medical Marijuana Provider (AMMPA) Meeting in Orlando, FL, in October 2019 and will be disseminated to all registered medical marijuana providers in Florida.

To promote the consortium and reach out to providers, patients and researchers, the Consortium has staffed an **exhibit table at the annual AMMPA meeting**. The purpose of participating in professional meetings and exhibits is to promote the Consortium to providers and researchers in the field and to strengthen research collaborations within the state of Florida and nationwide. Finally, outreach is realized through a comprehensive **Communication Plan** that includes an active website and quarterly newsletters distributed via email. An effective communication plan will facilitate new research collaborations, highlight new research findings and ensure that such findings reach local MMJ providers and patients, increase participation in the Consortium research program and provide links to other state MMJ resources.

Outreach — Year 1 Activities: planned and progress to-date	
GOALS	**ACHIEVEMENTS TO-DATE**
Launch quarterly newsletter	First issue distributed in December
Launch website	Completed
Participate in one statewide event to promote the consortium	Consortium exhibit at AMMPA conference
Conduct medical marijuana provider survey to gather input on research priorities and develop provider network	Pilot survey completed; state-wide survey to >2000 providers to be disseminated in March 2020

AMMPA Conference

Members of the Consortium for Medical Marijuana Clinical Outcomes Research Team attended and hosted an exhibit at the American Medical Marijuana Physicians Association (AMMPA) Annual Conference in Orlando, FL from October 4 through October 6, 2019. The Consortium networked with physicians, medical marijuana dispensary workers, scientists, and others knowledgeable in medical marijuana. During the conference, the Consortium also distributed and collected important information from providers related to medical marijuana use and research.

Results from 46 providers and other individuals interested in medical marijuana provided feedback around common practices and prescribing for medical marijuana (*Figure 4. Pilot survey respondents' MMJ research priorities*).

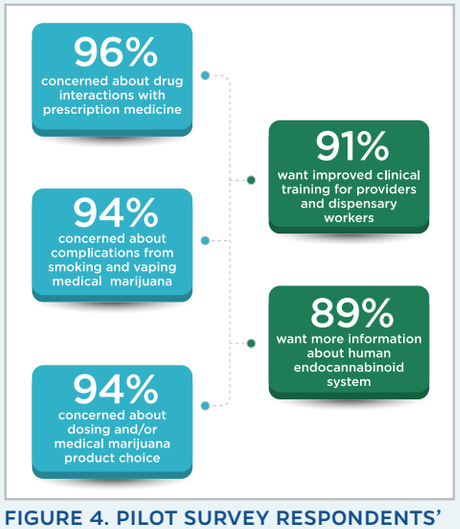


FIGURE 4. PILOT SURVEY RESPONDENTS' MMJ RESEARCH PRIORITIES

Of the 46 responses, 26 identified themselves as cannabis certified physicians in the state of Florida. The other 20 respondents include current dispensary employees, patients, and researchers. Primary concerns expressed in this pilot survey surround the use of MMJ, including dosing, product choice, interactions with other medications and desire for more clinical training regarding risk-benefit of MMJ for individual conditions.

Website

In 2019, the Consortium launched a website presence (*https://mmjoutcomes.org/*) to disseminate information to researchers, member institutions, physicians/providers, patients, and the public. The website provides a comprehensive and interactive hub for the grants program, research updates, and Consortium news. Since its launch in October, more than 500 web-users have visited the new website.

For the grants program and research, the website allows easy access for viewing currently funded research projects and for learning about future Consortium grant cycles including templates for the letter of intent (LOI) and the request for proposals (RFP). The Consortium created an online form for investigators at member institutions to submit LOIs directly on the website for the next Grants Program cycle.

The website will also serve as a central location to support collaboration between physicians/providers, researchers, and patients through various channels including a secure portal for patients to sign up for participation in research and a collaborative space for researchers to network with other researchers and practicing physicians/providers.

Newsletter

As part of the communication and outreach plan, the Consortium distributes quarterly newsletters via email to researchers, physicians/providers, people interested in medical marijuana, and more.

Content intended for the newsletter includes updates on Consortium activities and ongoing research. For recognition, the Consortium branded the newsletter as MEDICAMENT, which stands for **MEDICA**l **M**arijuana r**E**search **N**ewsle**T**ter. The distribution months for the quarterly newsletter will be March, June, September, and December. A total of 196 individuals have signed up for the newsletter as of January 2020.

In December 2019, the Consortium distributed the first issue of MEDICAMENT, which is available here at https://mmjoutcomes.org/newsletter/

EXPERT GROUP AND RESEARCH PRIORITIES DEVELOPMENT

MMJ research needs to span a broad range of clinical indications and requires a variety of methodological approaches. To ensure relevant expertise is available to inform the MMJ research agenda, the Consortium has established a nationwide expert group (table below — for bios see Appendix D), representing the full breadth of rapidly expanding clinical treatment scenarios and the evolving evidence on MMJ outcomes (desirable and undesirable). Experts in pharmacology and medicinal chemistry are included to inform clinical studies, as well as faculty in law and policy to help with interpreting legal issues and suggest changes and evaluations of policy. Expert group members, recruited nationally and from all Consortium universities, are expected to contribute to the development of the Consortium research agenda, provide scientific advice to the board and collaborate with Consortium members.

SCIENTIFIC EXPERT PANEL MEMBERS		
PARTICIPANT	**INSTITUTION**	**CANNABIS-RELATED EXPERTISE**
Jeffrey Cassisi	University of Central Florida*	Cognition and Pain
John Markowitz	University of Florida*	Drug-Drug Interactions (Kinetics)
Ellen Zimmermann	University of Florida*	Gastroenterology
Youn Ok Lee‡	Research Triangle Institute	Vaping, Smoking, other administration routes
Aimee McRae-Clark	Medical University of South Carolina	Cannabis Use Disorder
Tory Spindle‡	Johns Hopkins	Routes of Administration
Denise Vidot	University of Miami*	HIV/AIDS, Use Patterns
Kathleen Egan	Moffitt Cancer Center	Cancer
Sean Hennessey‡	University of Pennsylvania	Drug-Drug Interactions (Epidemiology)
Jodi Gilman	Mass General/Harvard Medical	Cognition and Addiction
Linda Simoni-Wastila	University of Maryland	Marijuana Use Patterns, Policy
Patricia Green-Powell	Florida A&M University*	Use Patterns, Stakeholder Engagement
Maija Reblin	Moffit Cancer Center	Palliative Care

‡ has provided invited FDA or congressional expert testimonial;
* Consortium member institution

The scientific expert panel has met over the past couple of months to advise on the 2021 Consortium research priorities. The expert group's work was supported by a broad literature mapping review aimed at highlighting evidence gaps in our understanding of the clinical outcomes of medical use of marijuana. Following is a summary of the evidence review and the expert group recommendations to lay the foundation for the Consortium research agenda outlined in the following section.

SCIENTIFIC EXPERT PANEL GOALS	
GOALS	**ACHIEVEMENTS TO DATE**
Assemble expert group charged with development of research agenda for year 2	Completed
Provide experts as needed to researchers who approach the consortium with request for advice in development of research proposals	In progress

Evidence Review Report

The objective of the evidence review was to quantify and evaluate the most recent scientific and clinical evidence related to the effects of medical marijuana by mapping this literature across topic area domains. The organizing framework for topic area selection was informed by a combination of expert input, Florida statute, and foundational works (*Figure 5. Topic areas for evidence report*). The key foundational work that guided the evidence review was the National Academies of Science, Engineering, and Medicine (NASEM)'s 2017 report "The Health Effects of Cannabis," which comprehensively evaluated the body of scientific knowledge of the effects of marijuana on several medical conditions through 2016.

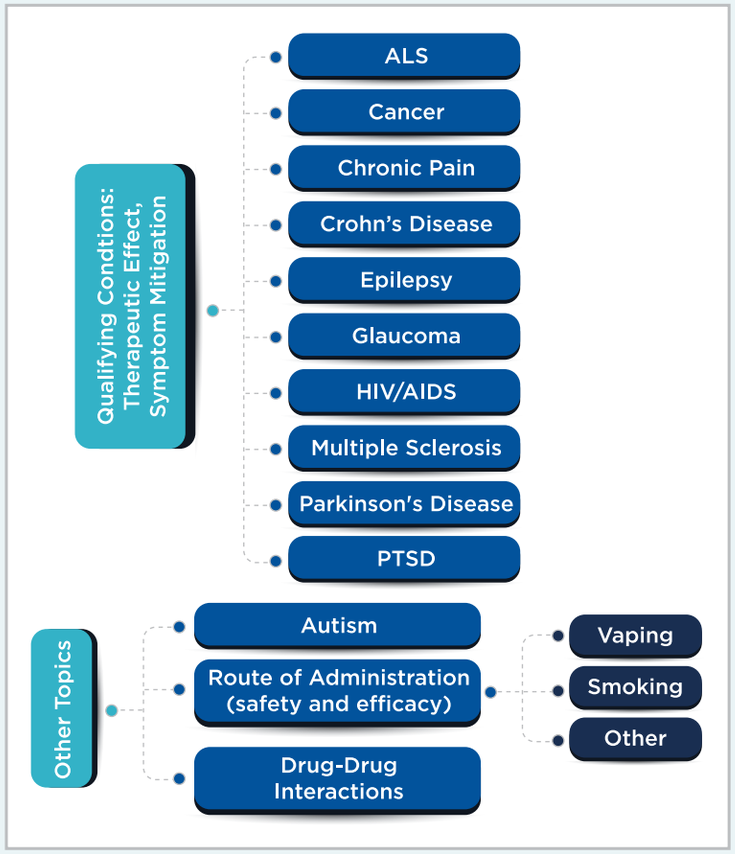


FIGURE 5. TOPIC AREAS FOR EVIDENCE REPORT

Search strategies for evidence regarding medical marijuana and each individual medical condition were developed in collaboration with the University of Florida Health Sciences Center Library using strings from the NASEM report and based on specialist contributions, where the search was restricted to studies published from July 2016 through October 2019. For topics not previously covered by NASEM, rapid review strategies were employed with date restrictions for studies published from 2000 through October 2019. The evidence review team identified and screened a total of 11,855 studies, then evaluated each study meeting inclusion criteria to summarize findings. Study findings from each topic area were quantified and compiled to produce summary statements of the latest available evidence. The full report will be published and available for public access.

While the number of studies on marijuana effects has increased, our literature review confirmed the 2016 NASEM report's conclusions that evidence for the effectiveness of marijuana for the vast number of targeted indications is lacking (see Table below and brief summaries for each topic area thereafter). In addition, information on marijuana safety is largely derived from study for recreational use and provides limited insight into its medical use by patients with serious health conditions and in need for other prescription medications, both with the potential to alter MMJ effectiveness and safety. Evidence on the clinical relevance of interactions with patient conditions and prescription drugs is missing, as is detail on differences in such effects for certain MMJ components, doses and administration routes.

Summary of Evidence Review Findings from Clinical Studies, 2016 through 2019

TOPIC	STUDIES	SUMMARY OF FINDINGS
ALS	9	There is **insufficient evidence** to support or refute the conclusion that cannabis is an effective treatment for ALS, but there is some evidence that orally administered THC and CBD may alleviate certain ALS-related symptoms.
Cancer	140	There is **insufficient evidence** to support or refute the conclusion that cannabis or cannabis-derived substances are an effective treatment for cancers, but there is substantial evidence that cannabis is an effective treatment for cancer pain and chemotherapy-induced nausea (oral formulations).
Chronic Pain	129	There is **substantial evidence** for "small" to "moderate" efficacy for the treatment of chronic pain and limited safety concerns, but there is limited evidence for dosing and/or considerations for route of administration.
Crohn's Disease	25	There is **insufficient evidence** to support or refute that marijuana or CBD are effective treatment options for Crohn's Disease.
Epilepsy	81	There is **substantial evidence** to support that cannabis is an effective treatment option for Epilepsy.
Glaucoma	14	There is **insufficient evidence** to support or refute that marijuana is an effective treatment option for Glaucoma.
HIV/AIDS	25	There is **insufficient evidence** to support or refute that marijuana is an effective treatment option for HIV/AIDS, but there is limited evidence to support that marijuana is an effective treatment for alleviation of pain among HIV/AIDS patients.
Multiple Sclerosis	27	There is **moderate evidence** to support that cannabinoids are effective and safe treatment for spasticity related to Multiple Sclerosis, but there is insufficient evidence to support or refute that marijuana is an effective treatment option for other symptoms of Multiple Sclerosis.
Parkinson's Disease	17	There is **insufficient evidence** to support or refute that cannabinoids are effective treatment for Parkinson's Disease.
PTSD	52	There is **insufficient evidence** to support or refute that cannabis is an effective treatment for PTSD; there is limited evidence that cannabis is an effective treatment for short-term alleviation of PTSD-related anxiety symptoms.
Autism	17	There is **insufficient evidence** to support or refute that cannabis or CBD are effective treatments for Autism symptoms.
Marijuana-Medication Interactions	62	There is **substantial evidence** to support that cannabinoids interact with medications and other substances, but there is **insufficient evidence** to definitely conclude which doses and formulations of each cannabinoid contribute to adverse events resulting from these interactions.
Route of Administration (smoking, vaping)	7,072	There is **insufficient evidence** to comprehensively assess safety, efficacy, and dosing for different routes of administration of cannabis, including smoking and vaping.

AMYOTROPHIC LATERAL SCLEROSIS (ALS). A total of 9 studies were evaluated in the ALS topic, including those that examined symptom relief for ALS-related spasticity, cramps, and changes in physical functioning following ALS diagnosis, in addition to a safety assessment for THC for ALS patients. Since 2016, 2 high quality systematic reviews were identified along with no randomized controlled trials (RCTs) and 1 controlled observational study. Orally ingested forms of THC as well as CBD were found to be well-tolerated in ALS patients with few safety concerns across all examined studies, but evidence was lacking for the therapeutic effect of marijuana for the treatment of ALS spasticity and cramps, though there were some improvements noted for other symptoms (e.g., pain, appetite).
CONCLUSION: There is insufficient evidence to support or refute the conclusion that cannabis is an effective treatment for ALS, but there is some evidence that orally administered THC and CBD may alleviate certain ALS-related symptoms.

CANCER. A total of 140 studies were evaluated for Cancer, including studies that examined the treatment effect on cancers and that examined cancer symptom and/or cancer treatment symptom relief. Since 2016, 2 RCTs were identified along with 18 high quality systematic reviews. Of the high-quality systematic reviews, 8 had accompanying meta-analyses. Both RCTs assessed the effect of cannabis-derived oral mucosal sprays on cancer-related pain as compared with placebo, and both reported improvement in pain symptoms. Additionally, 3 RCT protocols were identified but these trials are ongoing. Among meta-analyses that assessed therapeutic effects for cancer symptom alleviation, results were mixed and 1 meta-analysis reported a significant elevation in adverse events in included studies (hospitalizations). Among meta-analyses that assessed the risk in development of specific types of cancers as a result of marijuana use (i.e., head and neck, breast, lung, and prostate), results were inconclusive. Of systematic reviews that assessed symptom change for nausea and appetite, the majority reported improvement in these cancer treatment-related symptoms.
CONCLUSION: There is insufficient evidence to support or refute the conclusion that cannabis or cannabis-derived substances are an effective treatment for cancers, but there is substantial evidence that cannabis is an effective treatment for cancer pain and chemotherapy-induced nausea (oral formulations).

CHRONIC PAIN. A total of 129 studies were evaluated for Chronic, non-Cancer Pain. Four RCT protocols were published between 2016 and 2019, but none have published findings to date. The majority of literature published since 2016 in this topic are reviews, with 17 high quality systematic reviews and 8 of these with accompanying meta-analysis. Among the 6 meta-analyses that specifically assessed chronic, non-cancer pain following use and/or medically supervised treatment with marijuana or marijuana-derived substances as compared to either placebo or pain relief medication, 4 reported significant improvement and 2 were inconclusive. The other meta-analyses examined adverse events and health-related quality of life, where 1 reported an increased risk for anxiety and depression and the other was inconclusive as to the effect on quality of life.
CONCLUSION: There is substantial evidence for "small" to "moderate" efficacy for the treatment of chronic pain and limited safety concerns, but there is limited evidence for dosing and/or considerations for route of administration.

CROHN'S DISEASE. A total of 25 studies were evaluated for Crohn's Disease, including Inflammatory Bowel Disease (IBD). No RCTs were identified, 3 high quality systematic reviews and 4 observational studies were identified, and the remainder of studies in this topic area were structured as "other" types of reviews (i.e., clinical and narrative). From systematic reviews, findings were inconclusive as to the overall treatment effect of cannabis or CBD for the maintenance or remission of Crohn's Disease. In observational studies, 3 of 4 reported positive improvement in clinical outcomes (i.e., hospitalizations, presence of complications), while 2 of 4 reported no change in clinical outcome, where some studies assessed more than one outcome.
CONCLUSION: There is insufficient evidence to support or refute that marijuana or CBD are effective treatment options for Crohn's Disease.

EPILEPSY. A total of 81 studies were evaluated for Epilepsy and seizure disorders. Of these, 30 RCTs were identified and 19 high quality systematic reviews were identified, with 5 of 19 including meta-analysis. Among the RCTs, the majority reported improvements in clinical outcomes assessed (e.g., a reduction in the frequency and severity of seizures) and few adverse events were reported in safety studies. RCTs were conducted among both pediatric and adult epilepsy patients, with cannabidiol administered as adjuvant therapy as well as cannabis-derived medications (e.g., Epidiolex) assessed by multiple placebo-controlled RCTs.
CONCLUSION: There is substantial evidence to support that cannabis is an effective treatment option for certain types of epilepsy.

GLAUCOMA. A total of 14 studies were evaluated for Glaucoma. Of these, 4 were high quality systematic reviews and no RCTs were identified. Among the reviews, 1 concluded that marijuana was not an effective treatment option for ocular hypertension and ocular pressure and 2 reviews were inconclusive. One review concluded that marijuana was effective for the treatment of glaucoma-related pain, but reported adverse events among reviewed studies. Other studies evaluated for glaucoma consisted of other types of literature reviews (e.g., clinical, narrative) and the majority presented insufficient evidence to support or refute the potential for marijuana treatment for glaucoma.
CONCLUSION: There is insufficient evidence to support or refute that marijuana is an effective treatment option for Glaucoma.

HIV/AIDS. A total of 25 studies were evaluated for HIV/AIDS. Of these, no RCTs were identified and 3 high quality systematic reviews, all with accompanying meta-analysis, were identified. One of these reviews reported that smoked cannabis was an effective treatment option for HIV/AIDS-related pain. Another review with accompanying meta-analysis reported that improvements in health-related quality of life was observed across several studies, and the third review reported that heavy marijuana use among adolescents

and/or adults was associated with increased likelihood for HIV diagnosis. Observational studies in this topic primarily assessed marijuana use behaviors and prevalence among HIV/AIDS patients rather than treatment efficacy, though 2 survey studies report perceived improvement in HIV-related symptoms by patients.
CONCLUSION: There is insufficient evidence to support or refute that marijuana is an effective treatment option for HIV/AIDS, but there is limited evidence to support that marijuana is an effective treatment for alleviation of pain among HIV/AIDS patients.

MULTIPLE SCLEROSIS. A total of 27 studies were evaluated for Multiple Sclerosis. No RCTs were identified. A total of 10 high quality systematic reviews were identified, where 5 of 10 also conducted meta-analysis. The remainder of studies in this topic area were structured as "other" types of reviews. Among meta-analyses, 3 of 5 reported improvement of Multiple Sclerosis symptoms, including spasticity and spasm frequency and severity following treatment with marijuana-derived products (cannabinoids) and as compared to treatment with placebo. No change in symptoms was reported in the other 2 of 5 meta-analyses. Quality of Life was assessed by 1 of 5 meta-analysis, with no improvement reported.
CONCLUSION: There is moderate evidence to support that cannabinoids are effective and safe treatment for spasticity related to Multiple Sclerosis, but there is insufficient evidence to support or refute that marijuana is an effective treatment option for other symptoms of Multiple Sclerosis.

PARKINSON'S DISEASE. A total of 17 studies were evaluated for Parkinson's Disease. One RCT protocol was identified but study findings are not yet published. One high quality systematic literature review was identified and reported inconclusive evidence on both the treatment efficacy of cannabis for disease progression and for alleviation of symptoms. Four observational studies were identified and 3 of these 4 evaluated physician and patient perceptions of effectiveness of cannabis on symptom relief, with inconsistent findings across these studies. An additional observational study assessing adverse events in Parkinson's patients demonstrated that safety and tolerability of cannabidiol was moderate; no patients experienced serious adverse events, but events related to changes in weight, vomiting, dizziness, gastrointestinal problems, and allergic reactions were common.
CONCLUSION: There is insufficient evidence to support or refute that cannabinoids are effective treatment for Parkinson's Disease.

POST-TRAUMATIC STRESS DISORDER (PTSD). A total of 52 studies were evaluated for PTSD, and PTSD-related anxiety. Of these, 5 RCTs protocols were identified but study findings are not yet published. Eight high quality systematic reviews were identified, with mixed conclusions. Among the 6 of 8 reviews that examined clinical outcomes for anxiety, 4 reported improvements in anxiety symptoms, 3 reported no change in anxiety symptoms, and 1 reported an overall worsening of anxiety symptoms in PTSD patients. Two reviews

examined safety issues following initiation or use of cannabis in PTSD patients and both reported an increase risk for adverse events related to onset and frequency of psychosis in this population.
CONCLUSION: There is insufficient evidence to support or refute that cannabis is an effective treatment for PTSD; there is limited evidence that cannabis is an effective treatment for short-term alleviation of PTSD-related anxiety symptoms.

AUTISM. A total of 17 studies were evaluated for Autism. No RCTs were identified. One high quality systematic review with accompanying meta-analysis was identified and this assessed genetic variants associated with lifetime cannabis use among patients with autism, where a significant correlation was reported between phenotype indicative of autism (a single nucleotide polymorphism) and lifetime cannabis use. Among the 8 observational studies identified, 4 assessed the effect of CBD on autism symptoms and behaviors and 3 of these reported improvements in symptoms related to sleep problems and anxiety while others were inconclusive.
CONCLUSION: There is insufficient evidence to support or refute that cannabis or CBD are effective treatments for Autism symptoms.

MARIJUANA AND MEDICATION INTERACTIONS. The rapid review procedure for this topic resulted in the identification of 1,861 studies from literature search. A total of 62 studies remained after screening and each

Evidence Review Report...continued

of these were evaluated. Among these preclinical and clinical studies, significant evidence was identified regarding both clinically observed and biologically plausible interactions between compounds contained in marijuana and several types of medications or other substances such as alcohol. Specifically, 10 studies were identified that documented interactions, including 1 literature review, 5 experimental studies, 1 case-control study and 3 cross-sectional studies, which provided evidence of interactions between cannabis/CBD/synthetic cannabinoids and alcohol, antiepileptic drugs, HIV antivirals, azole antifungal agents, risperidone, acetaminophen and other CYP-metabolized drugs, which could potentially result in significant changes of drug serum levels and increased adverse events.

Additionally, the 52 remaining studies documented evidence of adverse events associated with interactions. Of these, 14 provided evidence that the use of cannabis could result in increased cardiovascular risk (e.g., myocardial infarction), 8 provided evidence of increased risk for lowered age of psychosis onset, 4 provided evidence of adverse events related to obstetrical outcomes and/or fertility, 2 provided evidence for other mental health adverse events, and 2 reported increased risk of organ dysfunction.

CONCLUSION: There is substantial evidence to support that cannabinoids interact with medications and other substances, but there is insufficient evidence to conclude which doses and formulations of each cannabinoid contribute to adverse events resulting from these interactions.

ROUTE OF ADMINISTRATION SAFETY AND EFFICACY. A wide array of literature was identified that assessed either safety or efficacy by route of administration of marijuana and marijuana-derived products, where 7,072 studies were published related to this topic between 2016 and 2019. Due to the nature of the topic, preclinical studies and case reports were not excluded during screening. Most predominately, routes of smoking, ingestion (e.g., "edibles"), and oral sprays, were featured in the literature, with significant gaps identified in evidence related to vaping safety and efficacy. Additionally, literature assessing evidence for dosing (e.g., THC/CBD ratios, and overall quantities of constituent compounds within individual doses, and dosing regimens) for different product routes were captured within this review, but the majority of these studies were preclinical and evidence from human studies is significantly lacking. There are significant gaps in the literature assessing the safety and efficacy of different routes of administration, particularly smoking and vaping, in clinical studies. Adverse events related to respiratory problems for both smoking and vaping cannabis were reported in a significant number of case reports, but at this time population-based prevalence estimates for respiratory adverse events from smoking and vaping were not identified within the time frame of published research.

CONCLUSION: There is insufficient evidence to comprehensively assess safety, efficacy, and dosing for different routes of administration of cannabis, including smoking and vaping.

Scientific Expert Panel Recommendations

Scientific Experts were convened in a series of open-ended discussion sessions moderated by Consortium leadership to comment on the evidence search strategies and evidence review protocols for the Consortium-produced mapping literature review. During each moderated session experts were also engaged in open-ended discussions to advise on priorities for the 2021 Consortium Research Agenda. Following these moderated discussion sessions all experts were contacted with a questionnaire and asked to assess research priorities for specific qualifying conditions for medical marijuana as well as an assortment of other topics relevant to assessing medical marijuana clinical outcomes, by voting on topic priorities. Experts were then asked to provide written comment to further support their votes and to advise on other specific topics that were not presented for vote within the questionnaire.

Experts then rates research priorities for medical marijuana as related to the therapeutic effect and/or the symptom management of the specific debilitating health conditions defined within Florida statute, where votes to rate priorities were cast on a scale of 1 (representing very low research priority) to 5 (representing very high research priority). When summed by condition, experts rated **Chronic Pain, Epilepsy, and PTSD**, highlighted in the table below as the top-rated priorities for medical marijuana research related to specific debilitating health conditions.

Health Condition	Mean Rating	Rank Order
Amyotrophic Lateral Sclerosis (ALS)		
Therapeutic Effect	2.75	13
Symptom Mitigation/Management	3.56	9
Cancer		
Therapeutic Effect	3.63	8
Symptom Mitigation/Management	4.00	7
Chronic Pain		
Therapeutic Effect	4.45	2
Symptom Mitigation/Management	4.64	1
Crohn's Disease and Inflammatory Bowel Disease (IBD)		
Therapeutic Effect	3.56	9
Symptom Mitigation/Management	3.50	10
Epilepsy		
Therapeutic Effect	4.20	5
Symptom Mitigation/Management	4.30	3
Glaucoma		
Therapeutic Effect	2.90	12
Symptom Mitigation/Management	2.56	14
HIV/AIDS		
Therapeutic Effect	2.50	15
Symptom Mitigation/Management	3.20	11
Parkinson's Disease		
Therapeutic Effect	2.90	12
Symptom Mitigation/Management	3.50	10
Post-Traumatic Stress Disorder (PTSD)		
Therapeutic Effect	4.10	6
Symptom Mitigation/Management	4.27	4

Experts were asked to propose other topics of interest relevant to medical marijuana, beyond the specific health conditions listed above. The most frequently mentioned topics, presented in the table below, were: **Route of Administration safety/efficacy (for smoking and vaping) and Interactions of Marijuana with Medications.**

Topic Area	# of votes
Route of Administration: Smoking/Flower	13
Route of Administration: Vaping	12
Marijuana and Medication Interactions	11
Other Routes of Administration: edibles (edibles were indicated by 9 experts), transdermal/topical, transmucosal, Epidiolex	11
Autism: Symptom Mitigation/Management	10
Autism: Therapeutic Effect	9
Other Topic Areas, not otherwise listed*	6
Other Medical Conditions, not otherwise listed**	5

**Experts also suggested: upper respiratory disease, adverse psychiatric effects, abuse potential, disclosure of use, combination with street cannabis, impact on tobacco use, measurement tools for cannabis impairment, depression/anxiety not related to PTSD.*
***Experts also suggested: anxiety not related to PTSD, tick-borne disease, sickle cell, insomnia.*

Experts were then asked to rank research priorities overall, resulting in the prioritized topic areas presented in the table below.

Topic Area	Rank Order
Chronic Pain	1
PTSD	2
Epilepsy	3
Cancer symptoms	4
Drug-Drug Interactions	5
Route of Administration (vaping)	6
Other Topics*	7
Parkinson's Disease	8
Route of Administration (smoking)	9
Route of Administration (other)	10
HIV/AIDS	11
Autism	12
Crohn's Disease and IBD	13
Glaucoma	14

**Other topics: potential adverse effects related to abuse behaviors and/or mental health, cannabis potential for the treatment of non-PTSD anxiety (indicated by 3 panelists).*

The expert recommendations regarding research priorities were considered in tandem with Consortium obligations per statute, the findings from the evidence review, and the recommendations expressed by stakeholders during the preliminary survey conducted during the AMMPA conference, to formulate Consortium research priorities in 2021.

Expert panelist recommendations and preliminary evidence review findings were presented to the Consortium Board during the January 2020 Board Meeting, held in Orlando, Florida on the University of Central Florida College of Medicine campus. Board Members were presented with the proposed Consortium Research Agenda for 2020-2021 which they approved via vote. The summary of Consortium research priorities is presented within the next section.

FUTURE PLANS FOR THE CONSORTIUM

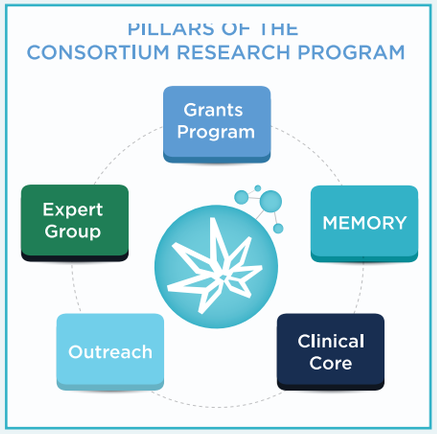
SUMMARY OF CONSORTIUM RESEARCH PRIORITIES

Research priorities were set in accordance with the Consortium's charge per statute, to "… contribute to the body of scientific knowledge on the effects of the medical use of marijuana and inform[s] both policy and medical practice related to the treatment of debilitating medical conditions with marijuana." Significant gaps in the body of scientific knowledge for medical marijuana efficacy and safety were identified upon review of the evidence. In consultation with nationally recognized experts as described above, research priorities have been adopted by the Consortium to direct research efforts in 2020-2021 that will address the identified knowledge gaps that can most immediately inform both policy and medical practice. These three research priorities for the next year are as follows:

1. **Clinical Outcomes**, with particular emphasis on studying the effect of marijuana on **chronic pain, anxiety, and symptomatic treatment of cancers.**
2. **Route of Administration**, particularly dosing and the effect of different routes on both efficacy and safety**,** with specific emphasis on studies that evaluate the health effects of **smoking and vaping**.
3. **Interactions of medical marijuana with other drugs/medications**, with particular focus on medications that are commonly used by patients who seek medical marijuana treatment.

These research priorities will be applied in both the Consortium's grants program as described in the next section and will also guide the research projects and proposals directed by Consortium leadership.

PROPOSED RESEARCH PLAN

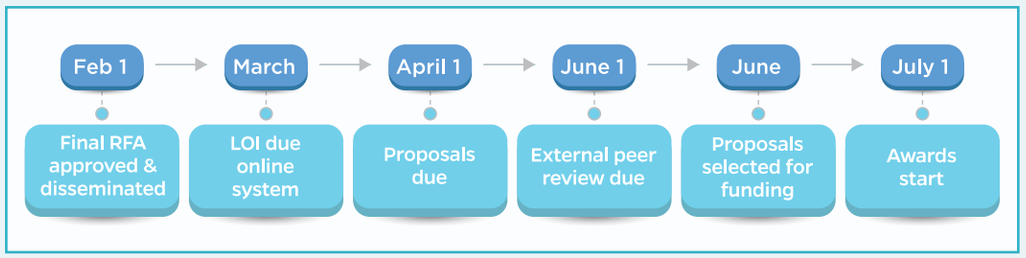


Since its inception in July 2019, the Consortium has made great strides towards facilitating and conducting research that will inform clinical care and policy about the medical use of marijuana to improve public health. To build on these initial efforts, we propose continued development of the five Consortium research program pillars that were established last year: the Grants program, MEMORY, the Clinical Core, Outreach and Scientific Expert Group Activities. The specific goals and plans for each pillar have been updated and are described below.

Assuming a consistent budget, the following describes the Consortium Research Plan for fiscal year 2021.

Grants Program

In light of the overwhelming response to the Consortium's grants program, the board has agreed to continue this effort without major changes in the coming fiscal year. The Consortium staff has implemented several procedural changes such as an online submission platform for the letter of intent that will streamline the application process. The application process will start March 1 with the goal to make awards by July 1, which will allow a full 12-months funding period and enhance the scope of studies that can be completed.



Assuming continued state support, the Consortium hopes to continue its funding at similar volume and magnitude as in the fiscal year 2020.

The most noteworthy modification of the first grants cycle is the introduction of **research priorities** that have been adopted by the board. The Consortium research priorities for fiscal year 2021 are:

1. **Clinical Outcomes:** with particular emphasis: chronic pain, anxiety and symptomatic treatment of cancer
2. **Route of Administration:** effect of dosing and routes on efficacy and safety; of particular interest will be studies that evaluate effects of smoking and vaping
3. **Interactions of Medical Marijuana with other drugs:** with particular focus on those medications that are expected to be prevalent in patients who seek medical marijuana

The 2020 Request for Proposals is available at https://mmjoutcomes.org/grants-program/2020rfp/.

MEMORY

Plans for MEMORY development remain unchanged for fiscal year 2021 with the key focus on establishing data sharing processes and procedures with OMMU. To facilitate rapid detection of emerging safety signals as exemplified with the recent concern about marijuana vaping products and severe lung disease, the Consortium considers two aspects of MEMORY as they relate to DoH data transmission particularly critical:

1. It is essential to have detailed descriptions of the specific marijuana product that licensed patients purchased from dispensaries. Detail on such products will ideally include not only the route and dose, but the exact product and manufacturer, because product composition and quality may vary.

2. For active surveillance, i.e., capture of emerging safety concerns, frequent update of data (as stipulated in the statute on a quarterly basis) is critical.

As envisioned, MEMORY can then serve in two capacities: for ***controlled studies*** on medical marijuana effectiveness and safety and for ***active surveillance*** to capture emerging safety issues among MMJ users. The former will employ rigorous study designs including control groups of patients who do not use MMJ but have similar health conditions, while the latter only follows MMJ to capture signals of unexpected adverse events that may be associated with a particular marijuana product for follow-up.

Clinical Core

Goals for the Clinical Core will include an expansion of the Consortium infrastructure to support patient recruitment into prospective research studies. This will include development of policies and procedures to engage patients and research partners (providers and industry) who have expressed interest in collaboration. The Consortium will pilot **prospective patient recruitment** to be conducted at one or more MMJ provider practices and/or dispensaries in Florida. Specifically, we propose to initiate a process by which persons who are using medical marijuana can sign up for a longitudinal cohort study, which can track detail on medical marijuana use and patient-reported outcomes. The Consortium hopes to establish a patient recruitment mechanism for clinical outcomes studies that has proven effective and that can be provided to investigators from all Consortium institutions to accelerate and enhance conduct of clinical outcomes studies. A proven patient recruitment platform is also critical for extramural grant applications (e.g., to NIH).

The Clinical Core will also work on **guidance for investigators on regulatory issues** involving use of medical marijuana in research studies. This will include guidance on DEA licensure and other relevant state and federal regulations

Outreach

The Consortium is planning to increase its Outreach through the first **Consortium Symposium on Medical Marijuana Clinical Outcomes Research**. This will be a research-centric meeting, though open to patients and providers, to share research findings and stimulate research collaborations throughout the state and nationally. All grant awardees funded by the Consortium, will be expected to present their findings at the symposium in addition to state and national invited researchers. The Consortium will make a particular effort to reach out to lawmakers and regulators to facilitate discussions on evidence-based policy to enhance both research on and the clinical use of medical marijuana. Other outreach activities through the Consortium website, its quarterly newsletter and participation in the AMMPA conference will continue.

Expert Group

Two new activities that complement Consortium outreach activities will be launched by the expert group, including publication of **emerging evidence reviews** and **patient/provider info sheets**. Emerging evidence reviews will model similar resources available to providers such as provided by MedScape or UpToDate. Such resources scan medical literature and highlight new and clinically relevant finding published studies along with brief commentaries. No such resource is available specifically for medical marijuana.

The Consortium plans to involve Consortium members from all participating institutions, led by the expert group, to put forward relevant research studies and provide commentaries about their scientific rigor and clinical implication for publishing on the Consortium website. These evidence reviews can also be disseminated to interested providers and other stakeholders through the Consortium newsletter. As pilot for FY 2021, the Consortium plans to publish and disseminate a minimum of six emerging evidence reviews.

For the fiscal year 2021 the Consortium will further develop patient and provider information sheets on two important topics:

- use of medical marijuana for treatment of anxiety
- interaction of medical marijuana with prescription drugs

Both topics are included in the Consortium research priorities and represent needs for information expressed by providers and patients.

Two versions of these info sheets will be developed, including a version using lay language for consumers and a version for providers that is similarly brief, but uses clinical terminology and provides references to the relevant primary literature for further study as desired. The purpose of these info sheet is to provide unbiased, evidence-based and up-to-date information for important topics on medical marijuana clinical outcomes. The Consortium considers the emerging evidence reviews and info sheets an important feature to enhance its communication with providers and patients and stimulate interest in medical marijuana clinical outcomes research.

2021 Research Plan Summary

The Consortium Research Program will rest on the same five pillars as established at its initiation including the **Grants Program**, **MEMORY, the Clinical Core, Outreach** and **Scientific Expert Group** activities (*Figure 6*). The Grants Program will continue to support investigator-initiated research across Consortium institutions with a purposeful focus on research priorities that represent the greatest need for evidence including chronic pain, anxiety, symptomatic treatment of cancer, dosing and routes of marijuana use with particular focus on smoking and vaping, and interactions with medications. MEMORY will support retrospective population-based studies on medical marijuana safety and effectiveness and active surveillance of emerging safety issues. The Clinical Core will complement MEMORY by providing support for prospective observational or experimental studies on MMJ outcomes. In addition to its website and newsletter the Consortium will enhance its outreach activities through participation in the annual AMMPA meeting and its first state-wide symposium on medical marijuana clinical outcomes research. Led by its scientific expert group, the Consortium will launch emerging evidence reviews that will provide a succinct summary of newly published research studies, and patient/provider info sheets on use of medical marijuana in the treatment of anxiety and its interaction with other medications.

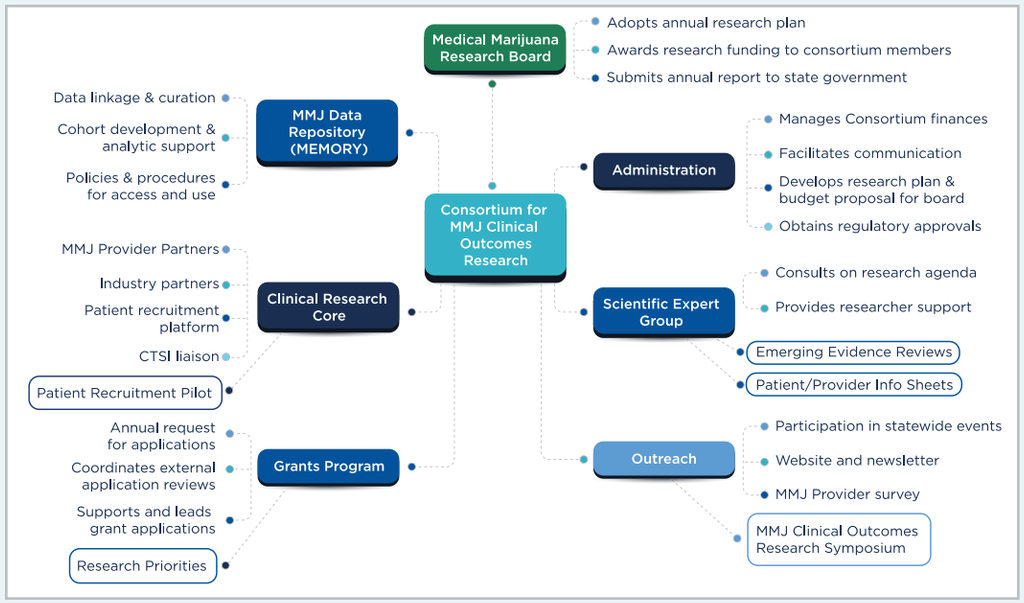


FIGURE 6. CONSORTIUM FOR MEDICAL MARIJUANA CLINICAL OUTCOMES RESEARCH — ORGANIZATIONAL STRUCTURE 2021. NEWLY INTRODUCED INITIATIVES (E.G. PATIENT RECRUITMENT PILOT) ARE HIGHLIGHTED IN BOXES

The board and Consortium staff would like to conclude this report by expressing strong continuing support and enthusiasm to advance the Consortium research program. We are convinced that the Consortium can address an urgent and critical need to inform patients, providers and regulators on the safe and effective use of MMJ, including dose, route and product choice, tailored to other concomitant treatments and patients' underlying dis-ease conditions. We believe that the medical use of marijuana must be guided by the same scientific evidence that is available for prescription medications and that the safety of MMJ products should be monitored with similar surveillance methods. The Consortium is devoted to building both.

APPENDIX A

THE CONSORTIUM FOR MEDICAL MARIJUANA CLINICAL OUTCOMES RESEARCH BOARD

WILLIAM (BILL) ANDERSON, PH.D.

Associate Vice President of Research, Florida International University

Associate Vice President William (Bill) Anderson leads initiatives that expand FIU's efforts in research development for faculty, doctoral students and postdoctoral scholars. Additional areas of leadership focus include research labs, core facilities, research integrity, and laboratory safety, among others. Dr. Anderson joined FIU in 2000 as Assistant Professor and has risen to the rank of Professor.

Administratively, he has served as Chair of the Department of Earth & Environment and Associate Dean of Faculty in the College of Arts, Sciences & Education where he most recently served as the Vice Dean.

He received a doctorate of Natural Sciences from the Swiss Federal Institute of Technology (ETH-Zentrum), a M.S. in Geology from Syracuse University and a B.A. in Geology from the University of Kansas. A stable isotope biogeochemist, Dr. Anderson's research focuses on biogeochemical cycling of carbon and nitrogen in marine systems, as well as the oxygen, carbon, and nitrogen isotopic signatures in organic material. His research has been published in top tier journals; he has presented in national and international conferences; and he has received funding from the NSF, the American Chemical Society, and the U.S. Department of the Interior, among others.

W. DALTON DIETRICH, PH.D.

Scientific Director, The Miami Project to Cure Paralysis; Senior Associate Dean for Discovery Science; Co-Director, Institute for Neural Engineering
Associate Director, Miami CTSI; Professor of Neurological Surgery, Neurology, Biomedical Engineering and Cell Biology; Leonard M. Miller School of Medicine; University of Miami

Dr. W. Dalton Dietrich is Scientific Director at The Miami Project to Cure Paralysis and the Kinetic Concepts Distinguished Chair in Neurosurgery at the University of Miami Miller School of Medicine. He received his Ph.D. in Anatomy from the Medical College of Virginia in 1979 and completed a postdoctoral fellowship in the Department of Pharmacology at Washington University, St. Louis, MO, 1981. In 1981, Dr. Dietrich joined the Department of Neurology at the University of Miami, with a joint appointment in Cell Biology and Anatomy, and in 1993 attained the rank of Professor. Dr. Dietrich served as Vice-Chairman for Basic Science in the Department of Neurology and in 1997 and accepted the position of Scientific Director of The Miami Project to Cure Paralysis. Dr. Dietrich also serves as the Senior Associate Dean for Discovery Science, Co-Director of the Institute for Neural Engineering and Associate Director of the Miami Clinical and Translational Science Institute (CTSI) at the University of Miami.

Dr. Dietrich's laboratory is focused on clarifying the pathophysiology of brain and spinal cord injury with the ultimate goal of developing new therapies to protect and enhance recovery of function. Over the last 35 years, Dr. Dietrich and colleagues have studied the cellular and molecular injury mechanism underlying various neurological disorders including stroke, cardiac arrest, traumatic brain and spinal cord injury. In terms of neuroprotection, he and his colleagues provided the initial preclinical data indicating that small differences in the temperature of the brain and spinal cord critically determine whether neurons die following neurological injury. Most recently, Dr. Dietrich and colleagues have investigated the importance of abnormal inflammasome activation in the brain and spinal cord after injury. These studies have uncovered a new therapeutic target for modifying the immediate immune response to injury. Finally, Dr. Dietrich and colleagues are using novel cellular and drug treatments to promote reparative process and functional recovery after brain and SCI. He is currently the Sponsor of first-in-man FDA approved clinical trials testing the safety of human Schwann cell transplants in people with severe spinal cord and peripheral nerve injuries.

Dr. Dietrich has published over 400 refereed journal articles, 60 book chapters and 4 books. His published work has been cited over 35,000 times. He has been listed by the Institute of Scientific Information as a "Highly Cited Researcher", placing him in the top 0.5% of all scientists based on the impact his research has made on other scientists. Dr. Dietrich has been a thesis/dissertation advisor to 9 graduate students and has trained over 40 postdoctoral fellows and visiting scholars. His research programs are supported by the NIH, Department of Defense, State of Florida and The Miami Project to Cure Paralysis. He serves on study sections for NIH, Department of Defense and several state brain and spinal cord injury research programs. He is currently Editor-In-Chief of the Journal Therapeutic Hypothermia & Temperature Management and Deputy Editor of the Journal of Neurotrauma. He is a co-founder of two start-up biotechnology companies, InflamaCORE, LLC and Aceso Therapeutics, LLC to help move new discoveries to the clinic.

ROGER B. FILLINGIM, PH.D.

Distinguished Professor, Director, University of Florida, Pain Research and Intervention Center of Excellence (PRICE), University of Florida

Roger B. Fillingim, Ph.D., a Clinical Psychologist, is Distinguished Professor in the University of Florida (UF) College of Dentistry and Director of the UF Pain Research & Intervention Center of Excellence. Dr. Fillingim maintains an active research program investigating individual differences in pain.

He has been continuously NIH-funded since 1994, and his current grants include a MERIT Award from the National Institute on Aging, which investigates biological and psychosocial factors contributing to ethnic group differences in osteoarthritis pain. He also serves as Director of the UF Center for Advancing Minority Pain and Aging Science. He has published more than 300 scientific articles and is a frequent speaker at national and international conferences. He served as President of the American Pain Society from 2012-2014, served as Co-Chair of the Federal Pain Research Strategy Disparities Workgroup, and is currently a member of the US Department of Health and Human Services Interagency Pain Research Coordinating Committee. He has received several awards, including a University of Florida Term Professorship, as well as the Fordyce Clinical Investigator Award and the Distinguished Service Award, both from the American Pain Society.

DANIEL C. FLYNN, PH.D.

Vice President for Research, Florida Atlantic University

Daniel C. Flynn, Ph.D., Vice President for Research, oversees research administration at Florida Atlantic University. In addition, he's responsible for the University's research institutes and centers as well as leading its economic development and entrepreneurial initiatives, such as FAU Tech Runway, an innovative start-up incubator. He also launched FAU Wave, a successful undergraduate research and entrepreneurship program, as well as the Florida Small Business Development Center at FAU.

Prior to joining FAU, Flynn served as Associate Dean for Research in the University of Delaware's College of Health Sciences where he helped grow the research enterprise by 60 percent, promoted invention disclosures, faculty patent applications and developed undergraduate entrepreneurial and research programs. He served as the founding Associate Dean for Research and Economic Development at The Commonwealth Medical College, a new medical school in Scranton, PA. Flynn spent 17 years at West Virginia University where he served as a Professor and Deputy Director of the Mary Babb Randolph Cancer Center. During his career, he has been awarded more than $40 million in research funding. The National Institutes of Health funded Flynn's research for more than 20 years. At WVU, he served as Director of a Center of Biomedical Research Excellence for Cancer Cell Biology, developed mentoring programs, organized core facilities and served as coordinator of the M.D./Ph.D. training program.

He has published 72 research articles and has also served on an editorial board, advisory committees and study sections for NIH and the Association of American Medical Colleges. He earned his B.S. at the University of Maryland, College Park, Ph.D. at North Carolina State University and his post-doctoral work at the University of Virginia.

TIMOTHY A. GILBERTSON, PH.D.

Professor of Medicine, University of Central Florida

Timothy A. Gilbertson is a Professor of Medicine in the Department of Internal Medicine at the University of Central Florida College of Medicine. Prior to his current appointment which he assumed in 2018, he was most recently Professor of Biology and Co-Director of the Neuroscience PhD Program at Utah State University. He received his Ph.D. in Neurobiology from the University of California-Davis in 1991 and his postdoctoral training at Colorado State University from 1991-1993.

From 1993-2000 he was Assistant/Associate Professor at Louisiana State University and the Pennington Biomedical Research Center. He has served as Chairman of the National Institutes of Health Communication Disorders Review Committee at the National Institute of Deafness and other Communication Disorders and

as Chairperson of the Health and Scientific Advisory Board and on the Board of Directors of the Institute of Public Health and Water Research (IWPR).

In the past 20 years, he has served as a consultant to or done contract research for numerous companies including Novartis Pharmaceuticals, Kraft Foods, Frito Lay, Purina, Givaudan, Nestlé, and Glaxo Smith Kline. He currently serves as a consultant to PepsiCo Global R&D. From 2007-2011 he served as the Director for the Center for Advanced Nutrition at Utah State University. His research focuses on how the body recognizes and responds to nutrients and how this process is tuned to the underlying nutritional needs of an organism. This has implications ranging from basic mechanisms for taste transduction and the design of taste mimetics to post-ingestive nutrient chemoreception and the control of food intake, dietary-induced obesity and diabetes.

His laboratory was the first to elucidate the mechanisms underlying the taste of both fat and sour and has been the first to show unequivocally that nutrient recognition in the peripheral taste system is modulated by diet and disease. Dr. Gilbertson has generated well in excess of $7 million in extramural funding, published over 70 research articles including in Science, PNAS, The Journal of Neuroscience and Neuron and received the Ajinomoto Award for Outstanding Research in Gustation and the Outstanding Graduate Mentor Award from Utah State University. He has served as advisor and mentor for 25 graduate students, 9 postdoctoral fellows and several visiting professors.

ERIC H. HOLMES, PH.D.

Assistant Vice President for Research, Florida State University

Eric Holmes has a PhD in Biochemistry from the University of California, Davis. Since 2013 he has been an Assistant Vice President for Research in the FSU Office of the Vice President for Research.

He currently also serves as the Interim Director for the FSU Office of Human Subjects. Prior to joining FSU, he was Director of Research at the University of Hawaii's John A. Burns School of Medicine.

Dr. Holmes has a long track record of directing NIH-funded research in biochemical oncology. He is an author of approximately 100 research publications and is an inventor on over 30 issued US and foreign patents. Dr. Holmes has also worked in the Biotech industry in development-stage pharmaceutical companies located in the Pacific Northwest focused on antibody therapy and drug delivery technologies, and has designed and managed clinical trials related to the development of these technologies.

CYNTHIA (CINDY) HUGHES HARRIS, PH.D., OTR, FAOTA, FASAHP

Dean, School of Allied Health Sciences, Florida A&M University

Cynthia Hughes Harris, Ph.D., OTR, FAOTA, FASAHP currently serves as the Dean of the School of Allied Health Sciences at Florida A&M University. As the Dean, Dr. Harris is responsible for the oversight and management of graduate programs in physical therapy, occupational therapy, and health administration as well as undergraduate programs in health science, health care management, health informatics and information management and cardiopulmonary science.

Dr. Harris is a graduate of the University of Illinois at both the graduate and undergraduate levels. Currently, Dr. Harris serves as the Research Director for the Medical Marijuana Education and Research Initiative at Florida A&M University.

Her interest in marijuana use began when, as a researcher, she focused on HIV prevention programs for high-risk urban adolescents. She successfully implemented such programs in Chicago public schools as well as schools in the South Bronx section of New York City. Additionally, she has been particularly successful in receiving external funding for the improvement of societal health and the elimination of health disparities in both urban and rural communities of Florida.

Other investigative initiatives addressed the results of the qualitative experiences of minority students in different academic environments. She has served as a Presidential appointee to the Advisory Committee of the White House Conference on Aging as well as the Health Resources Services Administration (HRSA) Advisory Committee on Interdisciplinary Community-Based Linkages.

MAX C. E. OREZZOLI, PH.D.

Assistant Professor of Sociology (Medical), Florida Memorial University

Max C. E. Orezzoli, Ph.D. is an Assistant Professor of Sociology (Medical) specializing in health and quantitative analysis at Florida Memorial University. Dr. Orezzoli has 15 years of experience in minority health disparities research focusing on Substance Use Disorder (SUD), including marijuana use, nutrition, and HIV research, and how these areas intersect. Additionally, Dr. Orezzoli has provided experimental and instrument design, data collection trainings, evaluation, statistical and methodological consulting and assistance to institutions, biomedical, educational, and healthcare organizations.

His expertise and research interests are centered on transdisciplinary and translational public health and Community Based Participatory Research (CBPR) interventions that positively impact the health of underrepresented communities regionally, nationally and internationally.

Dr. Orezzoli is bilingual and fluent in Spanish. He has extensive experience in formative and summative program evaluation using quantitative and qualitative methods, which are regionally and culturally appropriate. He has served as an evaluator on several Substance Abuse and Mental Health Services Administration (SAMHSA) grants addressing SUD in Hispanic, black, and Native American communities.

Moreover, Dr. Orezzoli is well equipped to conduct research involving human participants and, addressing sensitive issues/topics of focus (medical marijuana, diet research, HIV, SUD, violence, etc.) while adhering to all confidentiality and privacy requirements. Dr. Orezzoli serves as the Co-chair of the Institutional Review Board (IRB) at Florida Memorial University.

MARTHA S. ROSENTHAL, PH.D.

Professor of Neuroscience/Physiology, Director of the Cannabis Research, Education, and Workforce Initiative, Florida Gulf Coast University

Dr. Martha Rosenthal is a Professor of Neuroscience & Physiology at Florida Gulf Coast University, where she teaches courses in cannabis, drugs and society, neuroscience, human physiology, and human sexuality.

Dr. Rosenthal received her bachelor's degree in biology from the University of Virginia, her master's degree in neuropharmacology from Brown University, and her Ph.D. in neuroscience from UCLA. She began her career teaching in the College of Pharmacy at the University of Florida, and then moved to Fort Myers to be one of the founding faculty members of FGCU.

Dr. Rosenthal is the Director of the Cannabis Research, Education, and Workforce initiative (CREW) at FGCU, and runs the cannabis professional certificate program. She is the author of a number of textbooks, including Drugs: Mind, Body, and Society.

Dr. Rosenthal has been honored to receive the Teacher of the Year award at both the University of Florida and at FGCU and to have presented a TED talk about sex and gender.

APPENDIX B

LEADERSHIP AND STAFF OF THE CONSORTIUM FOR MEDICAL MARIJUANA CLINICAL OUTCOMES RESEARCH

ALMUT G. WINTERSTEIN, R.PH., PH.D., FISPE

Professor & Chair, Pharmaceutical Outcomes & Policy
Dr. Robert and Barbara Crisafi Chair for Pharmaceutical Outcomes & Policy
College of Pharmacy, University of Florida

CONSORTIUM DIRECTOR

Almut Winterstein, R.Ph., Ph.D., FISPE received her pharmacy degree from Friedrich Wilhelm University in Bonn, Germany and her Ph.D. in Pharmacoepidemiology from the Charité Humboldt University in Berlin, Germany.

She holds the position of Professor and Chair in the Department of Pharmaceutical Outcomes and Policy at the College of Pharmacy, and an affiliate appointment in the Department of Epidemiology at the Colleges of Medicine and Public Health and Health Professions, both at the University of Florida.

In 2017, she was named the Dr. Robert and Barbara Crisafi Chair in recognition of her research on evaluating drug safety and effectiveness in real-world populations and on devising ways to improve medication use.

Since joining the UF College of Pharmacy in 2000, Dr. Winterstein has served as principal investigator on more than 25 extramurally funded grants and contracts and published more than 300 manuscripts and conference abstracts. Her research interests have centered on the post-marketing evaluation of drugs in pediatrics and perinatal care, infectious disease and psychiatry and the evaluation and improvement of quality surrounding medication use using real-world data.As an internationally recognized expert in drug safety, she has chaired the Food and Drug Administration's Drug Safety and Risk Management Advisory Committee from 2012-2018. Recognizing her contributions in pharmacoepidemiology, Dr. Winterstein was inducted as a fellow of the International Society of Pharmacoepidemiology in 2013 and started her term as president-elect of the society in 2018.

Before she became department chair in 2016, Dr. Winterstein served as graduate program director in her department, which included responsibility for a M.S. program for the FDA. She has chaired a total of 21 Ph.D. committees and has served as member on several others in her department, and the Departments of Epidemiology, Biostatistics and Statistics.

ROBERT L. COOK, MD, MPH

Professor, Epidemiology, Medicine; Director, Southern HIV & Alcohol Research Consortium (SHARC); College of Public Health & Health Professions, University of Florida

CONSORTIUM ASSOCIATE DIRECTOR

Robert L. Cook, MD, MPH is a Professor of Epidemiology at the University of Florida, with a joint appointment in the Division of General Internal Medicine.

Over the past 20 years, Dr. Cook's research has focused on strategies to improve health outcomes related to HIV and sexually transmitted diseases. He is the Director of the Southern HIV Alcohol Research Consortium (SHARC), which supports collaborative research and training related to alcohol and HIV infection across the state of Florida.

Dr. Cook's research is translational, ranging from basic science to implementation science, and he is currently the PI or MPI of 4 major NIH grants with over $10 million in total research support.

Most recently, Dr. Cook has begun to study the effects of marijuana on HIV-related health and cognition, the systemic connections between the gut microbiome and neuro-inflammation, the use of clinical information systems to improve quality of clinical pain management, and the use of real-time monitoring to measure alcohol consumption.

Mentoring is also an important aspect of Dr. Cook's academic career. He has served as PhD dissertation chair for 7 students, PhD committee member for over 20 students, and mentor for numerous additional trainees, post-docs and junior faculty. When not working, Dr. Cook spends time with his family, plays in a rock-and-roll band, and tries to improve his tennis skills.

AMIE J. GOODIN, PHD, MPP

Assistant Professor, Pharmaceutical Outcomes & Policy, College of Pharmacy, University of Florida

CONSORTIUM LEAD, SCIENTIFIC EXPERT GROUP

Amie J. Goodin, PhD, MPP is an Assistant Professor within the Department of Pharmaceutical Outcomes and Policy (POP) at the University of Florida.

Dr. Goodin received her Master of Public Policy degree from the University of Kentucky (UK) and completed her Doctor of Philosophy degree at UK's Martin School of Public Policy, with specialization in pharmaceutical outcomes and an additional Certificate in Informatics. She completed a Postdoctoral Fellowship at University of Florida POP, specializing in pharmacoepidemiology methods while continuing her work in Health Services Research.

Dr. Goodin previously worked at the Institute for Pharmaceutical Outcomes and Policy as well as the Center for the Advancement of Pharmacy Practice, both of which were housed in the UK College of Pharmacy. Currently, Dr. Goodin's research projects incorporate mixed-method approaches to assess the impact of policy changes related to treatment access and utilization for Substance Use Disorders, particularly among persons enrolled in Medicaid and pregnant women.

JUAN M. HINCAPIE-CASTILLO, PHARMD, MS, PHD

Assistant Professor, Pharmaceutical Outcomes & Policy, College of Pharmacy, University of Florida

CONSORTIUM LEAD, MEMORY

Juan M. Hincapie-Castillo, PharmD, MS, PhD, joined the Department of Pharmaceutical Outcomes and Policy as an assistant professor in 2019.

Dr. Hincapie-Castillo is an alumnus of the College of Pharmacy at the University of Florida, where he received the degrees of Doctor of Pharmacy (2013), Master of Science in Pharmaceutical Sciences (2017), and Ph.D. with a concentration in pharmacoepidemiology (2019).

During his doctoral training, Dr. Hincapie-Castillo was appointed as a graduate fellow for the American Association of Hispanics in Higher Education, and he was the recipient of the University of Florida Graduate Student Teaching Award in 2016. His doctoral dissertation focused on evaluating the unintended consequences of policies aimed to address the opioid crisis on acute pain management outcomes.

Dr. Hincapie-Castillo's research interests include the study of drug utilization and safety in the area of pain management, the evaluation of the effects of State and Federal laws on patient outcomes (legal epidemiology), and the assessment of patient safety and quality for inpatient pain management.

YAN WANG, PHD

Assistant Professor, Epidemiology, College of Public Health & Health Professions, University of Florida

CONSORTIUM LEAD, CLINICAL CORE

Yan Wang, PhD is an Assistant Professor of Epidemiology at the University of Florida. Dr. Wang has training and expertise in both psychology and epidemiology. She received her MS and PhD in Child and Family Studies from Syracuse University in 2013. She joined the Department of Epidemiology as a postdoctoral research associate in 2014, working on NIH funded projects on risk behaviors among rural-to-urban migrants in China. In 2016, she was promoted to Research Assistant Scientist.

With an interdisciplinary perspective, her research focuses on leveraging advanced methodology and new technology (e.g., wearable sensor) to improve health behavior monitoring and intervention. One of her current research projects focuses on improving alcohol use monitoring using a wearable alcohol biosensor and ecological momentary assessment. She is also working on a UF funded pilot project to investigate the real-time and long-term health effects of medical marijuana among patients with chronic pain. Dr. Wang has also worked on a number of NIH funded projects including those on mental health and risk behaviors among rural-to-urban migrants in China, alcohol use and marijuana use among persons living with HIV/AIDS in Florida, and advanced quantum modeling on sexual risk behaviors.

One of her research papers, "Stress and Alcohol Use in Rural Chinese Residents: A Moderated Mediation Model Examining the Roles of Resilience and Negative Emotions" published in the journal Drug and Alcohol Dependence has been recognized by the Matilda White Riley Early Stage Investigator Honor Program, sponsored by the National Institutes of Health Office of Behavioral and Social Sciences Research (NIH/OBSSR).

JEEVAN JYOT, PHD, PMP

College of Pharmacy, University of Florida

CONSORTIUM PROGRAM COORDINATOR

Dr. Jyot received her PhD in Microbiology and Molecular Biology from the Institute of Microbial Technology (India) and completed her postdoctoral fellowship and was an Assistant Scientist at Division of Infectious Diseases and Global Medicine, Department of Medicine, University of Florida. In addition she has Project Management Professional credentials.

Dr. Jyot has previously served as Research Program Coordinator at Division of Research Program Development (DRPD) at Office of Research at University of Florida. Currently, Dr. Jyot is part of the Department of Pharmaceutical Outcomes and Policy (POP) at the University of Florida and serves the Medical Marijuana Clinical Outcomes Research Consortium.

ANNA SHAVERS, MPA

College of Public Health & Health Professions, University of Florida

CONSORTIUM COMMUNICATIONS SPECIALIST

Anna Shavers, MPA is the Communications Specialist of the Consortium for Medical Marijuana Clinical Outcomes Research.

Anna received her Master of Public Administration with a focus in Public Health Administration at Troy University. Her background includes various roles in marketing, communications, and health outreach initiatives.

Before joining the Consortium for Medical Marijuana Clinical Outcomes Research, Anna served with the Peace Corps as a Community HIV/AIDS Outreach Coordinator in South Africa.

APPENDIX C

2019 RESEARCH GRANTS PROGRAM REVIEWERS

Bradley Alger
University of Maryland Baltimore, Professor Emeritus

Omayma Alshaarawy
Michigan State University, Assistant Professor

Jim Anthony
Michigan State University, Professor

Dorie E. Apollonio
University of California, Professor

Elizabeth Arnold
University of Texas Southwestern, Professor

Shuhua Bai
Husson University, Associate Professor

Matthew Bertin
University of Rhode Island, Assistant Professor

Anat Biegon
Stony Brook University, Professor

Ian Carroll
University of North Carolina Chapel Hill, Assistant Professor

Tammy Chung
University of Pittsburgh, Professor

Karen F. Corsi
University of Colorado Denver - Anschutz, Associate Professor

Gabriella Ď Arcangelo
Rutgers, State University of New Jersey, Professor

Natacha M. De Genna
University of Pittsburgh, Assistant Professor

Chris Delcher
University of Kentucky, Assistant Professor

Rong Di
Rutgers, State University of New Jersey, Associate Professor

Julia Dilley
University of Washington, Senior Research Scientist/ Instructor

Nicholas V. DiPatrizio
University of California, Riverside, Assistant Professor

Joseph Ditre
Syracuse University,, Associate Professor

Greg Dussor
University of Texas at Dallas, Associate Professor

Emily Dworkin
University of Washington, Assistant Professor

Ronald Ellis
UC San Diego, Professor

Sylvia Fitting
University of North Carolina Chapel Hill, Assistant Professor

Matthew S. Freiberg
Vanderbilt University, Professor

Jadwiga M. Giebultowicz
Oregon State University, Professor

David H. Gorski
Wayne State University, Assistant Professor

Janna Harris
University of Kansas, Assistant Professor

George Hasko
Columbia University, professor

Thomas Heinbocke
Howard University, Professor

Brook Henry
University of California San Diego, Assistant Researcher

Michael Hoane
Augusta University, Professor

Kamaljit Kaur
Chapman University, Associate Professor

Pawel Kiela
University of Arizona, Professor

Kevin King
University of Washington, Associate Professor

Kelly Koltyn
University of Wisconsin System, Professor

Kate Lapane
University of Massachusetts, Professor

Tally Largent-Miles
University of Arizona, Assistant Professor

Geofroy Laumet
Michigan State University, Assistant Professor

Ken Mackie
Indiana University, Professor

Jianren Mao
Massachusetts General Hospital, Vice Chair for Research

Daniel Marks
Oregon Health & Science University, Professor

Michael Mason
University of Tennessee, Professor

Monique McHenry
University of Vermont, Assistant Professor

Mary Metcalf
Clinical Tools Inc, Vice President

Laurence Miller
Augusta University, Assistant Professor

Kelly Naugle
Indiana University, Assistant Professor

Charles Nichols
Louisiana State University, Professor

Eric Pedersen
RAND Corporation, Senior Behavioral Scientist

Ana Pocivavsek
University of Sourn Carolina, Assistant Professor

Jingjing Qian
Auburn University, Associate Professor

Mohamed Radwan
National Center for Natural Products Research, Senior Research Scientist

Shivani Sharma
California NanoSystems Institute at UCLA, Associate Director

Peter Shaw
UC San Diego, Assistant Professor

Linda Simoni-Wastila
University of Maryland Baltimore, Professor

Tory Spindle
Johns Hopkins University, Postdoctoral Research Fellow

Alex Straiker
Indiana University, Senior Research Scientist

David Todem
Michigan State University, Associate Professor

Greg Tung
University of Colorado Denver, Assistant Professor

George Weiblen
University of Minnesota, Professor

Dennis P. West
Northwestern University, Professor

Kelly Young-Wolf
Kaiser Permanente Division of Research, Research Scientist

APPENDIX D
EXPERT PANEL BIOS

JEFFREY CASSISI, PHD | ***University of Central Florida***
Jeffrey Cassisi, PhD serves as a Professor at the University of Central Florida College of Sciences in the Department of Psychology. As a clinical psychologist licensed in both Florida and North Carolina and a member of the American Psychological Association, Dr. Cassisi researches the physiology of emotions, anxiety, stress, and medical illness. He currently examines the influence of cultural factors in the practice of medicine and health psychology and to combine his psychophysiological and multicultural interests into studies of pre-chronic and chronic diseases.

KATHLEEN EGAN, SCD | ***Moffitt Cancer Center***
Kathleen Egan, ScD serves as a Senior Member at Moffitt Cancer Center Department of Cancer Epidemiology. She also serves as the Associate Program Director of a T32 Postdoctoral Training Fellowship in Molecular Epidemiology. Currently, Dr. Egan's research examines the impact of gut microbial composition on circulating estrogen levels in postmenopausal women in regards to breast cancer risk factors. Another key area of active research for Dr. Egan includes the research into risk factors for primary tumors of the brain which include one of the most devastating human tumors.

JODI GILMAN, PHD | ***Harvard University***
Jodi Gilman, PhD serves as an Assistant Professor at Harvard Medical School/Massachusetts General Hospital with the Center for Addiction Medicine. Using multi-modal imaging, cognitive testing, and behavioral methods, Dr. Gilman aims to understand the biological, psychological, and clinical aspects of addiction. She has developed a series of lectures on medical marijuana, its uses, and possible outcomes. Her research currently examines the short and long-term effects of addiction on the brain to understand the different stages of substance use, from initiation to maintenance to recovery. Dr. Gilman is one of the leading experts on the effects of marijuana on the brain and on cognition in young adults.

PATRICIA GREEN-POWELL, PHD | ***Florida A&M University***
Patricia Green-Powell, PhD serves as the Interim Executive Director at the Florida A&M University Medical Marijuana Education and Research Initiative (MMERI). As a transformational and innovative leader, Dr. Green-Powell oversees all medical marijuana initiatives and research at FAMU and serves as the primary liaison to university units and the Florida Department of Health. In her role as the Interim Executive Director, Dr. Green-Powell's efforts focus on educating and informing Florida's diverse communities about the benefits of medical marijuana and the potential consequence to health and well-being from recreational use.

SEAN HENNESSY, PHARMD, PHD | ***University of Pennsylvania***
Sean Hennessy, PharmD, PhD serves as a Professor at the University of Pennsylvania Department of Biostatistics and Epidemiology. Dr. Hennessy conducts research in the field of pharmacoepidemiology, which is the study of the health effects of drugs and other medical products in populations. During his experience, Dr. Hennessy has studied serious health consequences of drug-drug interactions involving high-risk drugs including anticoagulants, antidiabetes drugs, and antiplatelet agents. His research has also produced crucial knowledge about the cardiovascular safety of many widely-used drugs for mental health conditions including ADHD, depression, and schizophrenia.

JOHN S. MARKOWITZ, PHARMD | ***University of Florida***
John S. Markowitz, PharmD serves as a Professor at the University of Florida College of Pharmacy in the Department of Pharmacotherapy and Translational Research. Before transitioning to research positions, Dr. Markowitz served in clinical roles including as a Clinical Specialist in Psychiatry and a Clinical Coordinator within the Institute of Psychiatry at the Medical University of South Carolina. Dr. Markowitz's research examines the assessment of drug-drug interactions in psychiatric pharmacy, botanical-drug interactions, as well as their associated clinical effects. Recently, his research has focused on variability in drug metabolism, disposition, and therapeutic response as a consequence of genetic variability influencing both drug transporters and enzymes in the liver.

AIMEE MCRAE-CLARK, PHARMD | ***Medical University of South Carolina***
Aimee McRae-Clark, PharmD serves as a Professor at the Medical University of South Carolina Department of Psychiatry and Behavioral Sciences and Department of Neuroscience. She also serves as a Research Health Scientist with the Ralph H. Johnson VA Medical Center. Dr. McRae-Clark's research primarily focuses on medication and intervention development for cannabis, cocaine, and opioid use disorders. She also has had a long-standing interested in research related to women's health. As part of her interest in women's health research, Dr. McRae-Clark leads the NIH-funded Specialized Center of Research Excellence (SCORE) on Sex Differences at the Medical University of South Carolina.

YOUN OK LEE, PHD | ***RTI International***
Youn Ok Lee, PhD is a social scientist in RTI International's Center for Health Policy Science & Tobacco Research. Her research focuses on health behavior, social determinants of health, health policy, and marketing related to tobacco and cannabis use. She conducts qualitative and quantitative studies that draw on theories and methods from multiple areas, including sociology, health behavior, social psychology, and marketing. Youn Ok received her BA from Emory University then went on to complete a MA and PhD in sociology from UNC Chapel Hill. She then went on to complete a post-doctoral fellowship at the University of California, San Francisco. Dr. Lee has led research projects funded through grants and contracts by the U.S. Food and Drug Administration (FDA), National Institute on Drug Abuse (NIDA), and state health departments using a variety of data collection approaches, including surveys, passive monitoring, semistructured interviews, and focus groups. She also has experience collaborating on interdisciplinary research studies with co-investigators in a variety of fields, including communications, engineering, toxicology, pharmacology, and aerosol physics. Her work is published in leading health and sociological journals, including *Pediatrics, American Journal of Public Health*, *American Journal of Preventive Medicine, Tobacco Control, Nicotine & Tobacco Research,* and *Sociological Theory.*

MAIJA REBLIN, PHD | ***Moffitt Cancer Center***
Maija Reblin, PhD serves as an Assistance Member at Moffitt Cancer Center Department of Health Outcomes & Behavior. As a researcher, she concentrates her efforts on how the social context impacts the psychological and psychical health of family caregivers. Dr. Reblin's research focuses on two related lines of work: observational research and development and testing of strengths-based interventions. Her observational research serves to identify communication and relationship characteristics that are associated with caregivers and patient psychological and physical health outcomes.

LINDA SIMONI-WASTILA, PHD | ***University of Maryland***
Linda Simoni-Wastila, PhD serves as an Associate Research Professor at the University of Maryland School of Pharmacy and as the Director of the Long-Term Care Initiative at the Lamy Center. She also holds a faculty appointment at the University of Massachusetts School of Medicine in Worcester. For over 15 years, Dr. Simoni-Wastila has researched prescription drug issues including access to prescription drugs, outcomes related to reduced prescription drug access, cost and financing of prescription drug benefits and programs, appropriateness of drug prescribing, outcomes associated with inappropriate prescribing, and prescription drug misuse and abuse.

TORY SPINDLE, PHD | ***Johns Hopkins University***
Tory Spindle, PhD serves as a Postdoctoral Fellow at Johns Hopkins University School of Medicine at the Behavioral Pharmacology Research Unit (BPRU). Dr. Spindle's research focuses heavily on the use of tobacco and cannabis products. He has completed and collaborated on research regarding the impacts of vaping including use patterns, harm perceptions, and acute health effects. In June 2019, Dr. Spindle presented on Cannabis Drug Testing and Measurement of Impairment at the National Safety Council Meeting. The presentation focused on the changing laws around cannabis, the various forms of cannabis, and the implications for measuring and testing for impairment with cannabis use.

DENISE VIDOT, PHD | ***University of Miami***
Dr. Denise C. Vidot is an epidemiologist certified in cannabis patient care and a tenure-track assistant professor at the University of Miami (UM) School of Nursing and Health Studies. She is the Director of the Cannabis Health and Fitness Laboratory where she serves as PI to studies that examine the relationship between cannabis use and 1) subclinical cardiovascular disease risk, 2) the oral and gut microbiome, 3) mental health symptoms, and 4) cardiorespiratory fitness. Her program of research focuses on the health outcomes of cannabis use by route of administration across the lifespan among those with and without HIV/AIDS. Dr. Vidot's program of research, teaching, and service is based on a multidisciplinary, population-based approach to contribute epidemiologic evidence toward the impact of cannabis use on health across the lifespan.

ELLEN ZIMMERMANN, MD | ***University of Florida***
Ellen Zimmermann, MD serves as the Vice Chair for Academic Affairs at the University of Florida College of Medicine. She also actively participates in research and practices medicine as a physician at UF Health. With over 20 years of experience in academic medicine, Dr. Zimmermann has built a national reputation in Inflammatory Bowel Disease (IBD) and grown a clinical and research interest in the needs of college-aged patients with IBD. At the Zimmermann Research Lab, she focuses research on the molecular advance and social aspects around IBD including drug discovery including the potential use of medical marijuana, student adjustment to college, and non-invasive testing for Crohn's disease.

Consortium for Medical Marijuana
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