

# MEETING MINUTES

## Consortium for Medical Marijuana Clinical Outcomes Research: BOARD MEETING

**Friday, January 17, 2020 at 10:30am**

*Room COM 300, UCF College of Medicine, 6850 Lake Nona Blvd, Orlando or Remote Connection via Zoom*

### **Board Members Present (in-person):**

Roger Fillingim, Chair  
Dalton Dietrich  
William Anderson  
Max Orezza  
Timothy Gilbertson

### **Board Members Attending (via Zoom):**

Cynthia Hughes-Harris  
Martha Rosenthal  
Eric Holmes

### **Board Members Absent:**

Daniel Flynn

### **Attendees:**

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

### **Opening Remarks**

The Chair called the meeting to order at 10:30am. He recorded presence of 7 board members, fulfilling quorum. He welcomed all Board Members and requested all members to introduce themselves stating their Institutions and background. Board members were also asked to disclose any changes in conflicts of interest. There were none.

### **Consortium Board Bylaws Amendment**

The Chair presented a motion to make two amendments to the Consortium bylaws. Dr. Winterstein stated that these amendments will allow communication and board approval of meeting minutes prior to posting them on the Consortium website. Dr. Fillingim presented the motion for a vote. Voting results: Unanimous vote in the affirmative.

### **Research Priority Recommendations Presentation**

Dr. Winterstein informed the board that Dr. Amie Goodin was tasked with developing the Research priority recommendations which would be part of both the Consortium report to BOG, as well as the 2020-21 research agenda.

#### **Expert Recommendations**

Dr. Goodin presented the details of the process and steps involved in the recruitment of expert contributors, the methods for opinion solicitation. Priority recommendations involve consortium obligations per statute; expert recommendations and stakeholder recommendations. Both Florida (Consortium member institutions) and nationally recognized subject matter experts were involved. Overall priority rankings revealed a handful of topics, the top being pain, followed by PTSD, epilepsy, cancer and also drug-drug interactions (DDI) and route of administration (RoA).

## Evidence Review

Dr. Goodin presented the evidence review project strategy where topic area selection was informed by stakeholder input, statute, and seminal works. For each qualifying condition effects of marijuana both as key therapeutic or symptom mitigation were examined. National Academies of Sciences, Engineering, and Medicine had a report in 2016, and this evidence review covers the time after July 2016 until Oct 2019. Reference library curation was in collaboration with UF Health Sciences Center Libraries. Evidence was quantified, then summarized by topic area.

## Stakeholder engagement

- Dr. Robert Cook stated that there will be a detailed statewide medical marijuana provider survey that will be sent out to 3000 providers. He is collaborating with Dr. Martha Rosenthal and welcomed other collaborations. Dr. Winterstein asked Dr. Cook, Dr. Wang, and Dr. Rosenthal if the board members can review the survey before it is sent out. Dr. Orezza expressed keen interest in looking at the survey. Dr. Cook agreed to share the survey with all the board members once it was finalized.
- As a prelude to this survey, at the annual meeting American Medical Marijuana Physician Association (AMMPA), 46 respondents filled out a preliminary survey. The results of this survey were shared with the board members and these survey findings informed topic selection for the evidence review.

## Evidence Review (continued)

- Dr. Goodin made the recommendations for the upcoming grants program cycle to prioritize proposals focused on the assessment of clinical outcomes, with particular emphasis on the following conditions: chronic pain, anxiety, cancer; RoA including efficacy, dosing, and safety as well as DDI. The recommendations suggest continuing inclusion of preclinical research explaining their translational applications.

## Discussion of 2020 Request for Proposals (RFP)

- Dr. Winterstein began by stating the \$1.5M in the statute is listed as a recurring budget. There was discussion on marijuana becoming recreational in Florida. Dr. Anderson commented that even in that scenario knowing the clinical outcomes would be important. Dr. Winterstein added that Colorado State has used state revenue to fund research and we do hope our state does the same.
- Dr. Winterstein presented the timeline for the grants program for 2020 cycle. The RFP would be announced beginning Feb with a Letter of intent (LOI) due online by March 1. Full proposals would be due April 2. The board would meet and decide on awards in June.
- The board members had questions and suggestions as regards to the new RFP. Dr. Winterstein suggested a discussion.

### Scope of grant proposals

Dr. Fillingim initiated the discussion on the RFP by requesting board members to be mindful of the Florida statute.

### Guidance on inclusion of non-clinical studies

Dr. Fillingim reported that in the last grant cycle though the board did fund non-clinical studies (as they had translational potential), the applicants for the next cycle will be asked to clearly state the translational potential of their proposed research. All members agreed to this.

### Graduate student funding

Dr. Fillingim invited discussion on graduate student funding as regards a separate call for graduate students or allowing them to compete in the same pool. Dr. Anderson and Dr. Gilbertson suggested in the future we should ask the state to add a trainee portion as a separate pot of money.

### Institutional Limit

Dr. Fillingim invited comments on setting an institutional limit on the number of proposals submitted in the next cycle. Following discussion, Dr. Fillingim suggested that board members guidance be sought to review LOIs for compliance and conflicts. All board members were in agreement.

### Will resubmissions be regarded as such?

Dr. Fillingim asked the board if resubmissions should be allowed or should all submissions be treated as new submission? All board members agreed that all submissions should be treated as new submissions. Past awardees should explain how the current proposal relates to the previously awarded research and what has been accomplished to-date. Previous unsuccessful applicants submitting the same proposal, should address the reviewer comments in this submission.

### Should previous PIs be excluded one cycle?

Dr. Fillingim asked the board members if the awardees from the past cycle should be asked to skip a funding cycle. Dr. Cook commented that especially for clinical studies which involve IRB approvals etc. there is not enough time to complete

proposed research. Dr. Hughes-Harris and Dr. Holmes were in support of no restrictions. Dr. Cook raised a question if the \$75K award was adequate. After discussion it was decided to make no change and decide in later cycles if more money could be offered for inter-institutional collaborative projects.

### Lunch Break

The meeting was adjourned for lunch at 12:15 pm to reconvene in 15 minutes.

### Post Lunch Session

The meeting was called to order at 12:30 pm by the Chair, who invited Dr. Winterstein to present a draft of the Annual Report.

### Review of Annual Report Draft

- Dr. Winterstein began by saying that according to the statute, by February 15 of each year the board shall issue a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives on research projects, research findings, community outreach initiatives, and future plans for the consortium. Dr. Winterstein presented a timeline according to which a draft would be shared with the board members by Jan 31<sup>st</sup> and requested comments and edits would need to be returned back within a week. All board members agreed to the timeline.
- Updates about each of the core activities were presented. Dr. Winterstein stated that directory establishment of research partners is in progress and efforts are underway to assist researchers trying to obtain DEA license for research. Dr. Winterstein shared that all the goals for the research grants program had been met for this year, the first consortium quarterly newsletter has been released by Anna Shavers and the consortium website has been launched. There was participation in one statewide event to promote the consortium. Dr. Goodin developed the research agenda involving expert group and evidence review. Dr. Winterstein asked the board members if this progress was satisfactory. All members were enthusiastically appreciative of the accomplishments of the consortium. Dr. Winterstein requested board members to widely circulate the consortium annual report. Dr. Anderson suggested that UF BOT may be appreciative of this report as well and requested 10 copies per member institution.

### Research Agenda Presentation

- Dr. Winterstein presented the research agenda starting with pilot recruitment for prospective cohort as part of clinical core and a look at recruitment of both providers and participants. The grants program will have a new online submission platform. Dr. Goodin's report will enhance what NASEM has done. Dr. Winterstein shared plans to develop patients' information sheets about different conditions and what patients need to know, as well as what is currently unknown and useful resources for patients and plans to maintain a library overtime.
- Dr. Winterstein shared plans to host a conference later in the year with a call for abstracts, where national speakers would be invited, grant awardees could present their findings, have an expert panel discussion and make plans for a 2 day event. Dr. Fillingim remarked that would be fantastic and all board members agreed.
- Dr. Winterstein informed the board that she was approached by the Editor of a journal Medical Cannabis and Cannabinoids (KARGER) who expressed interest to be the consortium's official journal. Dr. Anderson had questions about their open source policy and Dr. Goodin said they are willing to negotiate. The board members examined the Journal copy presented. Board members expressed interest in publishing original research as well evidence review. Board recommended continuing conversations with the journal as regards conference sponsorship and publishing conference abstracts.
- Dr. Winterstein wanted to know from the board if they were interested in having exhibitors at our annual meeting. Dr. Fillingim suggested the consortium be aware of the Conflict of interest and ensure the exhibitors have no input into our content.
- Dr. Hughes-Harris stated that FAMU is focusing on MMJ with a big focus on outreach and dissemination and education. They have public service announcements, are developing education literature in different languages, describing the role of physician in making recommendations, impact of MMJ on family and school children. Dr. Fillingim suggested if the consortium did evidence review in layman language it could be disseminated. Dr. Rosenthal added that in FGCU they have several classes for MJ in plant biology, law, business, pharmacology, pharmacology etc.; premeds can do research; FGCU offers a Cannabis Professional Certificate Program currently in its 3<sup>rd</sup> cycle. Dr. Hughes-Harris expressed interest in sharing information about these classes as they do have grants on education for community. Dr. Rosenthal would like the consortium to help in future education efforts.

### **Voting on Proposal for Research Agenda**

Dr. Fillingim thanked everyone for their inputs and ideas and called for a vote on research agenda; Dr. Orezza motioned to vote, and Dr. Anderson seconded the motion. All Board Members present voted in favor of Research Agenda discussed. No Board Members opposed the decision, and no Board Members abstained from voting. The research agenda vote passed favorably.

### **Public Comments**

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

### **Closing Remarks**

The Chair reiterated that the RFP for the grants program must be approved and released by Feb, which means the Board will need to approve this via voting by email on the RFP contents next week. The board members will be contacted in March for screening LOIs. The next Board meeting must be scheduled to review grant proposals, so this must occur in May/June. Dr. Fillingim thanked everyone for a great meeting and complimented the board for being excellent to work with.

### **Adjournment**

Dr. Fillingim adjourned the meeting at 1:55 pm.