

MEETING MINUTES

Consortium for Medical Marijuana Clinical Outcomes Research: BOARD MEETING

Friday, Jan 29th, 2021 at 9 AM EST

Zoom Online Meeting

Board Members Present:

Roger Fillingim, Chair
William Anderson
Max Orezza
Timothy Gilbertson
Eric Holmes
Daniel Flynn
Dalton Dietrich

Board Members Absent:

Martha Rosenthal
Cynthia Hughes-Harris

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 9:00 am. He welcomed the Board Members and thanked everyone for attending.

Conference Planning Updates

Dr. Amie Goodin presented updates for the consortium's first conference CCORC and shared the progress timeline and noted that all activities were on schedule. Dr. Goodin stated that reviewers for upcoming abstracts have been recruited and shared screenshots of CCORC webpages. Dr. Goodin shared the updated preliminary agenda, with two half day sessions, featuring both live and web-based events. Dr. Goodin announced that an application for CME credits for CCORC is under review at UF's CME office. Abstracts submissions are ongoing and exhibitor recruitment is underway. Dr. Goodin requested board members to encourage participation from their communities and to keep their schedules open for a board member reception at the end of the conference. Dr. Fillingim and Dr. Winterstein thanked Dr. Goodin and her team in planning this virtual conference and requested everyone's participation.

Status updates for Prospective Cohort Recruitment

Dr. Robert Cook informed the board that the clinical core is creating, the contact registry and the patient cohort. The contact registry is for individuals interested in knowing more about medical marijuana (MMJ) studies, and to sign up to be contacted in future. Launched in fall 2020, it includes 209 participants. The patient cohort, launching Spring 2021, will include both new and current MMJ users and will involve 3 initial state-wide surveys (current user, new user baseline, new user follow-up). Dr. Winterstein sought to confirm that the contact registry participants could be contacted, if there was an opportunity to participate in research and Dr. Cook confirmed this. Dr. Cook shared that the cohort planning group included Faculty from UF, UCF, FGCU, students, 5 MMJ Providers and a patient representative. The cohort survey IRB is approved with key topics to measure identified, and several survey drafts and revisions have been made. Dr. Cook outlined future plans where a deidentified database once established, would be available to students and researchers. The survey information could be linked to OMMU data/the MEMORY database and any researcher will be able to use this database to support a grant application. Dr. Winterstein commended Dr. Cook and Dr. Wang and team for their efforts and affirmed the Consortium's intent to share the database and cohort information with interested researchers, ensuring that data usage is appropriate to answer different questions and to reduce overlap in research questions proposed. Dr. Dietrich enquired about participation from University of Miami and Dr. Cook confirmed that Dr. Jayweera and Dr. Denise Vidot, as well as a physician from Miami, were engaged in the cohort planning. Dr. Fillingim complemented Dr. Cook and wanted to know if a patient's information could be duplicated in a cohort, and Dr. Cook assured the board that there will be a mechanism to limit any duplication, based on his experiences working with an HIV cohort. Dr. Fillingim agreed that the patient cohort will be a great resource and Dr. Winterstein agreed that the prospective real-life situations can help generate interesting hypotheses from researchers, and provide feedback for translational research.

Presentation 2021 Annual Report Outline

Dr. Almut Winterstein presented the 2021 Annual Report Outline, which by statute will be submitted to the Governor, Speaker of the house and Senate Chair by Feb 15th. In this report, the Consortium demonstrates how productive and successful it has been. Dr. Winterstein stated that the annual report will be shared with the board for approval before final submission, after designer inputs and any suggested edits. The annual report will present an overview of Consortium activities since its creation and the return on investment generated by the grants program. Dr. Winterstein summarized that \$1.2M funded the grants program, which funded 19 researchers across 7-member universities of the Consortium. The outputs from the researchers included 1 patent filed, 1 IND obtained, 37 undergraduates trained and supported, including 3 from under represented minorities, 4 grants submitted for extramural funding, 8 peer reviewed publications, 8 talks and interviews, 7 conference abstracts, a new college course developed which was SUS approved, and a new database and visualization tool was created. Dr. Winterstein stated that with only 14 months of research effort and given the time lost due to COVID, these outputs were commendable. Dr. Dietrich agreed that these achievements were very impressive, and the need for emphasis to be laid on the duration when all this was accomplished. Dr. Anderson agreed and suggested these incredible achievements be shared by emphasizing the time span during which our researchers achieved it. Dr. Winterstein assured the board that in addition to emphasis in text, a legend highlighting this will be added. Dr. Anderson suggested adding *Early Outputs of Projects funded Dec 2019-Jan 2020* as legend. Dr. Fillingim also suggested highlighting the actual months during which these outputs were achieved. Dr. Winterstein credited the Consortium awardees for all their hard work especially given the current pandemic constraints.

2021-22 Research Plan

Dr. Almut Winterstein shared the 2021-22 Research Plan and plans to continue the work on the five pillars of the Consortium. Under the grants program, the expanded research priorities have been rolled out in the new RFP. Dr. Flynn suggested disseminating the RFP again. For MEMORY, the data dictionary has been developed and will be built further and DoH has agreed to work on the data usage agreement (DUA) soon. Under the Clinical Core activities, the patient contact registry is available on the website, with plans to build a CARMMA database, and to develop the patient cohort and continue to provide guidance to investigators on regulatory issues. Dr. Winterstein shared that the Evidence core will continue their evidence in context series, to be published next month in *Medical Cannabis and Cannabinoids* journal. The patient/provider sheets will be posted on the Consortium website, along with the evidence in context articles. Dr. Winterstein hoped that the lawmakers will see value in these evidence efforts and appreciate their importance. Dr. Winterstein added that under outreach, the second CCORC conference will be held live in spring 2022 at Orlando, either at UCF/UF site. Another new feature, a newsfeed will be added on the Consortium website. In addition, updates to the website, the quarterly newsletter and participation at AMMPA and RsMJ conferences will continue. Dr. Winterstein sought input and suggestions from the board members on the presented research plan. All the board members agreed that the plan was a good mix of hard science, activities and outreach and was very well received and appreciated.

Vote on Research Plan Approval

Dr. Fillingim proposed to start the voting process. The following were in attendance: Dr. Anderson, Dr. Orezzaoli, and Dr. Gilbertson, Dr. Holmes, Dr. Orezzaoli, Dr. Dietrich. Dr. Anderson motioned to vote, and Dr. Orezzaoli seconded the motion. All Board Members present voted in favor of approving the presented research plan. No Board Members opposed the decision, and no Board Members abstained from voting. The 2021-22 Research Plan was unanimously approved by the board. Dr. Winterstein thanked the board and reiterated that the statute delegates the Consortium to support, conduct and disseminate research, and to achieve those goals, the Consortium has mechanisms in place like the grants program, outreach and dissemination and the infrastructure that is being built to conduct research. Dr. Anderson added that communication with agriculture is appreciated and very logical, with all the industrial hemp growers feeding into companies that extract products. Dr. Winterstein affirmed that being in health sciences we sometimes ignore that focus but it is very important, and Nikki Fried has supported the MMJ initiative in a big way and she may be a great ally at the state. Dr. Dietrich stated that we have built some momentum on this program and there are new opportunities not just in basic but clinical research too. Dr. Cook emphasized the need to move forward with research from clinical perspective and hoped that we will receive grant proposals with that focus.

Dr. Winterstein hoped that the Consortium will continue to have support from the state for the value the Consortium brings. The board members were requested to provide updates about any specific researchers working on cannabis/marijuana in their institutions and their achievements, so it could be included as Consortium output. Dr. Dietrich reiterated the importance of reporting on our publications, grants when seeking funding renewal. Dr. Winterstein added that the grant awardees did report on the importance of their research and the need for consortium funding support. The awardees will be reminded to provide research updates and to acknowledge the Consortium funding in their publications and grant submissions.

Public Comments

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

Closing Remarks

Dr. Fillingim thanked Dr. Winterstein and the team for their contributions and presentation, as the Consortium forges ahead conducting impressive work, as well all the board Members for their participation and inputs. Dr. Fillingim stated that they eagerly await the annual report and will meet next in the summer to review the grants program.

Adjournment

Dr. Fillingim adjourned the meeting at 10:06 AM.