MEETING MINUTES

Consortium for Medical Marijuana Clinical Outcomes Research: B O A R D M E E T I N G

Friday, Sept 16th, 2022 at 1:00 pm

Remote Connection via Zoom & Live

Board Members Present:

William Anderson, Chair Jacqueline Sagen Charles Weatherford Max Orezzoli Dinender Singla Martha Rosenthal Roger Fillingim Peter Holland Board Members Absent: Eric Holmes

Attendees:

Almut Winterstein, Consortium Director Robert Cook, Consortium Associate Director Amie Goodin Yan Wang Jeevan Jyot Sam McKee <u>Students:</u> Sebastian Jugl Alicia Koshevoy Hannah Fechtel Gabriel Spandau Ruba Sajdeya

Opening Remarks

Dr. William Anderson opened the meeting with a welcome to the board members and thanked them for completing their significant financial conflict forms, which are required annually. Dr. Peter Holland from FAU was introduced as the new board member replacing Dr. Ximena Levy.

Overview of Research Plan 2022-23

Dr. Winterstein provided a recap of the research plan for 2022-23, included in the Annual Report submitted to the state in Feb 2022. Proposed research plans for the 5 Consortium pillars for the year were summarized. The Grants Program now in its fourth cycle, has been restructured to additionally fund two-year clinical studies, and the research priorities updated to emphasize a focus on clinical research. Dr. Winterstein proposed following the outcomes of these changes in the grants program over the next year before making any further modifications. MEMORY, an integrated data repository, once established will support controlled studies on MMJ effectiveness and safety, and allow for active surveillance of emerging safety issues among users. The progress around MEMORY has led to the establishment of all necessary DUAs and IRBs except for the DoH IRB and the DUA with DoH/OMMU. Dr. Winterstein shared that based on her most recent conversation with the OMMU director, Chris Fergusson, recommendations will be made to DoH leadership to comply with the statutory mandate to release data to the Consortium. Dr. Winterstein emphasized that MEMORY is at the Consortium's core and that data access from OMMU is needed to meet the intent of the statute that established the Consortium. The Clinical Core will continue to expand its collaborative database CARMMA and its contact registry with 1200 patients, provide guidance on regulatory issues to researchers, and continue its newly launched medical marijuana and me (M3) study. The Outreach pillar builds on the success of CCORC 2022, in planning its third CCORC conference to be held at Orlando in May 2023. Dr. Winterstein reported that distribution of the newsletter MEDICAMENT has reached 700 recipients and increased outreach plans include launch of researcher spotlight series and media interviews with consortium funded researchers, along with participation in other conferences, as well as maintaining a website. The Evidence Core continues to monitor emerging evidence, publish articles and meta-analysis, provide updates on research priorities and leads the scientific program for CCORC. The contract with the Consortium's journal Medical Cannabis and Cannabinoids has been renewed until Dec 31, 2023, to be renewed automatically annually from thereon. The journal is now PMC indexed and Consortium affiliates will receive a 50% discount for publishing open access. There is an interest from the journal in publishing living systematic reviews.

Summary of CCORC '22 and Plans for CCORC '23

Dr. Goodin shared that with 124 attendees, 32 poster presentations and 15 Consortium-funded research presentations, keynote presentations and exhibitors, CCORC 2022 was very successful. Feedback from participant survey responses indicated that the conference was informative, well-organized, professional, a good networking opportunity and relevant to their research or practice. For future conferences attendees requested specific content such as, clinical trial research with cannabis, cannabinoid-specific content, and more animal-model research to understand effects of marijuana on a neurobiological level. Dr. Goodin proposed continuing providing both CME & CPE credits for CCORC 2023. Abstracts and proceedings publications will be forthcoming with the Consortium's journal partnership. Dr. Anderson sought clarification on what extending reach would mean for the conference, and Dr. Goodin responded that the goal is to expand the audience and make it widespread beyond Florida and known at the national stage.

Dr. Singla commented that MEMORY provided a nice platform with a good patient pool, and could be a good resource to researchers and enquired if the consortium had any mechanisms/plans to invest towards research and collaborative efforts to promote clinical research with a preclinical component and vice-versa. Dr. Singla also wanted to know if MEMORY will include a group of control patients and if information such as patient level marijuana/CBD utilization pattern are captured. Dr. Winterstein clarified that MEMORY has not been established yet and is awaiting data from OMMU at FL DoH. Once OMMU provides the data on marijuana exposure, the plan is to link it with existing administrative healthcare claims data, which will facilitate study of clinical outcomes, with the ability to develop control groups. Once the MEMORY database is built any consortium researcher will have access to a deidentified version of this data set as well as M3 data, through a simple application process.

M³ Status Updates

Dr. Cook summarized that the strategic goals for M^3 -Medical Marijuana and Me, including the collection of patient-centered data (in adherence to the state statute) and providing researchers with access to data and recruitment infrastructure. The study design intended to include 500 new and 700 current MMJ users to participate in the survey and to date, a total of 762 users are enrolled. There are 10 recruitment sites which assist by sending out emails to their patient bases. The next steps for the M^3 team are to complete survey enrollment within 3 months and finalize an application process for Consortium-affiliated researchers to request M^3 de-identified data.

Funding Update & FY23 Budget Proposal

Dr. Winterstein shared that the state has funded the Consortium for \$1.5M for this fiscal year and presented the proposed budget for FY23 for a total of \$1,599,377 with plans to use residual carry forward funds from FY22, to cover all the expenses associated with the proposed research plan.

FY23 Budget Approval Vote

Dr. Fillingim motioned to accept the budget, seconded by Dr. Rosenthal. No board member opposed/abstained from the voting. The budget was approved with a unanimous vote.

Closing Remarks

Dr. Anderson thanked Dr. Winterstein for the organization and presentation, and the team. Dr. Winterstein requested board members to send in nominations for the CCORC 2023 scientific program committee. It was agreed to not make any changes to the RFP for the next grants cycle. The next Board meeting will take place in January 2023 to review the Annual Report 2022-23.

Adjournment

Members were thanked for their time, and all agreed to meet in January for the next meeting.