MEETING MINUTES

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

Monday, December 6th, 2021 at 4:00 pm

Remote Connection via Zoom

Board Members Present:
William Anderson, Chair
Martha Rosenthal, Vice-Chair
Roger Fillingim
Jacqueline Sagen
Charles Weatherford
Max Orezzoli

Board Members Absent:
Eric Holmes
Timothy Gilbertson
Ximena Levy

Attendees from Consortium team:
Almut Winterstein, Consortium Director
Robert Cook, Consortium Associate Director
Yan Wang
Joshua Brown
Amie Goodin
Anna Shavers
Jeevan Jyot
Sebastian Jugl
Ruba Sajdeya
Golnoosh Alipour-Haris
Alicia Koshevoy
Hannah Fetchel
Nicole Smolinski

Opening Remarks

Dr. William Anderson of Florida International University (FIU) and Chair of the Board, called the meeting to order at 4:02pm. He welcomed all board members and thanked them for attending and summarized the meeting agenda. He mentioned that Nova University has expressed interest in being part of the Consortium, which they are allowed to as part of the Florida statute, and their formal request is awaited.

Debrief on the House Professions & Public Health Subcommittee Presentation

Dr. Almut Winterstein, Director of the Consortium, debriefed the board on the testimony to the House Professions and Public Health subcommittee, in response to their request for information on the Consortium's accomplishments. It was made clear in the presentation that the Consortium does not have data yet on the medical marijuana (MMJ) dispensing and certification on patient level, which was to be provided by DoH and written in the statute. This data is critical to enable development of MEMORY which will link identifiable MMJ use information to other outcomes databases and provide information on clinical subjects and safety and effectiveness. DoH has been slow in establishing the necessary data user agreements and UF is still awaiting approval and release of the data.

Dr. Winterstein stated that the sub-committee members are fully aware of the current lack of research on clinical outcomes of medical use of marijuana and were very interested in seeing evidence-based results sooner than later. They were assured that such evidence can be generated reasonably quickly if the OMMU registry data is made available to the Consortium and the Consortium is committed to doing so.

Dr. Winterstein summarized that the subcommittee expects the Consortium to generate conclusive evidence on effects of MMJ use including both risk and benefit, conduct effectiveness and safety studies *in humans and not in animals,* and studies on dosing, in particular research on high potency THC. The sub-committee also expressed interest in learning more about accessibility across

diverse SES groups. The members also asked specifically about research on effects of MMJ use in reducing opioid dependency. In keeping with these expectations in terms of outputs, the Consortium focus needs to be on generating these outcomes expeditiously.

Based on the Policy chief's feedback, the Consortium's presentation was well received, and the objectivity in approaching the assessment of the Florida MMJ program appreciated. The subcommittee offered help with expediting the data sharing process with DoH. The OMMU Director has been asked to testify at the subcommittee in January and the policy chief hopes this will help speed the process. An information package of Consortium outputs was also shared with the sub-committee prior to the testimony. A budget release request was received by a political reporter after this presentation and the details of the board approved budgets have been shared. A similar request has been sent to FAMU. Dr. Anderson enquired if the budget release was requested by the house and Dr. Winterstein clarified that it was not by the subcommittee but a reporter.

2022 Grants Program

Dr. Almut Winterstein, shared that based on the reflections and internal team discussions arising from the house testimony and keeping in mind how the Consortium can boost the awaited outputs, some changes are proposed to the 2022 grants program. The major changes included adding focus to the research priority areas, introducing two funding levels, proposing a board review of the letters of intent (LOI), limiting those awarded thrice consecutively and discouraging repetitive research proposals.

In the 2022 RFP, emphasis will be laid on human subjects research and research on the human endocannabinoid system will no longer be a priority area. Epidemiological research areas have been broadened and studies on hemp or hemp products will no longer be part of the 5 priority areas. Two funding levels will be introduced, with 6 proposals funded at $75,000 for one year and two proposals to be funded at $130,000 for two years ($65,000 /year), with a non-competitive renewal for year 2 with year 2 funding dependent upon state support (lawmakers were quizzed about it but two year funding is impossible in the state budget), and an internal board review of progress made towards year 1 goals. Proposals with clinical focus will be prioritized for support for this level and applicants may apply to only one of the two funding categories. A board review of LOIs will be added this year to preselect proposals that align with the consortium mission and priority areas. The grants program timeline for RFP release and major milestones was shared.

Board feedback was invited on the proposed changes. Dr. Anderson felt that the approach was good and demonstrates responsiveness to the subcommittee concerns. Dr. Rosenthal seconded that sentiment and stated that these were great changes. Dr. Fillingim expressed concern that these changes could be viewed simply as tweaks and enquired if an internal discussion by the consortium team deliberated about not inviting basic research completely and invite only clinical contract research. Dr. Winterstein clarified that in parallel to the grants program, Drs. Cook and Wang are launching the prospective cohort that will provide answers on utilization patterns, doses etc. And if the dispensing data from DoH is made available, MEMORY can be built quickly and outputs can be generated rapidly, since AHCA Medicaid data and signed DUA on Vital Statistics are ready. Hence receiving the dispensing data is really important.

Dr. Winterstein also pointed that though the Grants program consumes a large amount of funding received and legislatures demand quick clinical results, the Consortium is in fact aiding and building research capacity at all member universities and is trying to ramp up research in this field. The team does not want to close the door on translational research, but at the same time if translational research is funded going forward, there needs to be a good argument to justify it. Dr. Winterstein shared that the Consortium needs to be compliant with the subcommittee asks, as the Consortium budget comes out of state budget and is not automatically generated from MMJ revenue, as is the case for FAMU.

Dr. Jacqueline Sagen expressed interest in adding how MMJ changes opioid dependence to the list of priorities. She also added that clinical data is hard to obtain at this stage and suggested that some priority areas could be targeted towards clinical research and others towards translational research, as some research areas are closer to having clinical data than others. Dr. Winterstein added that claims data can be used with validated algorithms for some studies on opioid dependence. Some studies have been done at state levels but not on patient level data. Dr. Winterstein suggested that MMJ use effects on opioid use could fall under priority areas relating to safety and efficacy studies, routes of administration, and drug-drug interactions. Dr. Sagen suggested spelling it out more clearly as a separate priority area in keeping with the outputs requested by the subcommittee.

Dr. Cook commented that researchers could track prescription opioid use through the prescription drug monitoring program. The second point Dr. Cook made was, in the future to urge legislatures to ask dispensaries to collaborate with researchers. This has been done in Colorado and if it is allowed in Florida it would allow research using the products available in Florida.

Dr. Anderson pointed that priority 3b also caters to studies on opioid dependence. Dr. Cook and Dr. Winterstein agreed to adding effectiveness of MMJ as an analgesic/adjuvant in pain management and reduction in opioid use as part of priority #1. Dr. Sagen felt that it should be worded as a separate priority area conveying its importance to legislatures and researchers, and all agreed.

Vote on Grants Program Approval

Dr. William Anderson, suggested there be a motion to approve the proposed RFP and Dr. Roger Fillingim initiated the motion and Dr. Martha Rosenthal seconded the motion. All present approved the motion and no one opposed or abstained. The motion for approval of the 2022 RFP was passed. Dr. Winterstein thanked the board members for their support and suggestions and conveyed that the updated RFP will be shared with them for final review and approval, and thereafter for wide dissemination.

Proposed Plans for M3 Data Use Requests

Dr. Robert Cook presented the strategic goals for Medical Marijuana and Me (M^3), and plans to enroll at least 500 new MMJ users and recruit 500 current MMJ users over a year. M3 will generate a lot of data and hence a data sharing policy was proposed.

Dr. Martha Rosenthal left the meeting at 4:48pm due to another commitment.

The data sharing policy will govern access to the M3 data for all interested Consortium members for the purpose of answering relevant research questions and write papers. It will provide a process by which the Consortium can monitor scientific rigor, assure non-duplication of work, provide appropriate opportunities for authorship and help monitor the outputs (papers, abstracts, etc.) and ensure appropriate acknowledgement. Data sharing requests could be made by consortium faculty members by filling out an online form. A scientific oversight committee can approve or deny requests and ensure compliance with the data sharing policies.

A similar process will be outlined for a patient contact registry that is being created. Dr. Cook invited comments to the proposed policy before it is finalized. Dr. Anderson commented that the approach looked complete and invited comments from the board. Dr. Anderson enquired if members were needed for the scientific committee and Dr. Cook acknowledged that broad representation of consortium universities on the scientific oversight committee would be preferable. Dr. Winterstein reiterated that it is important that it's not just a "UF only committee". She suggested that the M3 data may spark interest across a broad range of researchers at all Consortium institutions and requested the board to share these plans with those in their respective universities who could participate. Dr. Anderson appreciated the idea and stated that scientific oversight committee members do not have to be board members.

Dr. Cook added that there are a few members on the planning committee from 4/5 universities who have been helping in planning and designing the study and some of them might be interested. Dr. Anderson agreed.

Public Comments

The Chair invited comments from the public and none were submitted.

Closing Remarks

Dr. Anderson thanked the board members and Dr. Winterstein and her team. The board members will need to finalize and approve the 2022 RFP via email. Dr. Anderson reminded the board that the next meeting will be coming up in end of January 2022.

Adjournment

Dr. Anderson wished everyone Happy Holidays and adjourned the meeting at 4:56 PM.