

**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 teleconference on Wednesday, July 15, 2020. The Chair, John H. Alexander, MD, MHS, presided.

**CSSEC Members Present:**

John H. Alexander, MD, MHS – Chair	Hermes Florez, MD, PhD
Richard Chappell, PhD	Renee Martin, PhD
William Cushman, MD	Patrick O'Malley, MD
Deborah Grady, MD, MPH	

**Other Attendees Present:**

Lisa Brenner, PhD	Brian Hoshaw, PhD
Kevin Cooper, MD	Jimmy Le, ScD
Ramon Diaz-Arrastia, MD, PhD	Oliver Schein, MD
Donald Everett, MA	

**VA Staff Present:**

Grant Huang, MPH, PhD – Designated Federal Official (DFO)	Stuart Hoffman, PhD
David Burnaska, MPA	Timothy J. O'Leary, MD, PhD
Amanda Garcia, MPH	Kelli Potter (contractor)
	Rachel Ramoni, DMD, ScD

**Study Proponents Present:** see attached agenda

Drs. Alexander and Huang called the meeting to order at 8:35 AM and welcomed the attendees.

Dr. Huang remarked that this was the first time the committee had met entirely virtually and thanked them for accommodating. He reminded reviewers to submit their signed Conflict of Interest forms and to review the ethics rules available online. He then provided an update on VA research activities, commenting that COVID-19 was front and center. He briefly described VA's ongoing COVID-19 research, noting that CSP was serving as the platform for much of the efforts to battle the pandemic.

Dr. Huang then detailed VA efforts to continue developing the clinical research enterprise that includes establishing a lung cancer screening clinical and research network. He commented that the network would be somewhat like the VA Network of Dedicated Enrollment Sites (NODES) and the National Cancer Institute (NCI) and VA Interagency Group to Accelerate Trials Enrollment (NAVIGATE) network. He asked committee members if they were willing to create subcommittees to help with future reviews of applications. No one objected. He then briefly described the four studies being reviewed during the day and thanked participants for their time and effort

reviewing them. He also mentioned that there would be observers at the meeting, including representatives from the National Eye Institute who have been in discussions to collaborate with VA.

Dr. Huang expressed his appreciation for Drs. Alexander and Cushman as they completed their terms on the committee. He remarked that they had played a critical role in many studies to advance the health and care of Veterans and the nation. He also praised Dr. Alexander for his leadership as committee Chair for the past several years.

Dr. Alexander outlined the review procedures for the day, explaining how they would differ from a typical in-person meeting and noting that the committee had much to cover.

Dr. Ramoni, VA's Chief Research and Development Officer, thanked the participants for their time and effort and acknowledged Drs. Alexander and Cushman for their committee service. She described the heavy involvement of VA research in COVID-19 activities and the enterprise-wide approach being taken to connect with others inside and outside VA. Finally, she briefly mentioned that the VA research budget for fiscal year 2021 is still to be determined.

Dr. Huang closed the public session of the meeting at 8:55 AM to begin the study review portion.

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

*New Submissions:*

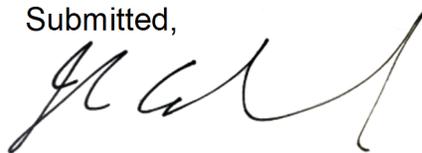
CSP #2013	"Treatment of Psychogenic Non-epileptic Seizures in U.S. Veterans"
CSP #2019	"Basal Cell Carcinoma Chemoprevention Trial (B3C)"
CSP #2020	"Topical versus Intracameral Moxifloxacin for Endophthalmitis (TIME) Prophylaxis Study"

*Resubmission:*

CSP #2018	"Growth Hormone Replacement Therapy in Veterans with mild traumatic brain injury (mTBI) and adult growth hormone deficiency (AGHD)"
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The meeting concluded at 4:25 PM on July 15, 2020.

Submitted,



John H. Alexander, MD, MHS  
CSSEC Chair

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

July 15, 2020

(via teleconference – see details in meeting/calendar invite)

**Wednesday, July 15, 2020 (all times Eastern)**

8:30 – 8:45 AM      Opening of General Session & Welcoming Remarks  
*Grant Huang, MPH, PhD*  
*Director, Cooperative Studies Program*  
*Deputy Chief Research & Development Officer – Enterprise*  
*Optimization (acting)*

8:45 – 8:55 AM      Remarks from the Chief Research & Development Officer  
*Rachel Ramoni, DMD, ScD*  
*Chief Research & Development Officer*

8:55 – 9:00 AM      Overview of Review Procedures  
*John Alexander, MD, MHS*  
*CSSEC Chair*

**1<sup>st</sup> Proposal**      **CSP #2013 – “Treatment of Psychogenic Non-epileptic Seizures in U.S. Veterans”**

9:00 – 9:15 AM      **Briefing Session**

9:15 – 9:30 AM      **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 – CSPCC Acting Director

9:30 – 10:15 AM      **CSSEC Review**

10:15 – 10:30 AM      **Executive Session**

10:30 – 11:00 PM	<b>BREAK / CSP Follow-up with Study Team</b>
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**2<sup>nd</sup> Proposal**      **CSP #2019 – “Basal Cell Carcinoma Chemoprevention Trial (B3C)”**

11:00 – 11:15 PM **Briefing Session**

11:15 – 11:30 AM **Study Team Presentation**

Martin A. Weinstock, MD, PhD – Co-Principal Proponent  
Robert Dellavalle, MD, PhD – Co-Principal Proponent  
Eileen Stock, PhD – Study Biostatistician  
Alexa Goldberg – Study Pharmacist  
Kousick Biswas, PhD – CSPCC Director

11:30 – 12:15 PM **CSSEC Review**

12:15 – 12:30 PM **Executive Session**

12:30 – 1:00 PM	<b>LUNCH / CSP Follow-up with Study Team</b>
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**3<sup>rd</sup> Proposal**

***CSP #2018 – “Growth Hormone Replacement Therapy in Veterans with mild traumatic brain injury (mTBI) and adult growth hormone deficiency (AGHD)” (Resubmission)***

1:00 – 1:15 PM **Briefing Session**

1:15 – 1:30 PM **Study Team Presentation**

Jose M. Garcia, MD, PhD – Co-Principal Proponent  
Ricardo E. Jorge, MD – Co-Principal Proponent  
Michael Winingar, PhD – Study Biostatistician  
Tassos Kyriakides, PhD – CSPCC Director

1:30 – 2:00 PM **CSSEC Review**

2:00 – 2:15 PM **Executive Session**

2:15 – 2:45 PM	<b>BREAK / CSP Follow-up with Study Team</b>
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**4<sup>th</sup> Proposal**

***CSP #2020 – “Topical versus Intracameral Moxifloxacin for Endophthalmitis (TIME) Prophylaxis Study”***

2:45 – 3:00 PM **Briefing Session**

3:00 – 3:15 PM **Study Team Presentation**

Glenn Cockerham, MD – Principal Proponent  
Amy Chomsky, MD – Co-Principal Proponent  
Ping Luo, PhD – Study Biostatistician

Anne Davis-Karim, PharmD – Study Pharmacist  
Domenic Reda, PhD – CSPCC Director

3:15 – 4:00 PM

**CSSEC Review**

4:00 – 4:15 PM

**Executive Session**

4:15 PM

**MEETING ADJOURNMENT**