

MEETING MINUTES

Consortium for Medical Marijuana Clinical Outcomes Research: BOARD MEETING

Friday, Dec 4th, 2020 at 1:00 PM EST

Zoom Online Meeting

Board Members Present:

Roger Fillingim, Chair
Dalton Dietrich
Martha Rosenthal
William Anderson
Cynthia Hughes-Harris
Max Orezza
Timothy Gilbertson

Board Members Absent:

Eric Holmes
Daniel Flynn

Attendees:

Almut Winterstein, Consortium Director
Robert Cook, Consortium Associate Director
Yan Wang
Joshua Brown
Amie Goodin
Sebastian Jugl
Anna Shavers
Jeevan Jyot
Brianna Costales
Ruba Sajdeya

Opening Remarks

Dr. Roger Fillingim of the University of Florida (UF) called the meeting to order at 1:00 pm. He welcomed all the Board Members and thanked everyone for attending.

Status of the Consortium

Dr. Almut Winterstein provided updates on consortium status. The consortium budget received a 2% budget cut so far on the initial \$1.5M award. Around 10% more cuts could be expected as per college and university leadership. Based on that, some reserves are being held until January. Attempts will be made to roll over any unspent funds into next year, especially since a tighter state budget is expected in FY 2021.

Dr. Winterstein also provided MEMORY database updates. There have been multiple delays working with FL DOH, in addition to delays caused by COVID. DoH is reviewing the DUA now due to renewed and continued efforts since July. A DUA with AHCA to obtain Medicaid data has been finalized and signed. Dr. Winterstein updated the board that a prospective cohort of MMJ users is being established as well and the infrastructure to recruit MMJ users has been developed. There is now a scientific advisory board to guide this effort including the development of initial assessment instruments. Dr. Cook will provide an update on the prospective cohort at the next board meeting in January.

In terms of next steps, Dr. Winterstein highlighted the importance of the Annual report, due to Governor, Speaker of House and Senate Chair by Feb 15th as per statute, in order to summarize the consortium's accomplishments. She urged the board to impress upon the grant awardees the importance of their progress reports to demonstrate the consortium's value to the state and communicate their research outcomes to the public. A draft annual report will be shared at the next board meeting in Jan 2021.

Dr. Winterstein informed the board that an agreement has been signed with the Journal: Medical Cannabis and Cannabinoids which is now the formal journal of the consortium. Drs. Brown and Goodin have joined the editorial board. The “Evidence in Context” series, which summarizes primary research findings for a clinical audience has been launched and will be published in 2021. Dr. Winterstein also shared information about the consortium’s presence in community outreach by Drs. Brown and Cook, as well as two student presentations at RSMJ.

Conference Planning Updates

Dr. Amie Goodin presented updates for the consortium’s first conference CCORC and shared the “save the Date” announcement as well as objectives and a preliminary agenda. Dr. Goodin stated that grant awardees are being encouraged to submit abstracts for CCORC enabling research dissemination along with a broad call for abstracts. The top 40 abstracts will be published in the consortium journal and efforts are underway towards providing CME credits. Dr. Goodin acknowledged the scientific committee for their participation and presented their responsibilities. The agenda for two half day sessions includes three keynote speakers and oral poster presentations and panel sessions. Dr. Goodin shared the CCORC planning timeline and requested board members to widely disseminate the call for abstracts. The CCORC landing page along with the abstract submission form is expected to go live shortly.

Dr. Fillingim remarked on the great progress and expressed his belief that CCORC will get a lot of attention.

Physician Survey Outcomes

Dr. Yan Wang presented a summary of the state-wide physician survey which was conducted in July 2020 in collaboration with Dr. Martha Rosenthal. Survey topics included questions about demographics, providers’ current MMJ practice, perceived medical marijuana research priorities, and needs for physician training/education. Physicians were asked about their recommendations in regards to a specific CBD:THC ratio and dosage, routes of administration, whether they recommend specific dispensaries as well their sources for information to inform prescribing. Dr Wang reported that studies on drug-drug interactions; different components of MMJ and potency levels of THC, research on the human endocannabinoid system, and serious side effects were the top research topic priorities.

Medical conditions or symptoms that providers were most interested in learning about were, chronic pain, anxiety, the potential for reducing use of other medications (opioids), insomnia and sleep disorders, and PTSD. Training topic areas in decreasing order of priority for the providers were drug-drug interactions; management of specific medical conditions or symptoms; information on doses and active ingredient compositions; strategies to help reduce use of opioids or other drugs and advantages and disadvantages of specific modes of delivery.

Dr. Fillingim asked Drs. Cook/Rosenthal if any of these findings were surprising or unexpected? Dr. Cook stated that though these results were not unexpected, the survey results will be further analyzed to compare various groups of providers to learn more about their prescribing practices. Dr. Rosenthal suggested that comparisons of providers by patient volume would be interesting. Dr. Dietrich added that demographics would be interesting and enquired if these physicians were all from Florida. Dr. Cook explained that the survey was limited to Florida physicians who are licensed to certify patients for use of medical marijuana and who are flagged as seeing patients. Dr. Rosenthal shared that they have a paper accepted for publication in the Journal Medical Cannabis and Cannabinoids about another patient survey they had conducted.

Dr. Winterstein reflected that it is a challenge for providers to “prescribe” medical marijuana without clear guidance on dosage, or route essentially asking patient to figure it out. Dr. Cook indicated that patient decision-making and experiences were an important focus area for the prospective cohort. Dr. Cook also discussed best ways to recruit users.

2021 Grants program

Dr. Almut Winterstein presented the 2021 proposed plans for the research grants program, contingent upon FY 2021-22 funding. Dr. Winterstein initiated discussion by stating that those research priorities dictated by statute and the outcomes of the expert recommendations and evidence review conducted by Dr. Goodin and her team last year would continue. Dr. Winterstein provided a summary of recommendations from the 2020 RFP, as well as shared two additional important pieces of information- the provider survey results, and NIH’s programmatic interests related to cannabis research. Dr. Winterstein invited discussion on adding these new priority areas or continuing only with the 2020 recommendations or a hybrid of the two.

There was discussion about the human endocannabinoid research focus as part of the priority areas in regard to its translational potential. Dr. Rosenthal, Dr. Dietrich and Dr. Anderson were in favor of including these studies and suggested assessment of their translational potential during review. Dr. Fillingim suggested that we need an aggressive strategy to keep state priorities on clinical outcomes research in mind when reviewing LOIs and inviting full proposals. Dr. Dietrich suggested instructing the review panel about such priorities. There were questions about allowing the awardees to have carryover money in case of delays in execution, especially for clinical studies which usually take more time. Dr. Winterstein clarified that UF restrictions on use of carry-forward funds would need to be addressed. Dr. Brown suggested adding cardiovascular outcomes to the serious side effects list and all agreed to the final list of research priority areas.

Vote on Grants Program Approval

Dr. Fillingim proposed to start the voting process. The following were in attendance: Dr. Hughes-Harris, Dr. Anderson, Dr. Dietrich, Dr. Orezzaoli, Dr. Rosenthal and Dr. Gilbertson. Dr. Anderson motioned to vote, and Dr. Orezzaoli seconded the motion. All Board Members present voted in favor of approving the presented grants program. No Board Members opposed the decision, and no Board Members abstained from voting. The research grants program for FY21 was unanimously approved by the board.

Dr. Winterstein brought forth a few other suggested changes for discussion. She revisited discussion about additional types of funding mechanisms besides continuing with the current seed funding mechanism. There was discussion about funding larger grants with a bigger funding limit, for a limited number of proposals (alternate cycle), and set aside funds for graduate student/dissertation funding. Dr. Anderson suggested exploring the possibility of longer award periods for the larger grants, if allowed by state/UF administrators. Dr. Fillingim wanted to know how we would define the scope of these larger grants- would they be interdisciplinary, multi-investigator building towards center type, different in what they propose? Dr. Winterstein explained that the logic was to attract senior investigators whose proposals would hopefully lead to higher impacts/value. Given uncertainty about next year's budget, the discussion was tabled until next year.

The board agreed to have no institutional limit on the number of proposals submitted and continue with one proposal/PI limit. Resubmissions would not have a separate funding allocation though applicants will need to respond to past reviewers' comments and awardees will not be excluded from applying to the next cycle.

2021 Grants program Administration

Dr. Jeevan Jyot presented the timeline for the 2021 RFP. Dr. Winterstein suggested preponing dissemination of the 2021 RFP to allow applicants to have more time. LOIs will continue to be submitted online on the consortium website. The applicants must list the source of marijuana used in their studies and are required to present results at the Annual Consortium Meeting CCORC. Based on the experiences from the previous cycle Dr. Jyot put forth some suggested changes for the 2021 RFP. These included an indication on the LOI form if the proposal was submitted in a previous cycle. The proposals would include a translational statement in the research plan of the proposal. There will be new sections in the application that would not be included in the research plan page limit: environment/resources section; and if applicable description for protection of human subjects; Inclusion of Women, Minorities, and Children; vertebrate animals and biohazards. PIs are required to include letters of support from dispensaries as Appendix if such support is needed. The board agreed to all these changes.

Dr. Winterstein announced plans for the next board meeting in January 2021 to share the research plan for FY 2021-22

Public Comments

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

Dr. Cynthia Hughes-Harris commented that their state funding came with the directive to focus more on community education and empowerment rather than research, since UF and consortium is focusing more on research. Dr. Fillingim remarked that this complements well what the consortium does and requested Dr. Hughes-Harris to present and share outcomes and the educational activities when ready. Dr. Cook suggested some partnerships would be good and the educational information can be provided on the Consortium website in collaboration with FAMU. Dr. Winterstein and Dr. Fillingim both agreed that this a great idea.

Closing Remarks

Dr. Fillingim thanked Dr. Winterstein and her team for the organization and presentation, and remarked that the consortium continues to conduct impressive work, and thanked all the board Members for their participation and inputs.

Adjournment

Dr. Fillingim adjourned the meeting at 2:51 PM.