

MEETING MINUTES

Consortium for Medical Marijuana Clinical Outcomes Research: Minutes of the Inaugural Board Meeting

Monday, August 19, 2019

Clinical and Translational Research Building (CTRB), Room 2161
2004 Mowry Road, University of Florida, Gainesville, FL 32610

Board Members Present:

Roger Fillingim, PhD (Elected Chair on August 19, 2019)
Daniel Flynn, PhD (Elected Vice Chair on August 19, 2019)
Eric Holmes, PhD [attended via web-conference]
Cindy Hughes Harris, PhD
Dalton Dietrich, PhD
Martha Rosenthal, PhD
Timothy Gilbertson, PhD

Invited Presenters in Attendance:

David Lewis
David Nelson, MD
Almut Winterstein, PhD (Appointed Consortium Director on August 19, 2019)
Robert Cook, MD, MPH (Appointed Associate Consortium Director on August 19, 2019)

Other Attendees:

Yan Wang
Juan Hincapie-Castillo
Amie Goodin
Sebastian Jugl
2 HOBI faculty members
1 COP dual-pharmacy/graduate student

Welcome and Opening Remarks

Dr. Roger Fillingim of the University of Florida (UF) called the meeting to order at 10:30am. He welcomed all Board Members and introduced Dr. David Nelson, Senior Vice President for Health Affairs, University of Florida and President of UF Health. Dr. Nelson welcomed Board Members and stated the commitment of UF to support and foster the Consortium's efforts in conducting and disseminating medical marijuana clinical outcomes research.

Overview of Florida Sunshine and Public Records Laws

David Lewis, Assistant Counsel, Office of the Vice President and General Counsel, University of Florida, gave a presentation on what is required under Florida's Sunshine Law, which requires that board meetings must be open to the public with reasonable notice of meeting time, place, and agenda, as well as the record of voting. Board members may not discuss business of the

board in private communications. All votes must be taken in the open and recorded in the minutes. Conflicts of interest must be noted prior to voting. The procedures and regulations regarding public records requests were also covered.

Board Member Introductions

Dr. Fillingim initiated Board Member introductions and requested that all Board Members state their affiliations and provide some introduction and background. Board Members were also prompted to declare any Conflicts of Interest, if applicable.

Board Nominations and Elections

Dr. Flynn motioned to nominate Dr. Fillingim as Chair. The Board voted unanimously in favor of Dr. Fillingim beginning his term as Chair.

Dr. Fillingim motioned to nominate Dr. Flynn as Vice Chair. The Board voted unanimously in favor of Dr. Flynn beginning his term as Vice Chair.

Adoption of Charter and Bylaws

The Chair requested that board members turn to the Consortium Charter and asked if there were any questions or points of discussion on the Charter document. Dr. Hughes Harris motioned to adopt the Consortium Charter. Dr. Rosenthal requested clarification regarding whether the Consortium was charged with providing guidance to healthcare providers on "...dosing" as defined in Article III, Section C. Dr. Hughes Harris responded that the Consortium is charged with conducting and disseminating research and so these recommendations would be out of scope. Following discussion, the Board unanimously voted to adopt the Consortium Charter as was presented.

The Chair introduced the bylaws document and commented that the intent of the bylaws is to guide the board regarding procedures and implementation of the charges set on the board by the Consortium Charter. Dr. Fillingim motioned to adopt the Board Bylaws. Following discussion, the Board voted unanimously to adopt the bylaws as presented.

Consortium Director Appointment

Dr. Fillingim motioned to appoint Dr. Almut Winterstein as the Consortium Director. He provided explanation that she initiated and submitted the original application outlining the plan for UF leadership of the Consortium. Dr. Winterstein introduced herself. The Board voted unanimously in favor of Dr. Winterstein beginning her appointment as Director. Dr. Winterstein then appointed Dr. Robert Cook as Consortium Associate Director.

Consortium Research Plan and Budget

The Chair invited Dr. Winterstein to present the research plan overview. Dr. Winterstein presented the consortium statutory obligations as well as the goals for the first year (fiscal year 2019-2020). Major goals proposed were to initiate research studies consistent with the charter (e.g., via the proposed grants program), create an evidence-based approach to prioritize/focus consortium research in future years, develop research infrastructure (i.e., MEMORY, the clinical

core, an expert group), and foster collaboration and disseminate evidence via the outreach plan. Following discussion of this presentation, Dr. Winterstein introduced Dr. Cook.

Dr. Cook, Consortium Associate Director, will lead the Clinical Core and build the infrastructure to conduct and support prospective clinical research. Dr. Cook proposed for Year 1 for the Clinical Core to initiate a provider survey, to generate a list of potential partners (from providers, patients, and industry), to create a patient recruitment platform and procedures for such recruitment, and to facilitate access to clinical research services for pilot studies. Following discussion, the Chair announced that the board will adjourn for lunch, then return in half an hour to continue the discussion of the research plan.

Break

At 12:15pm, the Board adjourned for a lunch break and the Chair called the meeting back to order at 12:45pm.

Consortium Research Plan and Budget, Continued

The Chair invited Dr. Winterstein to continue with the research plan presentation and she resumed with the presentation of the plans to administer a grants program. Next, she presented the plan for creating and administering the proposed scientific expert group with a charge to develop the research agenda for Year 2. The outreach plan in Year 1 will include the development of the consortium website, quarterly newsletter, participation in an exhibit in at least one statewide event to promote the consortium, create and conduct a medical marijuana provider survey to develop the provider network as well as to gather input on research needs. Dr. Gilbertson requested clarification regarding whether the expert group will be limited to only Florida members, and Dr. Winterstein confirmed that this is the case. Dr. Dietrich asked which meeting or conference that the Consortium intended to attend as an exhibitor and Dr. Cook responded that this is the annual meeting of medical marijuana-prescribing physicians that occurs in Orlando. Following discussion, Dr. Rosenthal motioned to adopt the research plan as presented. The Board votes unanimously to adopt the research plan as presented.

The Chair requested that Dr. Winterstein continue with the presentation of the budget. Dr. Winterstein provided a breakdown of the proposed major budget items, with approximately \$600k allocated to the first year's grants program. Dr. Flynn requested clarification on whether costs may be shared across other funding mechanisms and/or institutions for items such as personnel effort and Dr. Winterstein states that this discussion will be deferred until the grants program presentation. Dr. Flynn motioned to approve the budget as proposed. Dr. Dietrich requested clarification on the estimated distribution of the grants across individual awardees and Dr. Winterstein provided the estimates on which calculations were based (an estimated 8 awardees receiving ~75k each). The Board voted unanimously to adopt the budget as presented.

Consortium Grants Program

The Chair requested that Dr. Winterstein present the proposed grants program. Dr. Winterstein provided an overview of the process and timeline for releasing the request for proposals (RFP),

reviewing applications, and finalizing awards. The proposed timeline from RFP release to application submission will be 30 days, which would place application deadlines in mid-October of this year. There would be 2 weeks for external review, then board review in mid-November. Awards would be finalized December 1, 2019. Board members discussed the structure, content, and formatting suggestions for the RFP. It was decided that NIH formatting would be used as a guidepost and that CTSI pilot grant submission procedures would be consulted for guidance regarding the submission process. Board members were supportive of classifying pre-clinical proposals as eligible for consideration, but all proposed projects must demonstrate their contribution to understanding the effects of medical marijuana. Dr. Gilbertson motioned to implement the grants program as proposed. Following further discussion, the Board voted unanimously to implement the grants program as proposed.

Public Comments

The Chair invited public comment and reminded speakers that comments are limited to 5 minutes. A student at the UF college of pharmacy requested consideration by the board for expanding the grants program to include smaller sized grant funding mechanisms for graduate and professional students. The Board discussed this request and all expressed support. Dr. Fillingim motioned to table the discussion on initiating a separate grants mechanism for student applicants for consideration in a future meeting, to be included in Year 2. The Board voted unanimously to table this discussion for a future meeting and will consider a separate grants mechanism for students in Year 2.

Dr. Cook commented that the clinical core resources are open to all consortium members and invited discussion from all board members and their constituents about ways that the clinical core could further assist in their research efforts and/or provide resources and sharing of information and collaborators.

Remaining Business

The Chair summarized the business that was conducted in this meeting and then invited remaining questions from the board before moving on to next steps. Dr. Hughes Harris asked about when the legislature would like to see demonstrated progress. Dr. Winterstein responded that an annual report must be presented to the legislature and others by February 1, 2020.

Next Steps and Closing Remarks

The Chair announced that the RFP for the grants program must be released expeditiously and so there must be a conference call (i.e., a special meeting) very soon to vote on the RFP contents. The RFP may be reviewed and edited via email but voting must be done in the meeting. Board members agreed to convene for a special meeting on September 13, 2019 at 4:00pm via a web-conferencing platform. Board members agreed that the next regular meeting will be held in January of 2020.

Adjournment

The Chair adjourned the meeting at 2:15pm.