

Department of Veterans Affairs (VA)

Office of Research and Development (ORD) Cooperative Studies Program (CSP)

Minutes of the Cooperative Studies Scientific Evaluation Committee (CSSEC)

The meeting was held via videoconference on Thursday, May 23, 2024. The Chair, Hermes Florez, MD, PhD, presided.

CSSEC Members Present:

Hermes Florez, MD, PhD – Chair
Lisa Brenner, PhD
Richard Chappell, PhD
Stuti Dang, MD

Patrick O'Malley, MD
Michael Shlipak, MD, MPH
Brittany Zwischenberger, MD, MHSc

Other Attendees Present:

Jonathan Yabes, PhD

VA Staff Present:

David Burnaska, MPA – Designated
Federal Official (DFO)
Amanda Garcia, MPH – Alternate DFO

Grant Huang, MPH, PhD
Rachel Ramoni, DMD, ScD

Mr. Burnaska called the meeting to order at 10:02 AM. He welcomed participants and thanked them for attending. He noted that the public portion of the meeting would remain open for roughly the next two hours. He then asked Dr. Florez if he had any opening remarks.

Dr. Florez welcomed the participants and thanked them for their service. He noted that he had wanted this to be an in-person meeting and that he looked forward to having one, hopefully, soon. He welcomed Dr. Yabes as a new biostatistician for the committee starting in June, and thanked Drs. Chappell and O'Malley for agreeing to serve for additional 4-year terms. He explained that while, unlike typical meetings, there will be no specific study proposals reviewed at this meeting, the overarching goals remained the same, to advise ORD on: what is the best science to help advance care for Veterans; and what are ways to improve CSP studies in general given the committee members' expertise in clinical trials.

Dr. Huang, the VA Deputy Chief R&D Officer-Enterprise Optimization, and Director, CSP, thanked the participants for their time, and noted that it is a different meeting format today than usual. He explained that the morning session of the meeting will be dedicated mainly to administrative items, and the afternoon session will begin with details on the state of CSP and other enterprise optimization activities. He will then facilitate a discussion seeking advice on program operational activities, scientific and research method advancements, the broader clinical trial environment and directions,

and the broader clinical setting for implementation efforts. Comments were made about the budgetary environment and how that affects CSP directions, as well as the implications for committee activities.

Mr. Jeff Moragne, Director, VA Advisory Committee Management Office, then provided a training on the Federal Advisory Committee Act (FACA). He began by thanking the attendees for the opportunity to present to them today. He noted that this training for this committee had been waived for many years, but that it will now be an annual requirement. The training covered many specific topics, including: when FACA applies; what constitutes a “closed” meeting; when and how committee members can speak publicly about committee activities; and best practices for committee management and operations.

Dr. Ramoni, the VA Chief Research & Development Officer, began with a discussion of the recently enacted Promise to Address Comprehensive Toxics (PACT) Act goals and related research needs. She then outlined considerations that she would like committee members to make when recommending whether to approve a study in a time of scarce resources, including: Is the topic important enough? Is VA the right place to do it? Is it the right team to get the work done? Are the methods scientifically meritorious? And, would the results be feasible to implement within VA?

Dr. Ramoni delineated the broader upcoming research priority areas, which are psychedelics, military exposures, women’s health and access to clinical trials in remote and rural areas. She described efforts underway to coordinate networks of sites that are focused on both clinical care and research in specific disease areas, and commented that CSP has been instrumental in those activities. She also described the VA Lung Precision Oncology Program (LPOP) and possible ways to use that model for making an impact in care for other conditions. She then discussed ways to help communicate research studies and results more broadly across the clinical community. Finally, she thanked the members for all that they do to advance the health and care of Veterans.

Dr. Huang then provided an overview of CSP. This included descriptions of its infrastructure, major historical studies, organizational structure and personnel, scientific peer review process, study development process and the phases of active studies.

Mr. Burnaska noted that no members of the public were in attendance and closed the public session of the meeting at 11:47 AM.

The meeting proceeded as indicated on the attached agenda.
The meeting concluded at 2:15 PM on May 23, 2024.

Submitted,

/s/Hermes Florez, MD,
PhD CSSEC Chair

DEPARTMENT OF VETERANS (VA)
Cooperative Studies Scientific Evaluation Committee (CSSEC)

AGENDA

May 23, 2024

(via teleconference/web conferencing Platform)

Thursday, May 23, 2024 (all times Eastern)

10:00 – 10:05 AM Opening of General Session & Chair's Welcoming Remarks
David Burnaska, MPA
Designated Federal Official
Hermes Florez, MD, PhD
CSSEC Chair

10:05 – 10:20 AM Meeting Overview and Goals
Grant Huang, MPH, PhD
Deputy Chief Research & Development Officer –
Enterprise Optimization
Director, Cooperative Studies Program

10:20 – 10:45 AM Federal Advisory Committee Act (FACA) "101"
Jeff Moragne
Director, VA Advisory Committee Management Office

10:45 – 11:45 AM CSSEC Impacts on Advancing the Research Enterprise
Dr. Huang

11:45 – 12:15 PM Public Comment Period
Mr. Burnaska

12:15 – 1:00 PM **LUNCH**

1:00 – 2:00 PM Update on VA Research Enterprise Optimization (EO) &
CSP Activities/Studies
Dr. Huang

2:00 – 3:15 PM Discussion on Improving CSP Studies and their
Promise for Veteran Health
Dr. Huang & CSSEC Members

3:15 – 3:45 PM Future Directions/Studies
Dr. Huang & CSSEC Members

4:00 PM **MEETING ADJOURNMENT**