

Professions and Public Health Subcommittee

Wednesday, November 3, 2021
11:00 AM - 12:30 PM
Webster Hall (212 Knott)

Meeting Packet

Chris Sprowls
Speaker

Will Robinson
Chair

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

Professions & Public Health Subcommittee

Start Date and Time: Wednesday, November 03, 2021 11:00 am

End Date and Time: Wednesday, November 03, 2021 12:30 pm

Location: Webster Hall (212 Knott)

Duration: 1.50 hrs

Department of Health implementation update on:

- Office Surgery, HB 933 (2019)
- Prescription Donation Program, HB 177 (2020)

Presentation on Medical Marijuana Research:

Implementation update on SB 8A (2017) medical marijuana research provisions by Dr. Almut Winterstein, Director, Consortium for Medical Marijuana Clinical Outcomes Research

For information about attending or testifying at a committee meeting, please see the "Visiting the House" tab at www.myfloridahouse.gov.

NOTICE FINALIZED on 10/27/2021 4:01PM by Osborne.Erin

Office Surgery

Department of Health

Medical Quality Assurance
Legislative Implementation Update

Paul A. Vazquez, J.D.
Executive Director, Florida Board of Medicine
Division of Medical Quality Assurance

Florida House of Representatives
Professions & Public Health Subcommittee
November 3, 2021

HB 933 (2019) Office Surgery

- Overview of HB 933
  - Registration Requirements
  - Enforcement
  - Disciplinary Penalties
- Implementation Strategies
  - Florida Department of Health
  - Florida Board of Medicine
  - Florida Board of Osteopathic Medicine
- Enforcement Summary
- Next Steps

HB 933 (2019) Office Surgery Overview

- Requires registration of office surgery facilities.
- Provides authority for unannounced inspections.
- Establishes disciplinary penalties for offices and practitioners.

HB 933 (2019) Office Surgery Registration

Registration	Office Registration
	Designated Physician
	Financial Responsibility
	Practicing Physician Registration

HB 933 (2019) Office Surgery Inspections

Enforcement	Annual Inspections*
	Unannounced Inspections

* Unless the office is accredited by a nationally recognized accrediting agency approved by the Board.

HB 933 (2019) Office Surgery Discipline

Disciplinary Penalties	Suspension or Revocation of Office Registration
	Emergency Order Suspending or Restricting Registration
	Penalties for Designated Physician
	$5,000 Fine for Practicing Physician (per day)

Rule Promulgation

Florida Boards of Medicine and Osteopathic Medicine

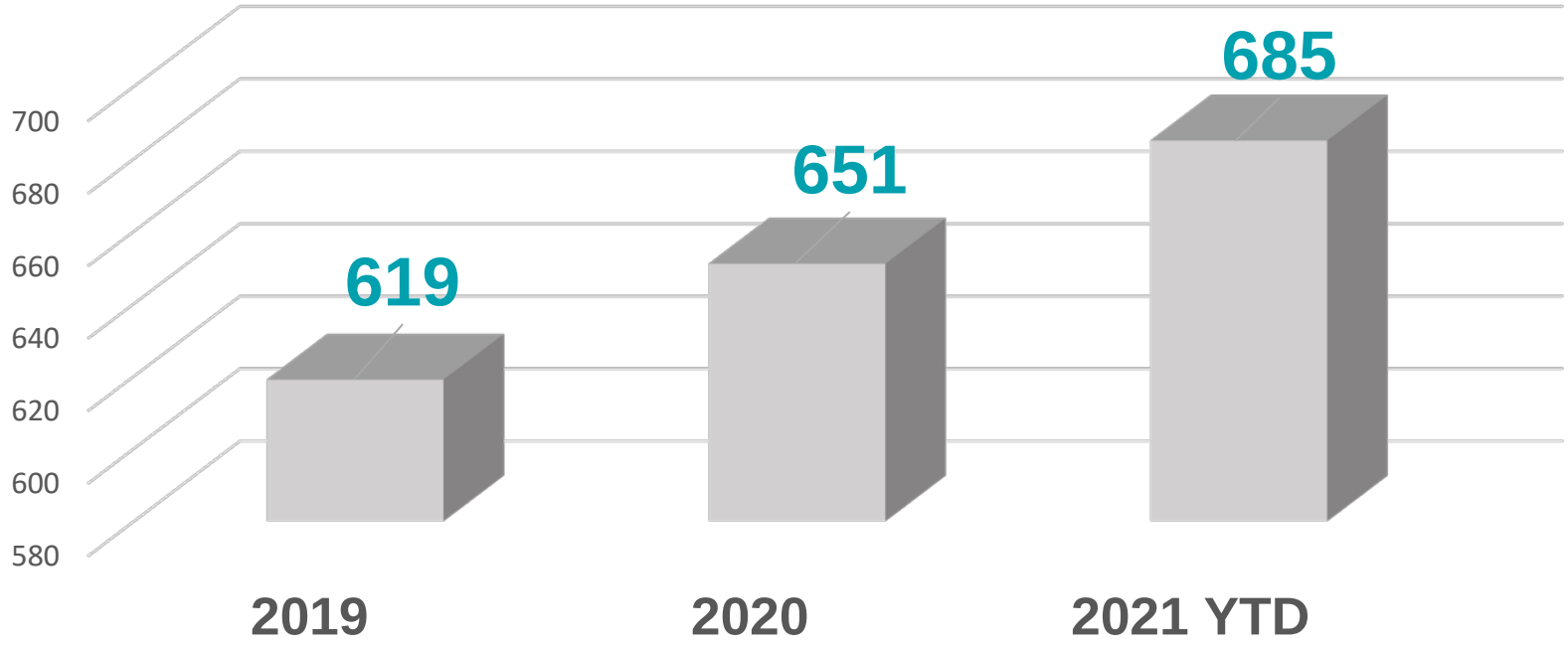
- Office registration requirement.
- Designated physician requirement.
- Physician registration requirement.
- Financial responsibility requirement.
- Physician compliance with standard of care as a condition of registration.

Department of Health

New facility application created:

- Facility ownership information.
- Designated physician identification.
- Surgeon information and qualifications.
- Disclosure of other personnel.
- Accreditation status.
- Criminal history disclosure.
- Liability coverage disclosure.

Office Surgery Registrations



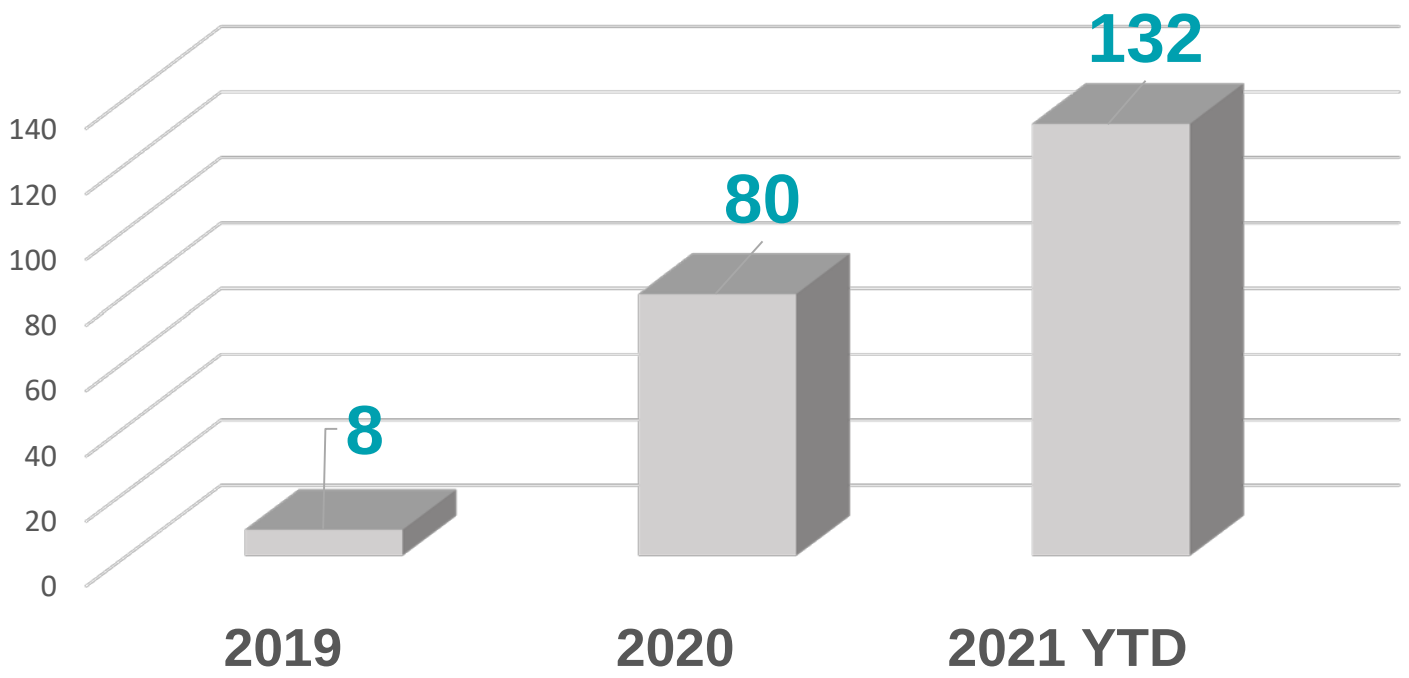
Office surgery facility registrations have continued to increase.

Office Surgery Enforcement Inspections

	2019	2020*	2021 YTD
Office Registration	619	651	685
Accredited Offices	184	155	186
Inspections Completed	437	48	397

*2020 – Executive Order 20-72 suspended all non-essential, elective, medical and surgical procedures.

Office Surgery Complaints



Investigations of office surgery complaints have resulted in **one** registration suspension and **two** emergency restriction orders.

Next Steps

- Ensure compliance with the office surgery application process.
- Assess qualifications of physicians seeking to associate with office surgery facilities.
- Discipline physicians who operate outside the scope of practice or who violate standards of care.
- Seek registration revocation of facilities operating outside the scope of the definition of an office surgery facility.
- Continue routine Surgical Care and Quality Assurance committee meetings.

Questions?

Contact:

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Executive Director

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Paul.Vazquez@flhealth.gov

Prescription Donation Program

Department of Health

Prescription Drug Donation Repository Program Implementation Update

Florida House of Representatives
Professions & Public Health Subcommittee
November 3, 2021

Department of Health

Niaz Siddiqui, PharmD, MBA, Chief
Bureau of Public Health Pharmacy
Division of Emergency Preparedness
and Community Support
Florida Department of Health

Overview of Program

- Section 465.1902, Florida Statutes, effective July 2020 (HB 177, enrolled February 19, 2020)
- Purpose: “The Prescription Drug Donation Repository Program (PDDR) is created within the department to facilitate the donation of prescription drugs and supplies to eligible patients.”
- Requires establishing three key elements and associated forms:
  - Eligible repositories
  - Eligible prescription drug donors
  - Eligible patients

Forms

Each of the following forms has been developed:

- Repository Application and Withdrawal Form
- Patient Application and Dispensing Form
- Donor Form
- Destruction of Drugs Form
- Transfer Form
- Inventory Form

Rule Promulgation

- Development of program processes, forms, and program guide.
- Development of draft rule language and required forms.
  - Chapter 64J-4 in the *Florida Administrative Code* establishes the program.
  - Rule workshop held May 16, 2021.
  - Required forms and process maps edited during June and July 2021.

Rule Promulgation (continued)

- Notice of Proposed Rule submitted to Department of State and published on September 17, 2021.
  - Received comments from Joint Administrative Procedures Committee (JAPC).
  - Rule hearing held on October 18, 2021.
  - Notice of Change-Early November 2021.

Outreach Activities

- Launched program website.
- Conducted complete national review of drug donation programs.
- Met with Iowa and Wisconsin PDDR programs to research and identify best practices.
- Florida Association of Free and Charitable Clinics (FAFCC)
  - Met with FAFCC Executive Director.
  - Met with FAFCC members to research and identify best practices.
  - Confirmed to speak at the FAFCC annual conference in November to promote awareness and encourage participation.
- Finalizing communication and outreach strategy.

Next Steps for Program Implementation

- Finalize rule promulgation.
- Obtain budget authority for grant funds received (will support maintenance of program and automation of system).
- Send promotional emails to eligible entities.
  - Utilizing mailing lists from the Agency for Health Care Administration and DOH Medical Quality Assurance.
- Conduct post implementation evaluation.
- Incorporate feedback into processes, program guide, webpages and forms as appropriate.

Questions or Comments?

For additional information, please contact:

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  Emergency Preparedness and Community Support
  850-245-4346, Victor.Johnson@flhealth.gov

- Niaz Siddiqui, PharmD, MBA, Chief, Bureau of Public Health Pharmacy
  850-922-9036, Niaz.Siddiqui@flhealth.gov

- Shannon Hughes, Project Manager
  850-841-8525, Shannon.Hughes@flhealth.gov

Medical Marijuana
Presentation

The Consortium for Medical Marijuana Clinical Outcomes Research

Almut G Winterstein, RPh, PhD, FISPE
Director
Distinguished Professor & Chair, Pharmaceutical Outcomes & Policy, University of Florida
Director, Center for Drug Evaluation and Safety (CoDES), University of Florida

Consortium for Medical Marijuana Clinical Outcomes Research

Professions and Public Health Subcommittee
House of Representatives
Nov, 2021



Section 1004.4351, Florida Statutes

- Established the Consortium for Medical Marijuana Clinical Outcomes Research to conduct, disseminate and support rigorous scientific research on the clinical outcomes of medical marijuana use.
- 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.

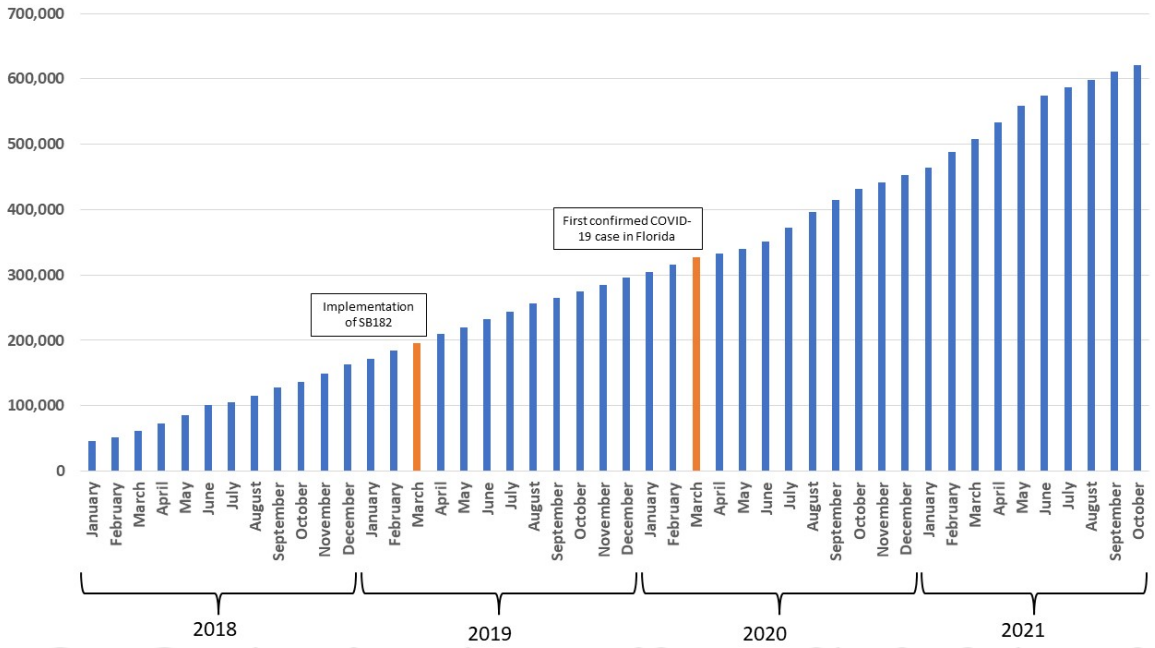
Why we exist…

Despite … the rapid rise in the use of cannabis both for medical purposes …, conclusive evidence regarding the short- and long-term health effects (harms and benefits) of cannabis use remains elusive. A lack of scientific research has resulted in a lack of information on the health implications of cannabis use…

Recommendations:

- Develop a comprehensive evidence base
- Improve research quality
- Improve surveillance capacity
- Address research barriers

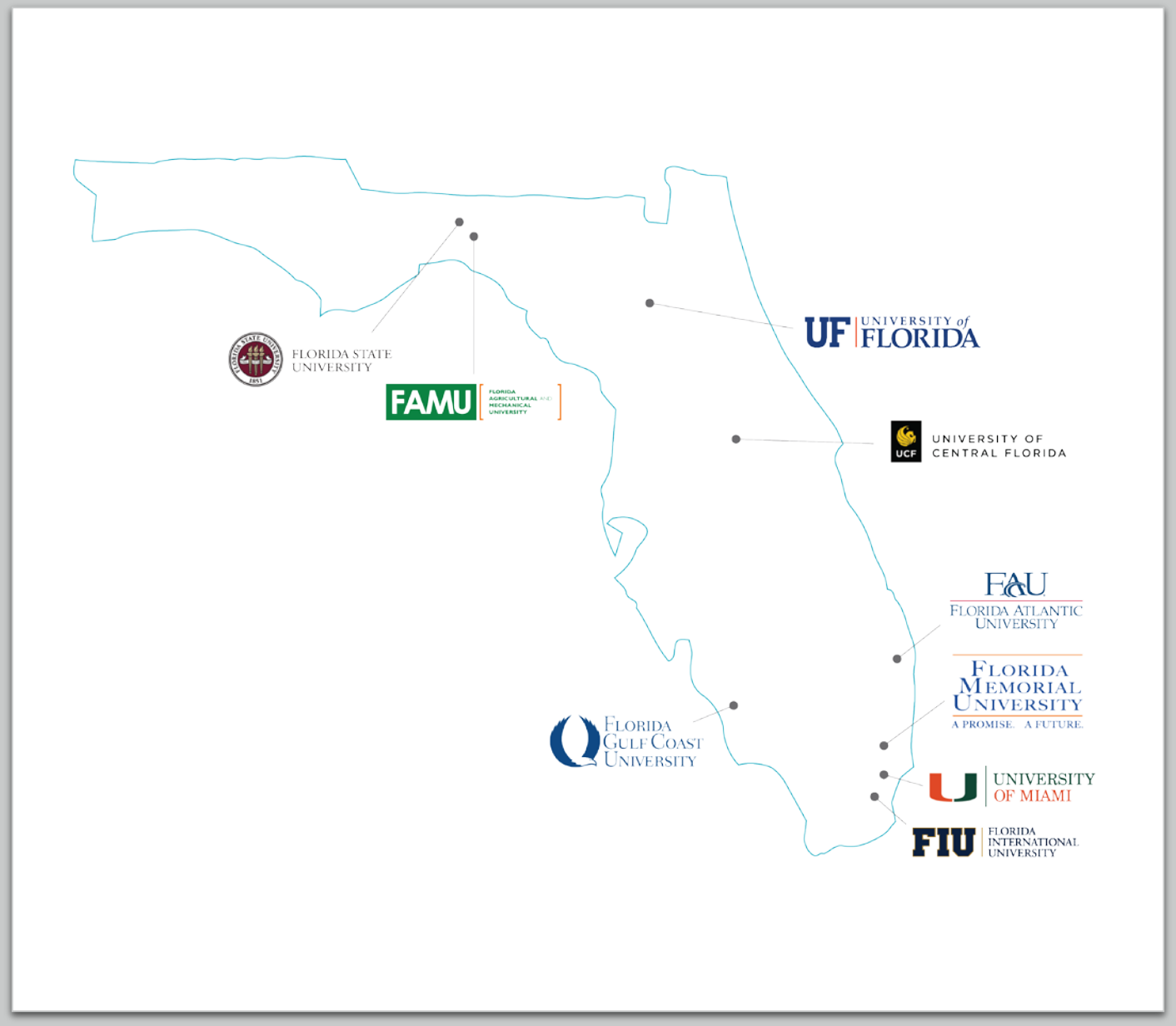
National Academies of Sciences, Engineering & Medicine 2017
https://www.nap.edu/download/24625



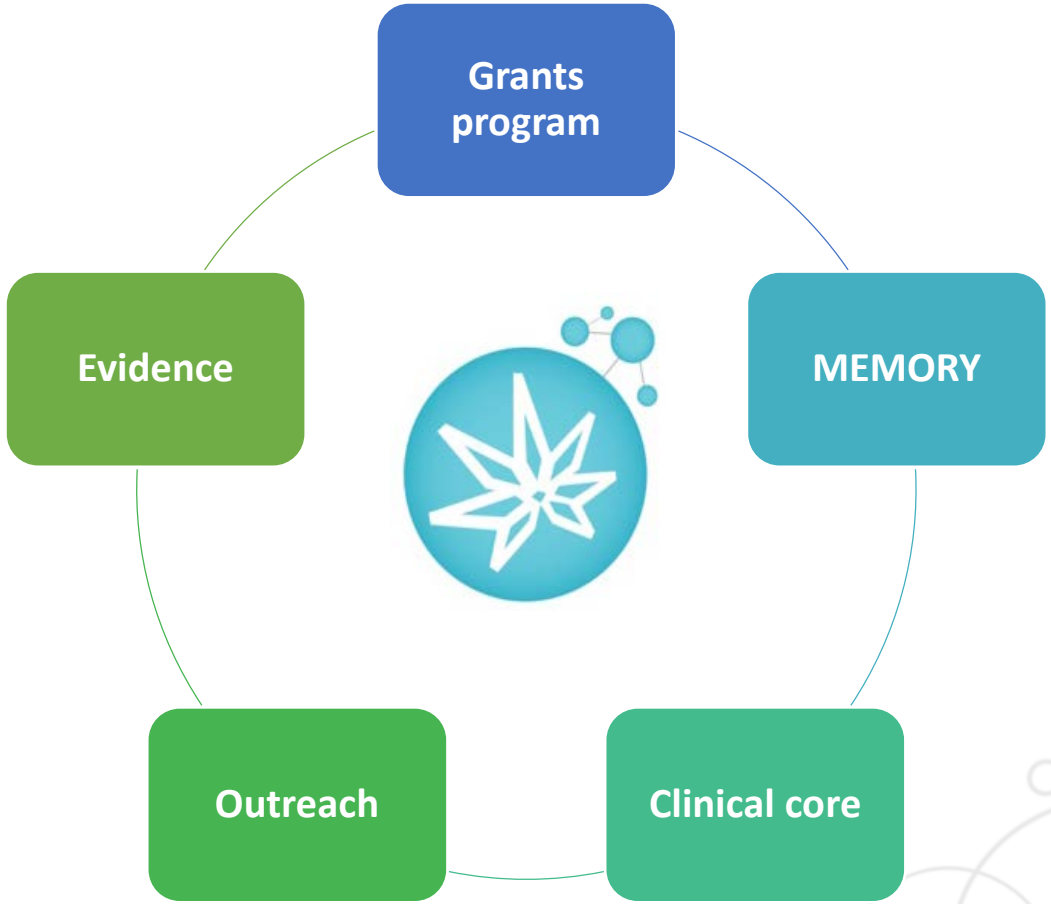
Number of Medical Marijuana Qualified Patients per Month, FL Jan 2018 – Oct 2021

Consortium Structure

- Consortium Board composed of 1 representative from each member institution
- Director serves at discretion of the board
- Funded through direct annual state appropriation
- Consortium has annual reporting requirement to governor and legislature that must include an annual research plan.



Consortium Research Program



- **Grants program:** offered annually to members; research focus based on statutory guidance and the annual Consortium research agenda
- **MEMORY:** a new and unique research data repository available to members
- **Clinical core:** provides infrastructure support for *prospective* studies; about to launch M^3
- **Outreach:** CCORC; newsletters; website, conference exhibits; provider survey
- **Evidence:** develops research priorities; publishes Evidence in Context series and patient info sheets

Grants Program Progress

2019

41 proposals

10 awards
(to 5 universities)

Final reports released

2020

20 proposals

9 awards
(to 5 universities)

Interim reports received

2021

24 proposals

11 awards
(to 5 universities)



The Consortium for Medical Marijuana Clinical Outcomes Research (Consortium) provides awards to support clinical and translational research related to Medical Marijuana (MMJ) to investigators within member institutions.

Research proposals focused on the clinical outcomes of MMJ use, routes of administration, interactions of MMJ with other drugs/medications, Epidemiology studies, human endocannabinoid system and measuring components of MMJ are encouraged.

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



LETTER OF INTENT DEADLINE FEB 1ST, 2022

VISIT MMJOUTCOMES.ORG/RESEARCH FOR DETAILS ON THE RESEARCH GRANTS PROGRAM

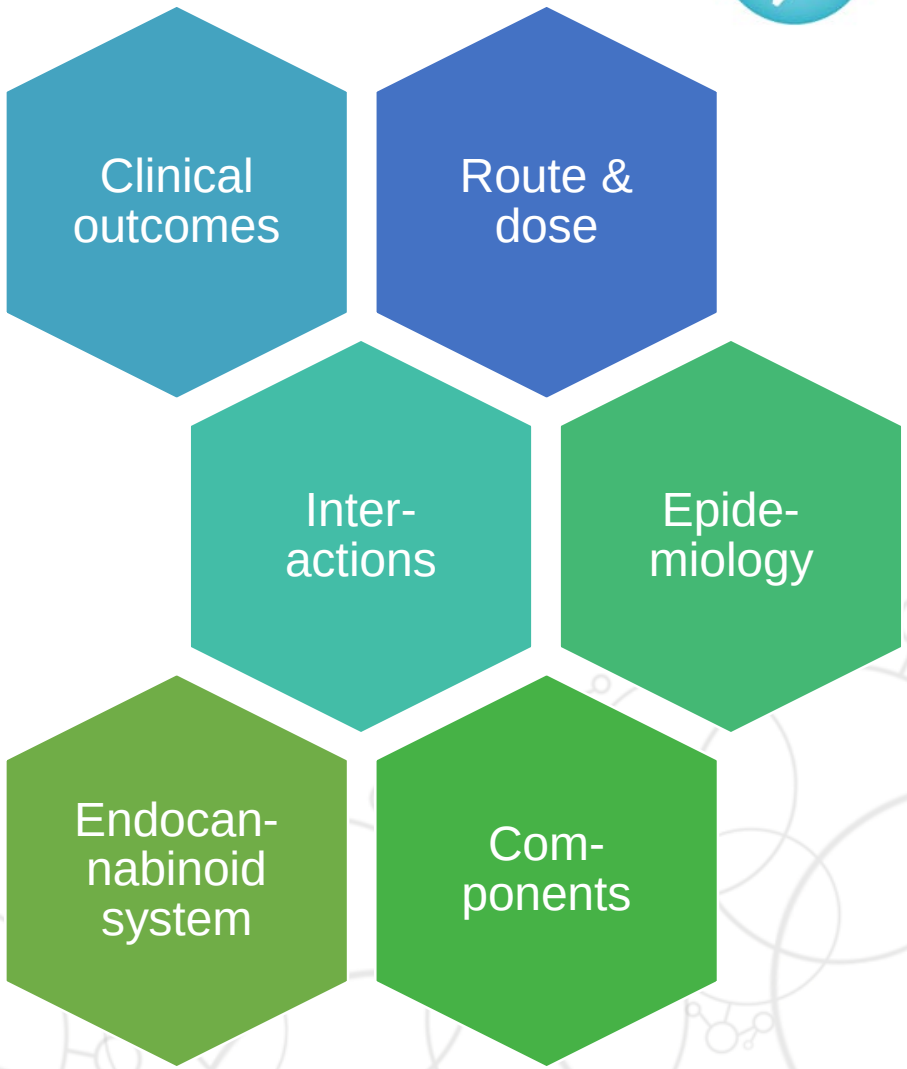
2021 Research Priorities



A Mapping Literature Review of Medical Cannabis Clinical Outcomes and Quality of Evidence in Approved Conditions in the USA from 2016 to 2019

Sebastian Jugl[a, b] Aimalohi Okpeku[a, b] Brianna Costales[a, b] Earl J. Morris[a, b]
Golnoosh Alipour-Haris[a, b] Juan M. Hincapie-Castillo[a, b] Nichole E. Stetten[c]
Ruba Sajdeya[d] Shailina Keshwani[a, b] Verlin Joseph[d] Yahan Zhang[a, b]
Yun Shen[a, b] Lauren Adkins[e] Almut G. Winterstein[a, b] Amie Goodin[a, b]

https://www.karger.com/Article/FullText/515069



Consortium Grants Program: > $1.97 million awarded

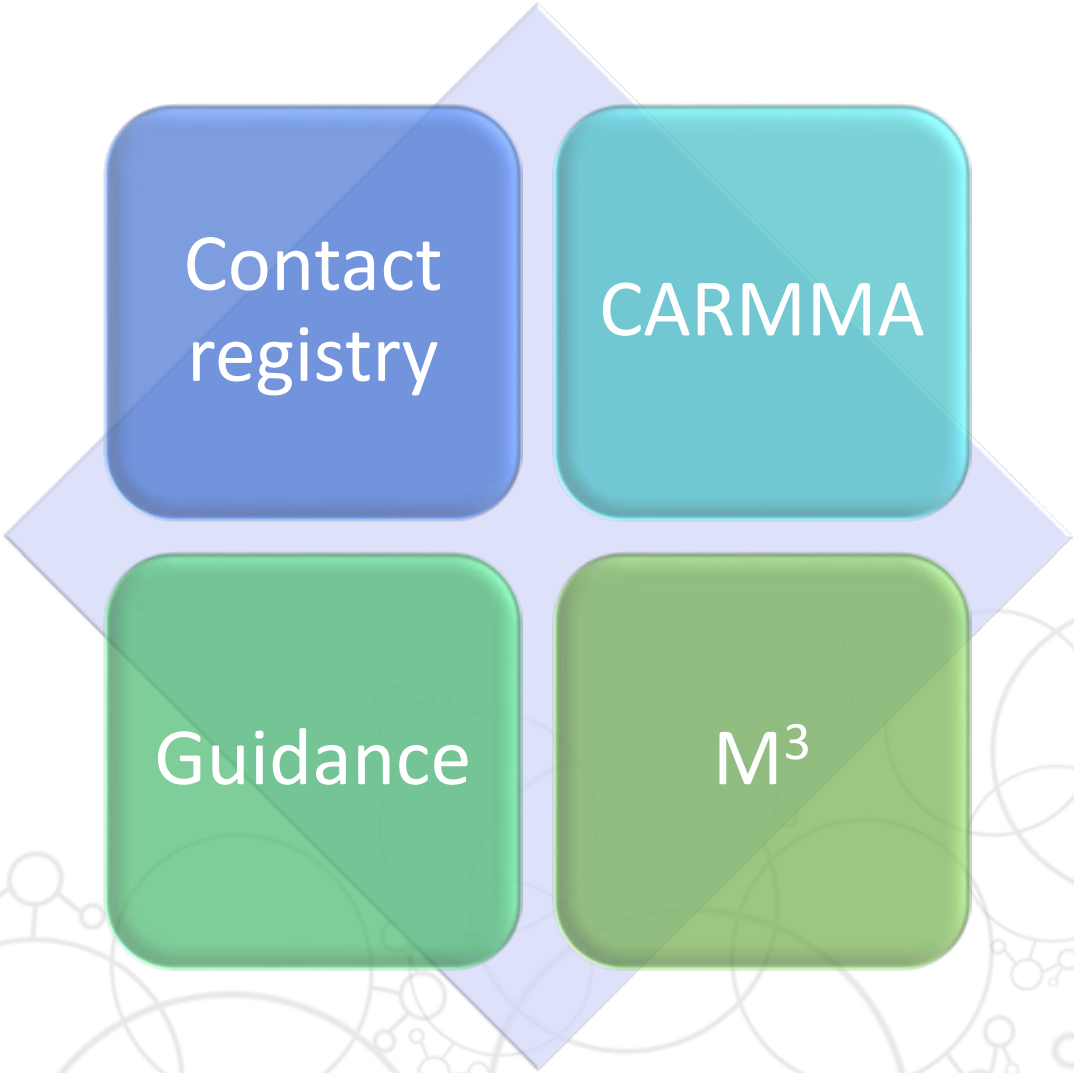
85 proposals

30 grants awarded

Brain & muscle injury	Cancer	Pain of various origins	Negative emotion & photophobia
Medical marijuana access in FL	PTSD	Drug Interactions	Pattern and motivation for use
Anxiety	Olfactory function	Anorexia nervosa	Neuropathy
MMJ/CBD use among Nursing Home Patients	Adverse Drug Events	Role of Endocanna-binoids	Reducing Inflammation

Clinical Core

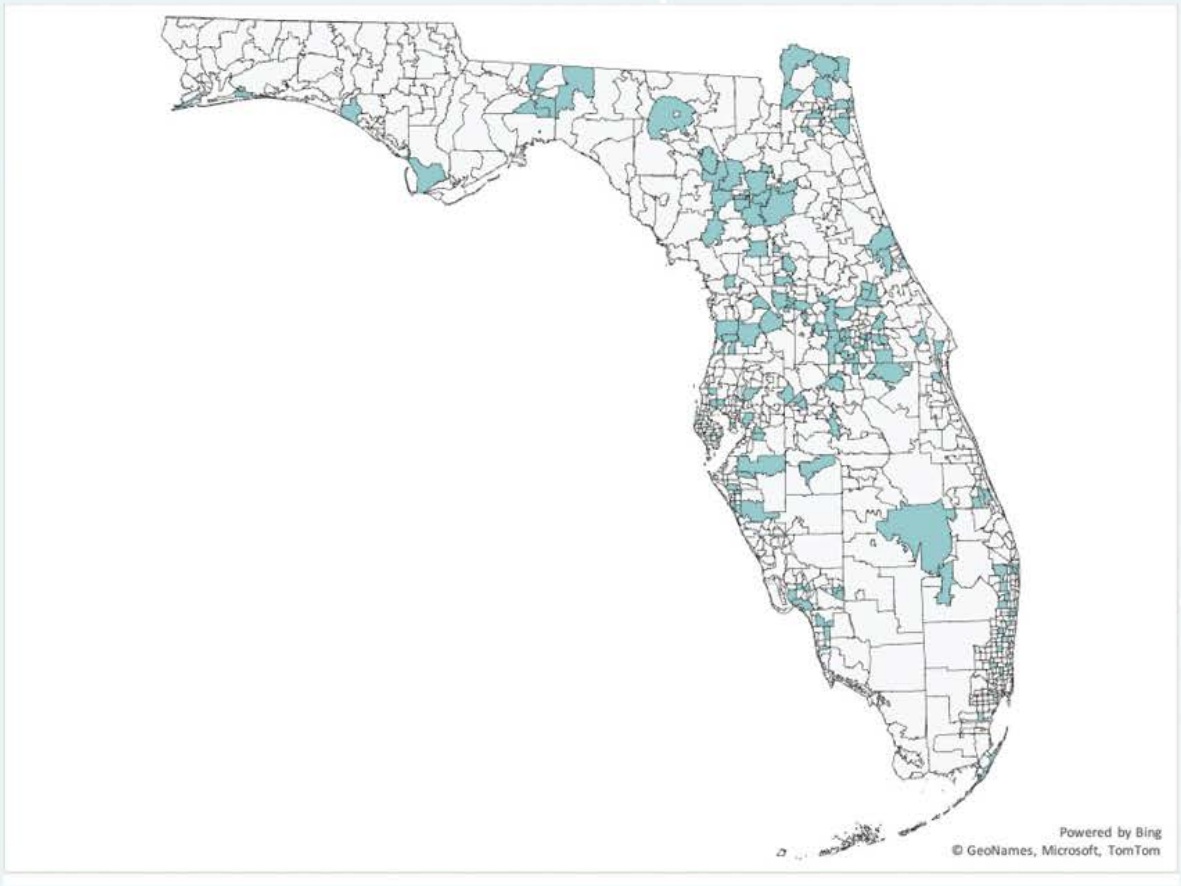
- Patient Contact registry – 439 enrolled participants
- CARMMA – Connecting and advancing research in medical marijuana database of collaborating researchers, clinicians and industries
- Guidance for investigators on regulatory issues involving use of MMJ in research studies
- Medical Marijuana and Me (M^3) – new prospective cohort



Patient Contact Registry (*https://mmjoutcomes.org/registry/*)



Clinics assisting in patient recruitment



Location of registered patients

Medical Marijuana and Me (M^3): Strategic Goals

1) Collect patient-centered data to characterize the experiences and clinical outcomes among a diverse group of medical marijuana users in Florida.
2) Provide access to data and recruitment infrastructure for Consortium researchers.
3) Support high-quality research that can inform state policy and clinician practice and improve patient outcomes related to medical marijuana.



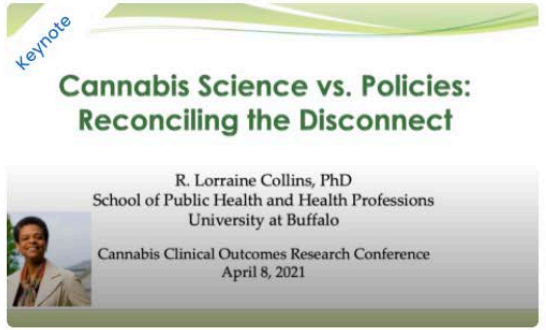
Outreach: CCORC (225 registrations)





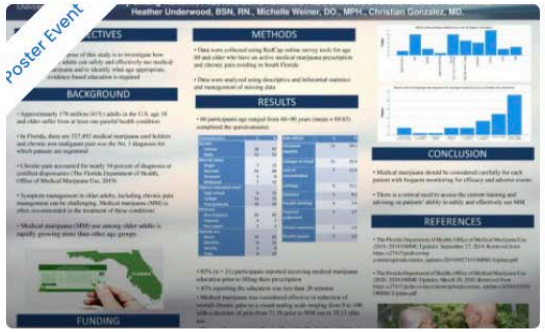
Welcome Address

KEYNOTE April 8, 2021



Cannabis Science vs. Policies: Reconciling the Disconnect

KEYNOTE April 8, 2021



Cannabis and Cannabinoids for Pain and Anxiety-Related Conditions

POSTER SESSION April 8, 2021



Research and Regulatory Barriers

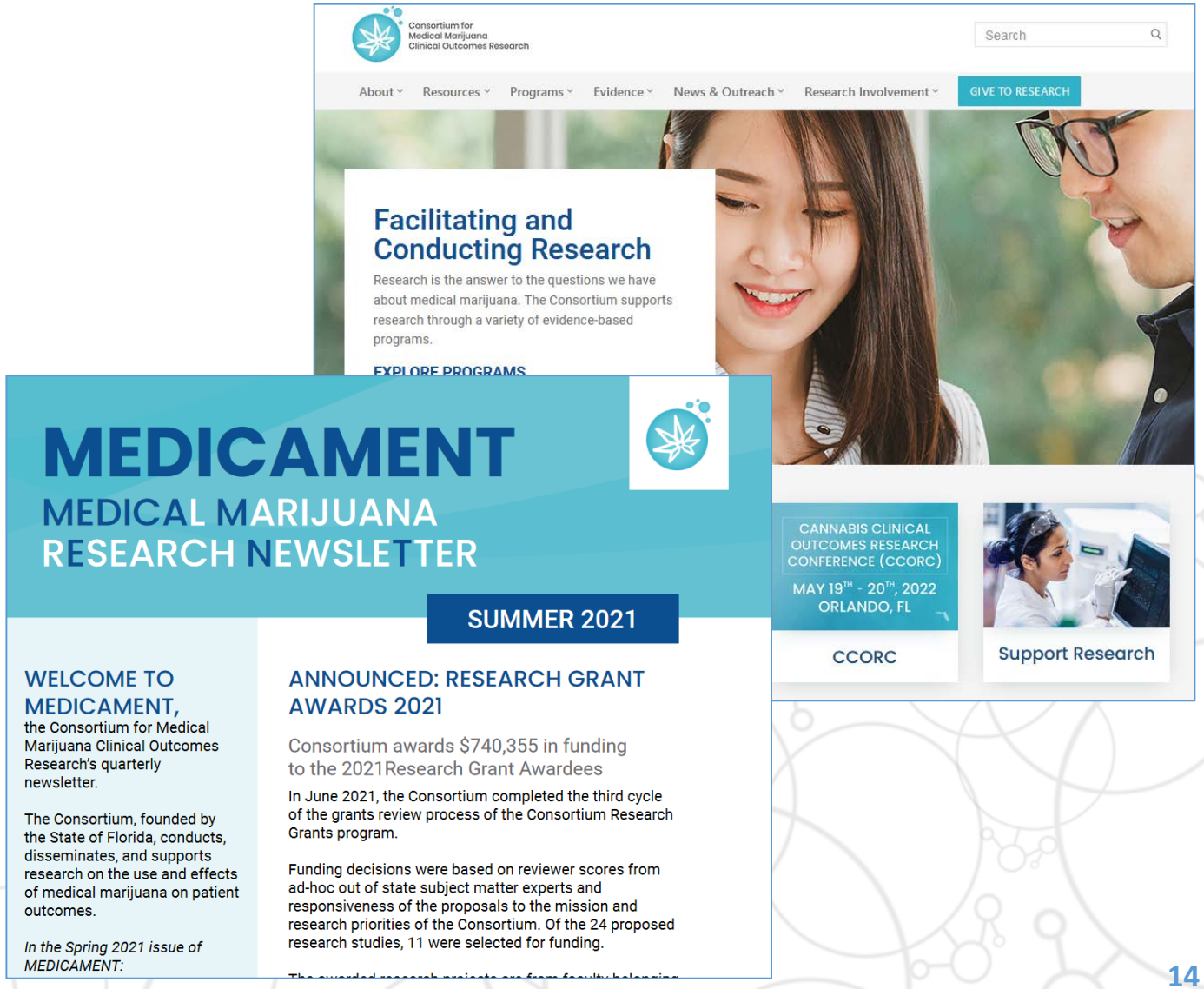
PANEL April 8, 2021

CCORC 2022


CCORC
SAVE THE DATE
CANNABIS CLINICAL OUTCOMES
RESEARCH CONFERENCE
MAY 19TH - 20TH, 2022 | ORLANDO, FL
Learn, Share, and Advance Medical Marijuana Research
MORE INFORMATION AT CCORC.MMJOUTCOMES.ORG

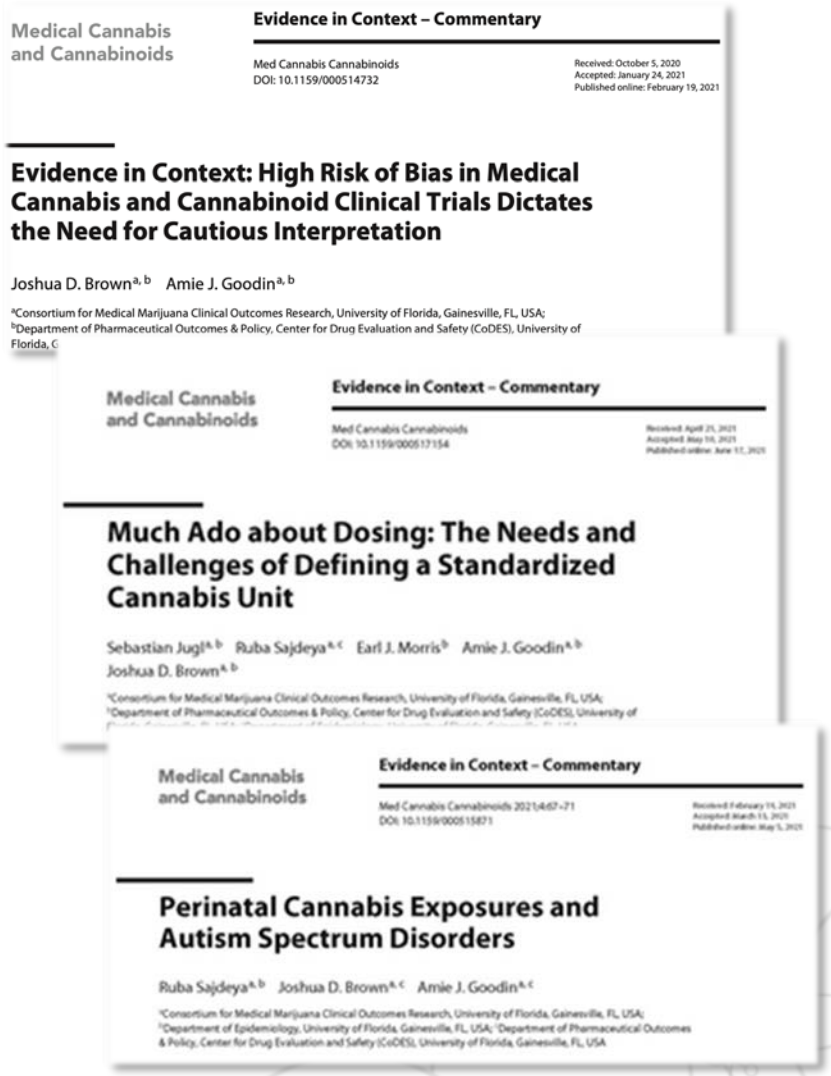
Other Ongoing Outreach Activities

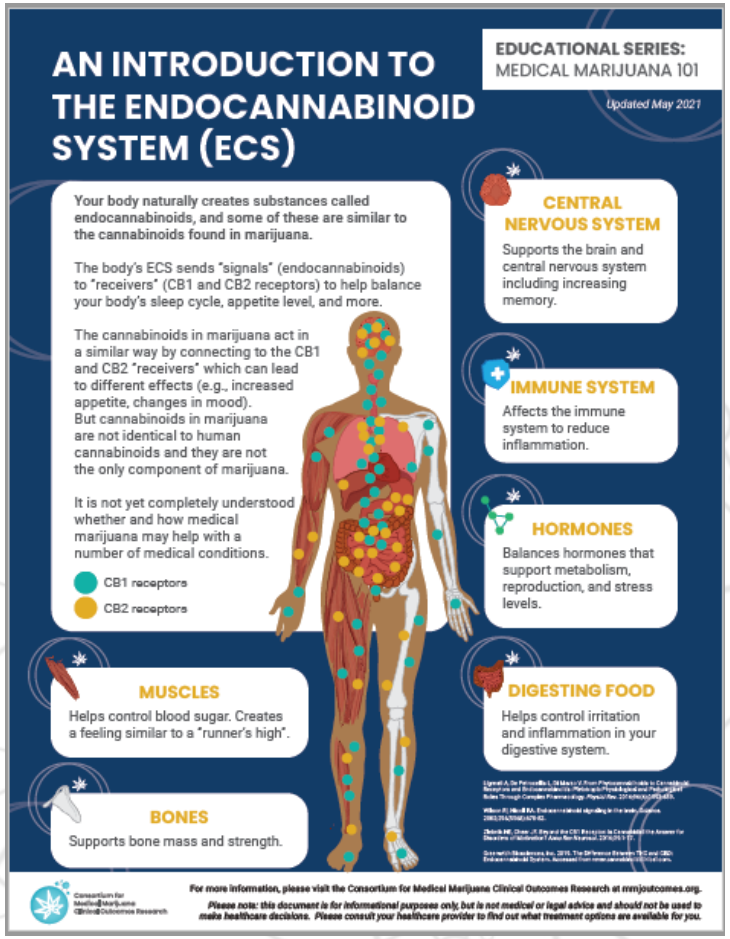
- Media interviews, press releases, participation in conferences
- MEDICAMENT (quarterly newsletter) 8 issues disseminated to 472 individuals
- Website: *mmjoutcomes.org*



Evidence

- New Evidence-in-context series
- Updates on research priorities
- Maintains expert panel
- Patient Info Sheets
  - The endocannabinoid system
  - Ways to consume MMJ
  - MMJ for treatment of anxiety and pain
  - MMJ Interactions with prescription drugs





Regulatory timeline involving medical marijuana research in FL

2014 Compassionate Medical Cannabis Act

381.986(2)(e) requires physicians to submit a treatment plan quarterly to the UF College of Pharmacy for research on the safety and efficacy of low-THC cannabis on patients

July 2016

UF launches website to collect treatment plans

January 2017

Presentation to Health Quality Subcommittee to propose comprehensive Medical Marijuana Surveillance System

July 2017

New Coalition for Medical Marijuana Research and Education

Requirement for data collection for UF removed; DOH to start registry

Registry certification data submitted to the coalition

July 2019

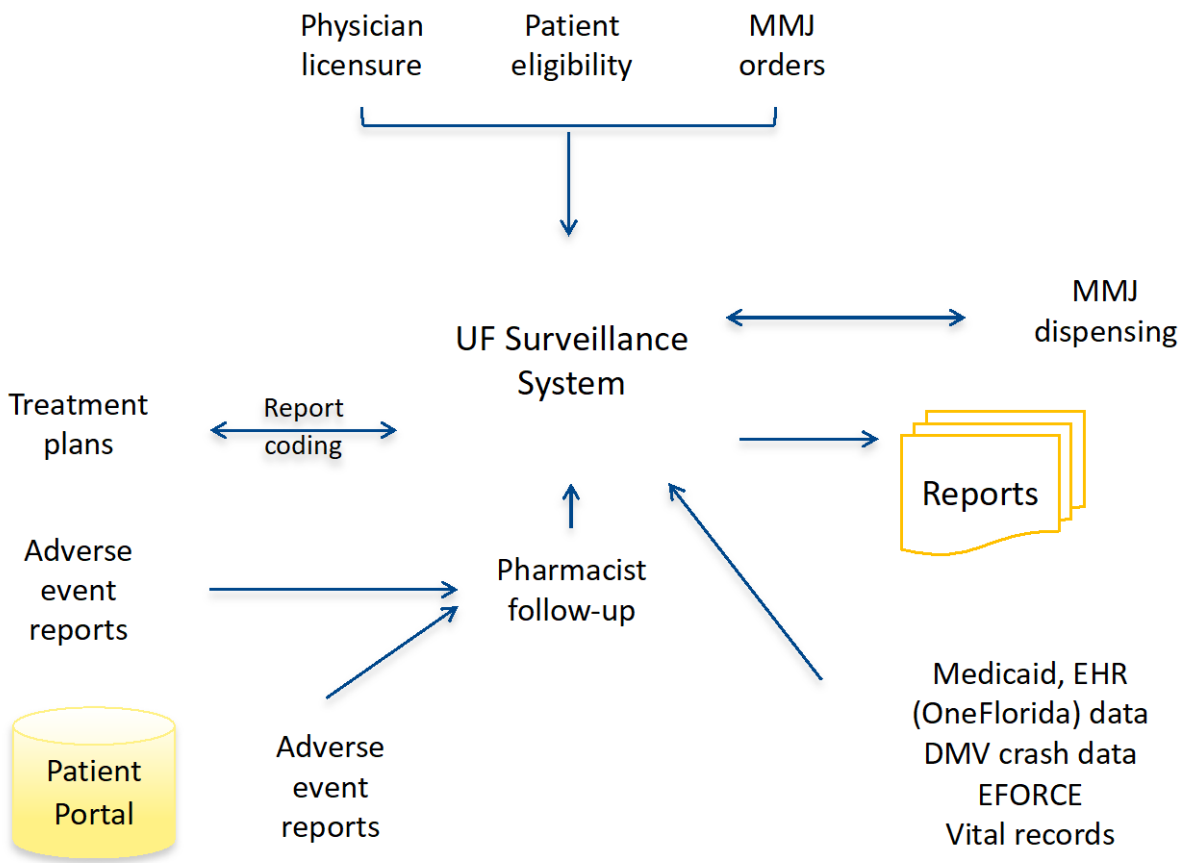
Consortium for Medical Marijuana Clinical Outcomes Research

UF selected by BOG to lead the Consortium

2017 proposal

Real-world evidence on medical marijuana safety and effectiveness requires data that provides

- Detail on medical marijuana use
- Detail on patient clinical history
- Longitudinal follow-up to ascertain outcomes
- Control groups



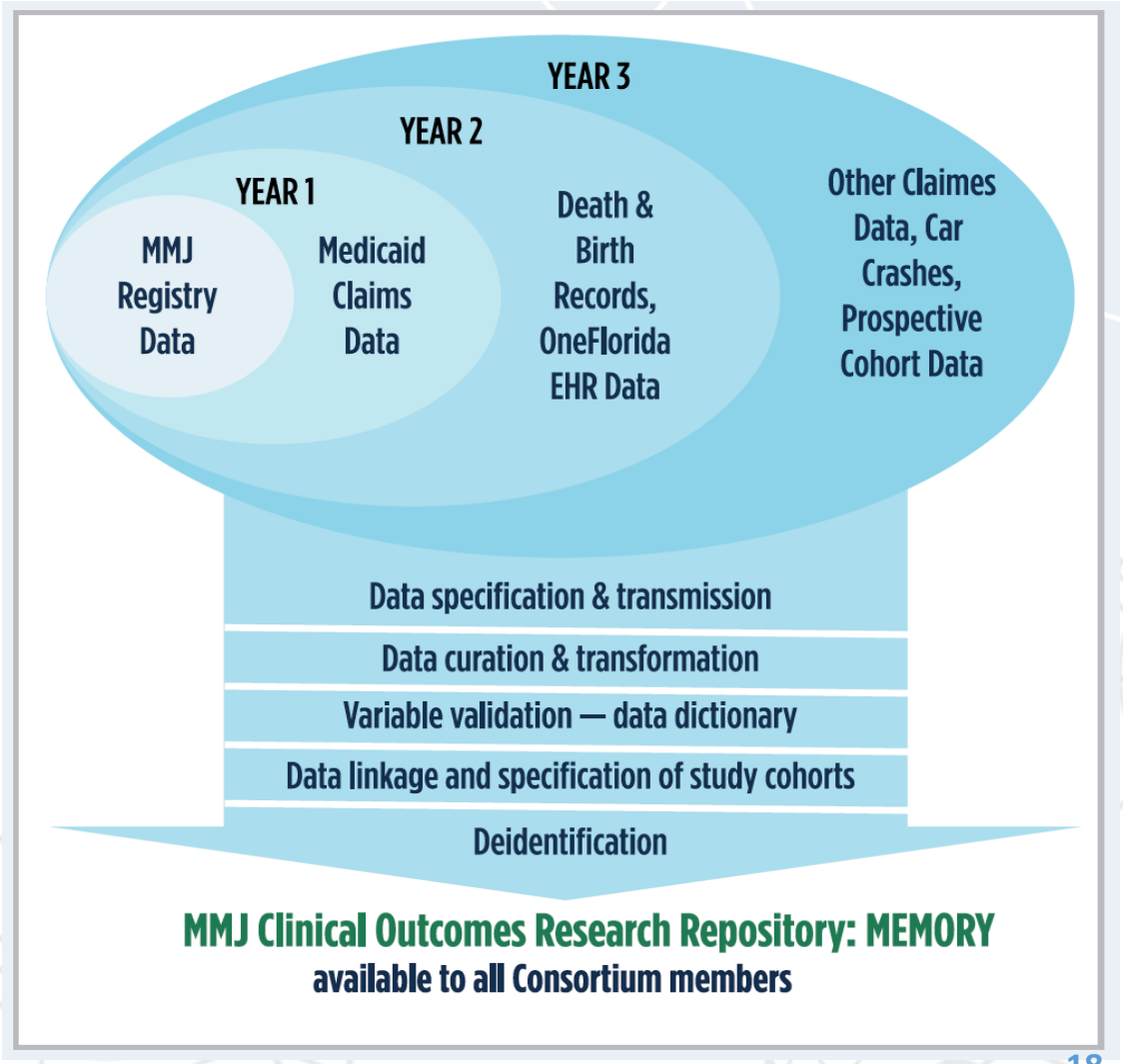
MEMORY: MEdical Marijuana Clinical Outcomes RepositorY

Integrated data repository that captures medical marijuana utilization and clinical outcomes

- Unique resource nationally
- Supported by statute

MEMORY will support:

- *controlled studies* on MMJ effectiveness and safety and
- *active surveillance* to capture emerging safety issues among MMJ users.



MEMORY - Progress

OMMU registry data access per current law

1004.4351 (4)(f): Beginning August 1, 2019 and quarterly thereafter, DOH shall submit for each patient in the registry, the patient's qualifying medical condition, … daily dose, routes of administration, and forms of marijuana certified for the patient.

381.987(2)(h): The department shall allow access to confidential and exempt information in the medical marijuana use registry… to the Consortium

381.987(3)(b): The department shall allow access to the confidential and exempt information pertaining to the physician certification for marijuana and the dispensing thereof, whether in the registry or otherwise to the Consortium …… for the purpose of conducting research regarding the medical use of marijuana.

Request

Broad request for identifiable data (to allow data linkage) with both certification and dispensing detail for all patients in the registry

Vital Stats (BC/DC) Medicaid MMUR

MEMORY – Progress contd.



New communication with DoH/OMMU started in spring 2021, which outlines three steps:

1. OMMU registry access approval – completed: access to a deidentified version of the OMMU registry along with automated queries
2. DUA for provision of deidentified data per 1004.4351 – reviewed and returned by UF with edits to DoH on 8/17/21
3. DUA for provision of identifiable data including dispensing data - pending

Scope of work for MEMORY (reflected in approved IRBs/DUAs)

- Safety of medical marijuana considering variety of
  - sub-populations defined by clinical indication or specific high-risk status (e.g., pregnancy)
  - adverse events (e.g., psychosis, cognitive development, injury)
  - doses, routes, concomitant medications and other factors, such as comorbidities that may alter effects.
- Effectiveness and comparative effectiveness of medical marijuana for a variety of
  - indications (e.g., effects on pain management, anxiety, PTSD)
  - doses and routes and
  - patient characteristics that may affect outcomes.
- Effects of certification standards on access, utilization patterns and outcomes of medical marijuana.
- Active surveillance of emerging health issues and specific products or routes of administration.

Consortium Staff



Almut G. Winterstein, RPh, PhD, FISPE
Consortium Director



Robert L. Cook, MD, MPH
Consortium Associate Director



Amie J. Goodin, PhD, MPP
Faculty Lead, Evidence



Yan Wang, PhD
Faculty Lead, Clinical Core



Josh Brown, PharmD, MS, PhD
Faculty Lead, MEMORY



Jeevan Jyot, PhD, PMP
Program Coordinator



Anna Shavers, MPA
Communications Specialist

Consortium Board Members



William Anderson, PhD (Chair)

Florida International University



Martha S. Rosenthal, PhD (Vice Chair)

Florida Gulf Coast University



Charles A. Weatherford, PhD

Florida A&M University



Ximena Levy, MD, MPH, CIP

Florida Atlantic University



Max. C. E. Orezzoli, PhD

Florida Memorial University



Eric H. Holmes, PhD

Florida State University



Timothy Gilbertson, PhD

University of Central Florida



Roger B. Fillingim, PhD

University of Florida



Jacqueline Sagen, PhD, MBA

University of Miami