

**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, July 1, 2021. The Chair, Hermes Florez, MD, PhD, presided.

CSSEC Members Present:

Hermes Florez, MD, PhD, MPH – Chair	Renee Martin, PhD
Richard Chappell, PhD	Patrick O'Malley, MD
Deborah Grady, MD, MPH	

Other Attendees Present:

Lisa Brenner, PhD	Andrew Muir, MD
Daniel Edmonston, MD	Chad Ritch, MD, MBA
Ravi Madan, MD	

VA Staff Present:

Grant Huang, MPH, PhD – Designated Federal Official (DFO)	Kenute Myrie, PhD
David Burnaska, MPA	Timothy J. O'Leary, MD, PhD
Amanda Garcia, MPH	Kelli Potter (contractor)
William Lance, MBA, MPA, MS	Rachel Ramoni, DMD, ScD

Study Proponents Present: see attached agenda

Dr. Huang called the meeting to order at 8:33 AM and welcomed the attendees. He then announced that Dr. Florez has been named the new CSSEC Chair and welcomed him in that role.

Dr. Huang thanked the participants for their willingness and ability to accommodate a virtual meeting. He reminded reviewers of the importance of signing the conflict of interest statements and following other administrative processes as part of their participation in this federal advisory committee meeting. He proceeded to provide updates on VA research activities including recent interest in Congress and the Administration about CSP-led initiatives, including a study on traumatic brain injury (TBI) that the committee reviewed last year.

Dr. Huang mentioned the COVID-19 studies reviewed by a CSSEC subcommittee and noted that VA took part in all the major COVID-19 vaccine trials, for which CSP provided significant assistance. He noted that CSP has been prominent in the national clinical trials landscape in battling the pandemic more generally and provided examples.

He then described efforts underway to transform CSP and VA research overall into a more enterprise-wide research program, including efforts involving the studies being

reviewed that day. He discussed how the VA Office of Research and Development (ORD) is working with other VA program offices and groups to help leverage CSP as a clinical research enterprise as part of a learning healthcare system. For example, he described the CSP partnership with the VA Quality Enhancement Research Initiative (QuERI) aimed at improving the implementation of CSP research results into the care given to Veterans.

Dr. Huang mentioned the proposed expansion of the VA Network of Dedicated Enrollment Sites (NODES), a consortium of 10 VA medical centers that have teams in place dedicated to conducting CSP studies and serving as part of VA's clinical research enterprise. The committee was asked about creating a CSSEC subcommittee to conduct the review of the NODES expansion proposals. No objections were raised. He noted NODES role in several COVID-19 studies, as well as its role as the foundation of the National Cancer Institute (NCI) and VA Interagency Group to Accelerate Trials Enrollment (NAVIGATE) network. He concluded with announcing several personnel changes in CSP leadership.

Dr. Florez then welcomed and thanked the participants. He commented on his time with CSSEC so far and remarked that it has been a wonderful experience.

Since no public comments were noted, Dr. Huang closed the public session of the meeting at 8:47 AM to begin the study review portion.

Dr. Ramoni, VA's Chief Research and Development Officer (CRADO), thanked the participants for their time and effort and mentioned that the CSSEC review model is being employed more in reviewing other VA research activities. She explained several leadership changes in the Veterans Health Administration (VHA) and VA and announced that Dr. Huang is now officially the Deputy CRADO for Enterprise Optimization. She also mentioned Dr. Huang's role leading the VA research COVID-19 response.

She then described a few CSP collaborations underway with other VA offices and groups, including with Pharmacy Benefits Management and the VA National Oncology Program, noting the 2 oncology studies under review that day. She also described efforts to promote diversity, equity and inclusion among investigators and study participants. ORD activities have included working with the VA Office of Rural Health, and initial efforts aimed at engaging Native American Veterans in research. Dr. Florez noted potential opportunities to engage the older Veteran population, too.

Dr. Ramoni concluded her remarks by mentioning that there is significant interest in research on toxic exposures, mental health and TBI in Congress and the Administration. A discussion on platform trials and adaptive trial designs ensued.

Dr. Florez outlined the review meeting procedures for the day, and Dr. Huang described the virtual meeting logistics. Dr. Florez then led a round of introductions.

The study review portion of the meeting proceeded as indicated on the attached agenda with three new submissions and one resubmission reviewed.

New Submissions:

CSP #2022	“Screening Asymptomatic VEterans for Bladder Cancer Early Detection (SAVE)”
CSP #2023	“Preventing Liver Cancer Mortality through Imaging with Ultrasound vs. MRI (The PREMIUM Study)”
CSP #2026	"Beta Blocker Dialyzability on Cardiovascular Outcomes (BRAVO): Metoprolol Succinate vs Carvedilol for prevention of adverse cardiovascular outcomes in hemodialysis patients"

Resubmission:

CSP #2013	“Treatment of Psychogenic Non-epileptic Seizures in U.S. Veterans”
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The meeting concluded at 4:20 PM on July 1, 2021.

Submitted,



Hermes Florez, MD, PhD, MPH
CSSEC Chair

**DEPARTMENT OF VETERANS AFFAIRS (VA)
COOPERATIVE STUDIES SCIENTIFIC EVALUATION COMMITTEE (CSSEC)
AGENDA**

July 1, 2021
(via teleconference/web conferencing platform)

Thursday, July 1, 2021 (all times Eastern)

- 8:30 – 9:00 AM Opening of General Session, Welcoming Remarks & Update of CSP Activities
*Grant Huang, MPH, PhD – Designated Federal Official
Deputy Chief Research & Development Officer – Enterprise Optimization
Director, Cooperative Studies Program*
- 9:00 – 9:15 AM Remarks from the Chief Research & Development Officer
*Rachel Ramoni, DMD, ScD
Chief Research & Development Officer*
- 9:15 – 9:30 AM Chair's Comments and Overview of Review Procedures
*Hermes Florez, MD, PhD
CSSEC Chair*

1st Proposal **CSP #2022 – “Screening Asymptomatic VETerans for Bladder Cancer Early Detection (SAVE)”**

9:30 – 9:45 AM **Briefing Session**

9:45 – 10:00 AM **Study Team Presentation**

Joshua J. Meeks, MD, PhD – Principal Proponent
Cynthia Davis, PhD – Study Director
Robert Lew, PhD – Study Biostatistician
Alexa Goldberg, PharmD, MS – Study Pharmacist
Ryan Ferguson, ScD, MPH – CSPCC Director

10:00 – 10:45 AM **CSSEC Review**

10:45 – 11:00 AM **Executive Session**

11:00 – 11:15 AM	Break / CSP Follow-up with Study Team
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2nd Proposal

CSP #2026 – "Beta Blocker Dialyzability on Cardiovascular Outcomes (BRAVO): Metoprolol Succinate vs Carvedilol for prevention of adverse cardiovascular outcomes in hemodialysis patients"

11:15 – 11:30 AM **Briefing Session**

11:30 – 11:45 AM **Study Team Presentation**

Areef Ishani, MD, MS – Co-Principal Proponent
James Kaufman, MD – Co-Principal Proponent
Sarah Leatherman, PhD – Study Director
Gheorghe Doros, PhD – Study Biostatistician
Anne Davis-Karim, BA, PharmD – Study Pharmacist
Ryan Ferguson, ScD, MPH – CSPCC Director

11:45 – 12:30 PM **CSSEC Review**

12:30 – 12:45 PM **Executive Session**

12:45 – 1:15 PM	Lunch / CSP Follow-up with Study Team
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3rd Proposal

CSP #2013 – "Treatment of Psychogenic Non-epileptic Seizures in U.S. Veterans" (Resubmission)

1:15 – 1:30 PM **Briefing Session**

1:30 – 1:45 PM **Study Team Presentation**

Martin Salinsky, MD – Co-Principal Proponent
W. Curt LaFrance, Jr., MD, MPH – Co-Principal Proponent
Ilana Belitskaya-Levy, PhD – Study Biostatistician
Mei-Chiung Shih, PhD – Senior Biostatistician
Anne Davis-Karim, BA, PharmD – Study Pharmacist
Ying Chen, PhD – CSPCC Director

1:45 – 2:15 PM **CSSEC Review**

2:15 – 2:30 PM **Executive Session**

2:30 – 3:00 PM	Break / CSP Follow-up with Study Team
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4th Proposal

CSP #2023 – "Preventing Liver Cancer Mortality through Imaging with Ultrasound vs. MRI (The PREMIUM Study)"

3:00 – 3:15 PM

Briefing Session

3:15 – 3:30 PM

Study Team Presentation

George Ioannou, MD, MSc – Co-Principal Proponent

Tamar Taddei, MD – Co-Principal Proponent

Beata Planeta, MS – Study Biostatistician

Jane Zhang, PhD – Study Biostatistician

Tassos Kyriakides, PhD – CSPCC Director

3:30 – 4:15 PM

CSSEC Review

4:15 – 4:30 PM

Executive Session

4:30 PM

Meeting Adjournment