

**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 at the American Association of Airport Executives (AAAE) Conference Center, 601 Madison Street, Alexandria, VA, on Thursday, June 29, 2017. The Chair, John Alexander, MD, MHS, presided.

CSSEC Members Present:

John Alexander, MD, MHS – Chair	Hermes Florez, MD, MPH, PhD
Daniel Clauw, MD (via teleconference)	Theodore Karrison, PhD (via teleconference)
William Cushman, MD	Renee Martin, PhD
Barry Davis, MD, PhD	John Powers, MD
Deborah Grady, MD, MPH (via teleconference)	

Other Attendees Present:

Kerri Cavanaugh, MD	Michael Priebe, MD
David Goldfarb, MD	

VA Staff Present:

Grant Huang, MPH, PhD – Designated Federal Official (DFO)	Timothy O’Leary, MD, PhD
David Burnaska	Kelli Potter
Marcus Johnson	Daphne Swancutt
	Christina Williams, PhD

Study Proponents Present: see attached agenda

Dr. Alexander called the meeting to order at 8:45 AM and welcomed the attendees. He led a round of introductions and outlined the agenda for the day.

Dr. Huang, Acting Director, CSP, thanked the group for their time and efforts. He reminded participants to sign their Conflict of Interest forms and briefly discussed other meeting logistics.

Dr. Huang then offered updates on activities within VA and CSP. He described the ongoing modernization efforts in VA Central Office, explaining that they involve a proposed reorganization focused on increasing efficiency and helping to achieve the Secretary’s priorities for the Veterans Health Administration. He mentioned that the VA hiring freeze remains in place, and that additional trimming of positions may occur.

Dr. Huang explained that there has been a large increase in the number of Letters of Intent (LOIs) recently received by CSP, meaning that an extra CSSEC meeting may be necessary in the next year or so. He updated the committee on the Million Veteran Program, including that it has surpassed 570,000 enrollees and that papers and

abstracts are beginning to get published from this project. He then noted that the new Chief Research & Development Officer, Dr. Rachel Ramoni, is now on board. He described her three top priorities as "big data" which include informatics and efforts with the CSP Epidemiology Centers and the Department of Energy; the technology transfer program, focused on increasing disclosures of VA inventions and other intellectual property activities; and clinical trials, particularly partnerships. Regarding the latter point, CSP is involved in discussions with the National Cancer Institute, industry and other nonprofits.

Dr. Huang remarked that while there is uncertainty about the VA research budget, CSP remains in very good standing, and that the efforts of this committee help tremendously. He provided updates on various CSP studies and discussed a desire to pursue ways to improve patient recruitment and participant engagement. He also discussed the success of the HEROES program, a new CSP initiative that includes handwritten thank you notes sent to clinical trial participants thanking them for their participation.

Dr. Alexander then explained the review process: The reviewers meet in executive session to give brief synopses of their comments on the proposal before the Committee; study proponents are then brought in, apprised of reviewer comments and asked to make brief presentations and responses to the Committee; an interactive discussion with CSSEC begins. A closed Executive Session follows to discuss recommendations for the proposal and to score it.

Dr. Huang closed the public session of the meeting at 9:15 AM to begin the study review portion.

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

Resubmission:

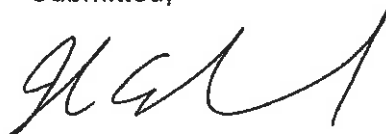
CSP #2008, "Pentoxifylline in Diabetic Kidney Disease"

New Submission:

CSP #2003 Sub-study, "Prevalence and Risk of Fractures of the Calcaneus in Persons with SCI"

The meeting concluded at 2:35 PM on June 29, 2017.

Submitted,

A handwritten signature in black ink, appearing to read 'J Alexander', written over a light blue horizontal line.

John Alexander, MD, MHS
CSSEC Chair

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

June 29, 2017

American Association of Airport Executives (AAAE)
601 Madison Street
Alexandria, VA 22314

Thursday, June 29, 2017

8:30 – 8:45 AM Opening of General Session & Welcoming Remarks
Grant Huang, MPH, PhD
Acting Director, Cooperative Studies Program

8:45 – 9:00 AM Overview of Review Procedures
John Alexander, MD, MHS
CSSEC Chair

1st Proposal **CSP #2008 – “Pentoxifylline in Diabetic Kidney Disease”**

9:00 – 9:15 AM **Briefing Session**

9:15 – 9:30 AM **Study Team Presentation**
David Leehey, MD – Co-principal Proponent
Nicholas Emanuele, MD – Co-principal Proponent
Kimberly Carlson, MS – Study Biostatistician
Domenic Reda, MS, PhD – CSPCC Director

9:30 – 10:15 AM **CSSEC Review**

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

10:30 – 10:45 AM	BREAK
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2nd Proposal **CSP #2003 Sub-study – “Prevalence and Risk of Fractures of the Calcaneus in Persons with SCI”**

10:45 – 11:00 AM **Briefing Session**

11:00 – 11:15 AM **Study Team Presentation**
William A. Bauman, MD – Principal Proponent
Ann M. Spungen, EdD – Co-principal Proponent

Karen Jones, MS – Study Biostatistician
Kousick Biswas, PhD – CSPCC Director

11:15 – 11:45 AM **CSSEC Review**

11:45 – 12:00 PM **Executive Session**

12:00 – 12:30 PM **LUNCH & OPEN DISCUSSION**

12:30 PM CSSEC Lessons for Improving Clinical Trial Proposals

2:30 PM **MEETING ADJOURNMENT**