## Center for Medical Cannabis Research Legislative Update



## December 2023



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#### Origination of CMCR

On July 1, 2023, the University of Utah established the Center for Medical Cannabis Research (CMCR) after the Utah State Legislature approved House Bill 230. The bill creates invaluable opportunities to study the use of medical cannabis in Utah and to gain vital information surrounding its risks and benefits.

The approval of H.B. 230 demonstrates intentional effort by the Utah legislature to elevate understanding of cannabis as a potentially beneficial health tool for Utahns. It also recognizes constituents' interest in utilizing medical cannabis for treatment while also protecting public health.

The CMCR is an integral part of creating an advantageous feedback loop to advance medical cannabis research, thereby providing knowledge and education that support:

- Utah patient and provider interactions
- Utah State Medical Cannabis Program policy updates
- Innovative, outcome-driven translational research that contributes to cannabis research nationally and worldwide

#### Charge of CMCR

By cultivating research opportunities for experts within the University of Utah and among other academic and research institutions across Utah, external partners, and community stakeholders, we foster a research-based approach that impacts public health and educates stakeholders on the therapeutic benefits and safe use of cannabis and cannabis products.

- The CMCR will lead the advancement of cannabis research through funding grants and sponsored collaborative projects, creating a community of multidisciplinary faculty who generate translational understanding of how cannabis impacts public health.
- The CMCR will inform the statewide application of cannabis research by providing continued support and understanding of current and future cannabis science.
- The CMCR will build a comprehensive educational platform uniting patient, provider, and policymaker knowledge surrounding cannabis as a therapeutic tool.
- The CMCR will initiate DEA Bulk Manufacturing licensing to become a provider of pharmaceutical grade medical cannabis product for research purposes, thereby improving quality and upholding standards among scientists and community stakeholders.

#### High Level Accomplishments

Following approval of H.B. 230 in May 2023, the CMCR launched into immediate action to ensure the following high-level structural requirements and directives were prioritized and executed:

- Onboarded a senior manager, Valerie Ahanonu
- Appointed an interim director, Gerald Cochran, PhD, MSW
- Identified steering committee and external advisory board members
- Contributed to the Utah DHHS Medical Cannabis Program Annual Report
- Released a Request for Applications (RFA) for the CMCRs first seed grant competition
- Initiated a collaborative project with the Medical Cannabis Outcome Research and Evaluation (MCORE) Center

#### Immediate Future Funding Needs

The CMCR has evaluated the landscape of current cannabis research centers and the national approaches to developing a sustainable medical cannabis research center. The CMCR has identified additional funding opportunities that would ensure success and stability, including the following:

- Identify and hire a medical cannabis research expert to serve as the CMCR faculty director.
- o With funding support, the CMCR can initiate a national outreach campaign to engage medical cannabis researchers that demonstrate the academic prowess and leadership capabilities necessary to solidify Utah as a cannabis research leader.
- Increased pilot and feasibility grant funds which will allow the CMCR to:
- o Address the deficit in research product supply.
- o Support the regulatory costs that impede researcher interest and limit effective research.

#### Conclusion

With continued support from legislators, stakeholders, and grants, the CMCR will promote deeper understanding and advancement of medical cannabis research that is a resource for developing medical cannabis guidelines and policy provisions in Utah.

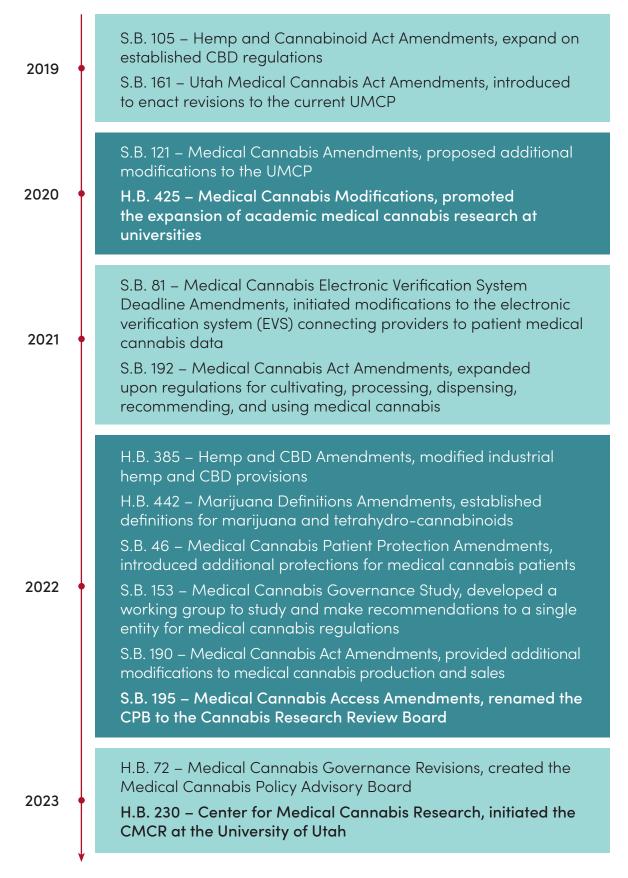
#### What is medical cannabis?

As cannabis use has become more broadly accepted, patients, clinicians, and policymakers have worked to establish criteria for medical cannabis treatment solutions and access within federal regulations. Approaches to enacting such routes has been met through state decriminalization, thereby allowing the introduction of medical cannabis program measures. Medical cannabis refers to using the cannabis sativa-L plant and its constituent chemicals primarily  $\Delta$ -9 tetrahydrocannabinol (THC) and cannabidiol (CBD)—in medical dosing forms to treat specific medical conditions and/or disease symptoms. While the dynamic nature of the components of the cannabis plant and federal scheduling of cannabis impose barriers to the indepth research required to identify consistent dosing and use guidelines, efforts by researchers and legislative bodies continue to support the potential for medical cannabis as a mechanism to address several conditions requiring supportive options within their standard of care models.

#### **Historical Timeline**

Utah's legislative road to developing access and protections for medical cannabis patients has been a bipartisan effort to promote a research-based medical cannabis program that improves understanding of the potential for medical cannabis as a therapeutic tool.





### LETTER FROM THE INTERIM DIRECTOR

The state of Utah is among the newest states in the US to allow cannabis to be recommended for a variety of health care conditions. With the passage of H.B. 230 the Center for Medical Cannabis Research (CMCR) was initiated. CMCR is a statewide research center that works with universities across Utah, with its home at the University of Utah. This concentrated legislative movement places the state of Utah in an excellent position as a leader for health sciences research and discovery.

In the five months the CMCR has been in operation, a number of activities have been underway to form a foundation for the center's growth and to establish it as a foremost leader in medical cannabis research and development. Highlights of notable activities include the following:

Hiring a Senior Program Manager: The first item of business the CMCR accomplished was conducting a search for an administrative leader to initiate the center's work. The CMCR offered the position to its most qualified and dynamic candidate, Valerie Ahanonu. Mrs. Ahanonu came to the CMCR from a long and impressive career in clinical research management and rich experience in plant medicine policy and advocacy. She has a deep passion for the topic of medical cannabis research and possesses a vision for the center that has rapidly and strategically brought forth its organization and a trajectory centered on success in multiple areas.

Pilot Grant Program: A central tenant of the CMCR mission is to support medical cannabis research across all universities in the state. CMCR leadership moved quickly in launching its pilot grant funding program, making grants available to researchers across Utah. The pilot program offers three \$50,000 awards. With topical and methodological flexibility, applicants can propose pilot projects that will generate needed preliminary data and have a strong potential for larger-scale funding from organizations such as the National Institutes of Health, Food and Drug Administration, Centers for Disease Control and Prevention, national foundations, or similar sponsors with the resources to make significant research investments.

Patient and Health Care Professional Educational Materials: An additional area of focus from the CMCR has been developing educational materials about medical cannabis for patients and health care professionals. Clinical guidance materials are already available for things like dosing and managing of health conditions. The CMCR noted a lack of accessible training materials related to clinical conversations about medical cannabis. Materials now being produced by the CMCR will educate patients, providers, and pharmacists on how to start those conversations.

These examples of CMCR activities are only a small picture of the exciting work currently underway at the center. These activities are helping the center build traction for advancement and for future milestones. The CMCR is working closely with University of Utah leadership to position the center for hiring an inaugural director. The scope of the search will be national. It will target the foremost experts in medical cannabis.

Altogether, the CMCR is a significant investment by the Utah legislature in advancing medical cannabis science and clinical practice. The center's leadership and affiliated faculty enthusiastically invite you to learn more by reading the following report, visiting our website, and getting involved in the important work that is in motion.

Sincerely,

Muald T. Corl

Jerry Cochran, PhD, MSW Professor of Internal Medicine, Division of Epidemiology Interim Director Center for Medical Cannabis Research Spencer Fox Eccles School of Medicine at the University of Utah

### Mission

The mission of the Center for Medical Cannabis Research (CMCR) is to promote methodologically sound research evaluating the safety and efficacy of cannabis and cannabis products used with therapeutic intent.

#### CMCR Organizational Structure

The CMCR has taken a timely approach to identify experienced leadership, staff, committees, and board members interested in its operational success. By engaging a multidimensional and innovative team of people, we seek to build a center that solidifies Utah as a leader in medical cannabis research. Unless otherwise noted, the following are University of Utah employees.

- Leadership and Staff
- o Interim Director– Gerald Cochran, PhD, MSW; Professor of Internal Medicine and Director of Research for the Program on Addiction Research, Clinical Care, Knowledge, and Advocacy; Division of Epidemiology
- o SVPHS Research Unit Staff, Senior Manager– Valerie Ahanonu
- Steering Committee Members
- o Bruce Bugbee, PhD– Director of the Crop Physiology Laboratory and Professor of Crop Physiology; Utah State University Department of Plants, Soils and Climate
- o Deborah Yurgelun-Todd, PhD– Professor of Psychiatry and Vice Chair of Research; Huntsman Mental Health Institute
- o Guangzhen Wu, PhD– Assistant Professor, Department of Sociology
- o Karen Wilcox, PhD– Professor and Chair, Department of Pharmacology and Toxicology; Department of Biomedical Engineering
- o Meeyoung Min, PhD, MSW– Associate Professor and the Belle S. Spafford Endowed Chair in Women and Families, College of Social Work
- o Michael Moss, MD, FAACT– Medical Director, Utah Poison Control Center; Assistant Professor, Department of Emergency Medicine
- o Misty Smith, PhD– Co-investigator, Anticonvulsant Drug Development (ADD) program; Research Assistant Professor, Department of Pharmacology & Toxicology; Assistant Professor in the Oral Biology, Medicine, and Pathology Section of the School of Dentistry
- o Perry Fine, MD– Professor of Anesthesiology; faculty in the Pain Research Center; and Attending Physician in the Pain Management Center
- o Sarah Ponce, RN, MS– Registered Nurse with the Compassionate Use Board and the Utah Department of Health and Human Services (DHHS)

- External Advisory Board Members
- o Representative Jennifer Dailey-Provost, MBA– Utah House of Representatives 22nd district, PhD Candidate, Division of Public Health
- o Richard Oborn– Director, Center for Medical Cannabis, Utah Department of Health, and Human Services (DHHS)
- o Russell H. Cashin, PhD, CBGT– Adjunct Professor of Psychology, Mohave Community College; and Faculty Instructor, Utah Tech University Continuing Education

#### Milestones

Following legislative approval, funding for the CMCR began on July 1, 2023. Accomplishments of the center thus far include the following:

- The SVPHS Research Unit assembled cannabis-focused researchers and DHHS representatives to introduce the center and gather input.
- Conducted preliminary landscape analysis of other medical cannabis centers nationwide.
- Hired and onboarded an administrative senior manager, Valerie Ahanonu, to oversee development and operations.
- Appointed an interim faculty director, Gerald Cochran, PhD, MSW.
- Convened a steering committee and conducted meetings within the five-month oversight period.
- Met with key collaborators, including DHHS and legislators to understand the scope of the provisioned requests noted in H.B. 230.
- Established communication channels, including a website, newsletter, and email listserv.
- Released the CMCRs first pilot RFA which will provide funding for three seed grant awards that promote innovative medical cannabis research studies from institutions of higher learning in Utah.
- Partnered with the University of Utah Genetics Science Learning Center (GSLC) to begin developing research-informed tools that support educating the public and providers on the therapeutic use of cannabis.
- Initiated collaborations with the Eccles Library Reference and Research team to outline cannabis research literature review services.
- Disseminated a call for academic researchers throughout Utah institutions to join the CMCR faculty of multidisciplinary researchers via the CMCRs newsletter.
- Began outlining a data-linking project in collaboration with the MCORE, which evaluates patient experiences within the Utah State Medical Cannabis Program. The MCORE's SUBLIME study will provide invaluable feedback that supports understanding of the effectiveness of the current program policies. It will also inform updates to improve patient experiences.
- Established a working group to begin applying for the NIH Resource Center for Cannabis and Cannabinoid Research notice of funding opportunity (NOFO) released October 26, 2023.

#### Communications

The CMCR launched its website in September 2023.

The CMCR has also initiated a monthly newsletter focused on providing stakeholders with vital information regarding cannabis research locally, changes in cannabis regulations, research in the national forum, and funding opportunities for medical cannabis research.





The CMCR has begun to meet this urgency by implementing projects that address some of these directives on an ongoing basis.

#### • Literature Review

The CMCR has conducted several meetings with the Spencer S. Eccles Health Sciences Library (EHSL) at the U to outline and validate an approach to conducting literature reviews of current and past cannabis research publications with the goal of creating an accessible library of evidence-based information.

#### • Public Education/Outreach

In partnership with the Genetics Science Learning Center (GSLC), a University of Utah education center that develops consumer-driven science education materials, the CMCR is working on tools to improve understanding of medical cannabis science. The result will be research-based videos and digestible content for general audiences.

#### Annual Symposia

The CMCR will host its first annual symposia on January 30, 2024, at the University of Utah S.J. Quinney College of Law. In addition to inviting an expert keynote, we will gather researchers across Utah interested in medical cannabis. The goal is to create collaborative conversations that generate translational study opportunities to advance cannabis research in the state.

#### **Pilot and Feasibility Projects**

With limited, competitive funding for medical cannabis research, the continued support of donors, the state legislature, and federal funding agencies is critical to ensuring the advancement of cannabis research. To address the disparity within the funding space, the CMCR will serve as a source to seed funding for researchers in Utah interested in engaging in medical cannabis research.

The CMCR released its first RFA on October 26, 2023, calling for applications that build upon the mission of the CMCR and support early research collaborations. Such collaborations are needed to develop further competitive grant applications and commercialization opportunities.

The center will award three seed grants in the amount of \$50,000 each.



Scan to visit the CMCR home page.

## SNAPSHOT OF UTAH MEDICAL CANNABIS RESEARCH

Barriers to cannabis research exist. A consistent cannabis supply, measuring participant dosing, and placebo controls, are only a few.

Despite the barriers, Utah researchers have done deep reviews and identified study models to expand translational knowledge. Cannabis study spans many research disciplines. From in vivo research to neurology and social sciences, the resulting discoveries will help guide appropriate application of medical cannabis.

#### University of Utah Cannabis Research Highlights

Effect of Cannabinoids on Brain Metabolites: A Review of Animal and Human Studies Jiyoung Ma, PhD, In Kyoon Lyoo, MD, PhD, MMS, Perry F. Renshaw, MD, PhD, MBA, and Deborah A. Yurgelun-Todd, PhD

This review summarizes the effects of two major cannabinoids, delta-9-tetrahydrocannabinol and cannabidiol, on brain metabolites. It focuses on human studies applying 1H-magnetic resonance spectroscopy (MRS) and animal studies using more invasive and direct methods to measure brain metabolites associated with glutamatergic neurotransmission or glial and neuronal functions. Although studies are limited in number, current evidence suggests that two major cannabinoids, each thought to have differential effects on the brain, may alter the brain metabolite levels in distinct ways. Potential limitations of present studies of cannabinoids on brain metabolites and suggestions regarding future studies are also discussed. The issues clarified in this review may contribute to designing future studies of cannabinoids on brain metabolites.

# Cannabidiolic acid exhibits entourage-like improvements of anticonvulsant activity in an acute rat model of seizures

Misty Smith, PhD and Cameron Metcalf, PhD

Cannabidiolic acid (CBDa) is physically and chemically unique from cannabidiol (CBD). Its chemical instability poses challenges for potential clinical usefulness. Using magnesium ions to stabilize two cannabidiolic acid-enriched hemp extracts (Mg-CBDa and Chylobinoid, the latter of which also contains minor cannabinoid properties), researchers compared their antiepileptic activities with CBD in the maximal electroshock seizure test (MES) in rats. The results showed that CBDa-enriched extracts provided protection against seizures, but they were not more effective than CBD. Chylobinoid, which had lower CBDa content, was more effective than Mg-CBDa. Test compounds should be compared by sub-chronic dosing in the MES test in order to measure safety and how the body interacts with these compounds. CBDa should be evaluated in drug resistant and chronic animal models of epilepsy.

**Impact of Recreational Cannabis Legalization on Adolescent Cannabis Use in Washington State** Guangzhen Wu, PhD and Anya Biskupiak, PhD

An important public concern about the impact of recreational cannabis legalization is how it may affect adolescent cannabis use. Prior research on this issue has primarily focused on implications of medical cannabis legalization for adolescents. Those studies used data that cover a relatively short post-legalization period. This study extends this line of research by examining the relationship between recreational cannabis legalization and adolescent cannabis use in Washington State. It uses National Survey of Drug Use and Health (NSDHU) data from 2005 to 2019. Based on a quasi-experimental research design, this study found evidence suggesting that recreational legalization increases adolescent cannabis use and cannabis initiation. Such findings highlight the need to create a cannabis regulatory environment that minimizes adolescent access to this drug.

#### Utah State University Cannabis Research Highlights

Photons from NIR LEDs can delay flowering in short-day soybean and Cannabis: Implications for phytochrome activity

Paul Kusuma, PhD, Mitchell Westmoreland F., PhD student and Bruce Bugbee, PhD

Photons (tiny particles of electromagnetic radiation waves) during the dark period delay flowering in short-day plants (SDP). Red photons applied at night change phytochromes (parts of the plant that detect light) to the active far-red absorbing form (Pfr), leading to delays of flowering. Far-red photons (greater than 700 nm) restart flowering when applied after a pulse of red photons during the dark period. However, far-red photons at a high rate over time delay flowering in sensitive species. Routinely, this response occurs because phytochrome-red (Pr) absorbance is not zero beyond 700 nm. When nighttime photons were applied from near infrared (NIR) LEDs (peak 850 nm) over a 12 h dark period, flowering was delayed in Glycine max and Cannabis sativa (two photosensitive species) by 3 and 12 days, while the change of photons from NIR LEDs was increased. This suggests that long wavelength photons from NIR LEDs can activate phytochromes (convert Pr to Pfr) and thus effect plant development.

#### Utah Cannabis Research Active Clinical Trial

A Multicenter, Double-blind, Placebo-controlled, Randomized, Parallel-group, Phase 2b Study in Treatment-seeking Patients With Cannabis Use Disorder to Assess the Efficacy, Safety, and Tolerability of AEF0117 in Reducing Cannabis Use Cedar Clinical Research by Numinus Paul Thielking, MD

Cannabis use is increasing and will only further escalate with legalization of recreational and medical cannabis use in western countries. Approximately 9% of cannabis users will become addicted. The number goes up to about 17% among those who start using cannabis as teenagers and 25 to 50 % among those who smoke cannabis daily. Consequences of cannabis abuse in the most prone population (14-25 years of age) are extremely serious. They may include addiction, altered brain development, poorer educational outcomes, cognitive impairment, lower income, greater welfare dependence, unemployment, and lower relationship and life satisfaction. There are no available drug treatments for cannabis use disorder (CUD). Thus, the development of safe and effective medications for treating CUD is an urgent public health priority. The preclinical effectiveness and available ADMET (Administration, Distribution, Metabolism, Elimination and Toxicology) in animal and human data suggest that AEF0117, an investigational new study drug, could be an efficacious and safe treatment for cannabis abuse disorders. This is a phase 2b, randomized, double-blind, placebo-controlled, 4-arm, parallel-group, prospective, multicenter study. The purpose of this research is to study how AEF0117 influences the potential effects of cannabis in subjects with CUD. AEF0117 acts in the same parts of the brain as THC (tetrahydrocannabinol), the active ingredient of marijuana, and may temporarily alter some cannabis effects. The safety and acceptability of AE0117 has been shown in the clinical studies conducted to date. This study will provide additional data on the effectiveness of AEF0117 on treatment-seeking subjects with moderate to severe CUD.

## OVERVIEW OF CANNABIS RELATED NIH FUNDING

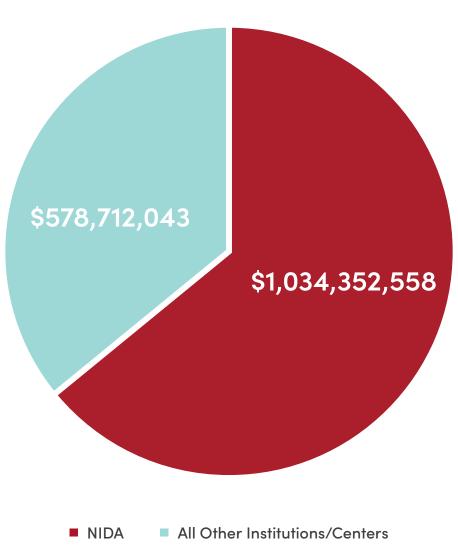
To develop a competitive approach to implementing the CMCR's structural design, the SVPHS research unit has analyzed the current scope of medical cannabis research funding along with comparative overviews of other cannabis centers nationally. Currently the University of Utah ranks 21st in NIH-funded cannabis research with \$13,077,938 received amongst seven principal investigators.

#### NIH Funding Rank for Medical Cannabis Research by Institution Fiscal Years 2019–2023, Direct Costs

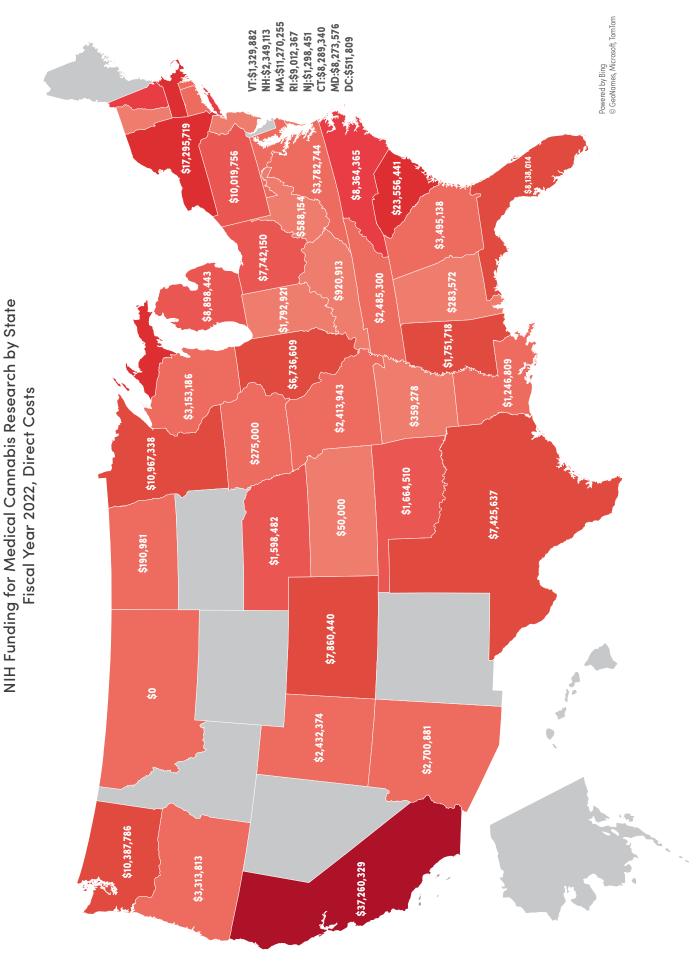
Rank	Organization	Direct Cost
1	MEDICAL UNIVERSITY OF SOUTH CAROLINA	\$59,253,493
2	UNIVERSITY OF MICHIGAN AT ANN ARBOR	\$48,989,788
3	UNIVERSITY OF WASHINGTON	\$40,626,946
4	UNIVERSITY OF CALIFORNIA, SAN DIEGO	\$39,772,540
5	UNIVERSITY OF CALIFORNIA LOS ANGELES	\$34,101,004
6	YALE UNIVERSITY	\$33,851,441
7	JOHNS HOPKINS UNIVERSITY	\$22,392,587
8	UNIVERSITY OF MINNESOTA	\$20,018,375
9	BROWN UNIVERSITY	\$19,961,895
10	UNIVERSITY OF PITTSBURGH AT PITTSBURGH	\$17,917,416
11	NEW YORK STATE PSYCHIATRIC INSTITUTE	\$16,834,900
12	VIRGINIA COMMONWEALTH UNIVERSITY	\$16,603,829
13	UNIVERSITY OF COLORADO	\$16,555,763
14	UNIVERSITY OF MARYLAND BALTIMORE	\$16,376,215
15	ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI	\$15,816,285
16	DUKE UNIVERSITY	\$15,235,172
17	UNIVERSITY OF COLORADO DENVER	\$14,610,188
18	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	\$14,381,918
19	UNIVERSITY OF FLORIDA	\$13,712,470
20	UNIVERSITY OF CALIFORNIA-IRVINE	\$13,539,856
21	UNIVERSITY OF UTAH	\$13,077,938
22	NORTHWESTERN UNIVERSITY AT CHICAGO	\$12,724,873
23	DARTMOUTH COLLEGE	\$12,706,307
24	OREGON HEALTH & SCIENCE UNIVERSITY	\$12,630,386
25	WASHINGTON UNIVERSITY	\$12,520,611

The majority of medical cannabis funding nationally is supported by the National Institute on Drug Abuse (NIDA). States that decriminalized cannabis and implemented centers for research early on are amongst national institutions and centers receiving a large majority of available cannabis research funds.

While NIDA contributes to invaluable research surrounding abuse potential, additional funding support focused on promoting clinical research on therapeutic benefits and standard use practices would help to address the current deficits in guidelines surrounding medical cannabis treatments.



Funding for Medical Cannabis Research by NIH Institutes, Fiscal Year 2019–2023, Total Cost Comparison



#### Fiscal Year 2024 Budget, Project Expenditures, and Justification

The CMCR was allocated a fiscal budget of \$650K for its first developmental academic year. These funds are supported by the Qualified Patient Enterprise for Medical Cannabis Fund. All funds will be managed by the CMCR interim director and senior manager. They will be directed to support strategic planning and meeting discretionary goals established by the steering committee and the legislative requirements as noted in H.B. 230.

Expense description	Total
CMCR Personnel	\$165,000.00
Literature Review and GSLC Education Outreach	\$100,000.00
Pilot Grants	\$150,000.00
Flexible Spending/Legislative Projects	
Travel to Other Cannabis Research Centers	\$8,000.00
Cannabis Research Conference Attendance	\$7,000.00
Faculty Outreach & Engagement	\$30,000.00
DEA Manufacturers Application Strategic Development	\$50,000.00
QMP/LMP Outreach & Engagement	\$20,000.00
Public Communications & Engagement	\$20,000.00
GSLC Supplemental Education Support	\$30,000.00
Clinical Cannabis Research Database Development	\$40,000.00
Events	\$20,000.00
General Operations	\$10,000.00
Budget Total	\$650,000.00

#### Center for Medical Cannabis Budget and Expenditures FY24

In the upcoming year, the CMCR will prioritize efforts to enhance our research capacity. The CMCR plans to focus on our mission and elevate Utah's national cannabis research profile to better serve the people of Utah by the following means:

- Hire a nationally recognized cannabis researcher as faculty director of the CMCR. The CMCR will lead a national search to identify candidates for this position.
- Establish regular communications and faculty outreach events. The CMCR will create a consortium of current and future researchers to serve as an interdisciplinary collective that places Utah at the forefront of cannabis research.
- Seed innovative new research primed to advance understanding of medical cannabis. The CMCR will provide pilot and seed grant funding to researchers spanning the field of cannabis and cannabis related research and foster opportunities to expand the research footprint within Utah.
- Perform literature reviews to understand best practices for medical cannabis science. The literature reviews, in coordination with EHSL librarians, will produce a matrix of research materials that deepen understanding of cannabis science and its therapeutic application.

- In tandem with GSLC, the CMCR will generate research-based educational tools to improve public and provider knowledge about medical cannabis.
- Create partnerships with other established cannabis research centers. Such partnerships will lead to collaborative research and additional grant funding opportunities.
- Aid Utah State University's Department of Plant, Soil, and Climate in applying to the DEA Approved Bulk Manufacturer Growers Program. This program will support whole cannabis plant and cannabis product development for research, leading to opportunities for Utah to support cannabis research nationally.
- Develop an approach to in-human laboratory research to support medical cannabis clinical trials research. By collaborating with experienced human research units, the center will be able to conduct controlled and rigorous clinical trials leading to more comprehensive translational research outcomes.

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