

**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 Wednesday, June 29, 2016. The Chair, John Alexander, MD, MHS, presided.

**CSSEC Members Present:**

John Alexander, MD, MHS – Chair  
Daniel Clauw, MD  
William Cushman, MD  
Barry Davis, MD, PhD

Deborah Grady, MD, MPH  
Theodore Karrison, PhD  
Renee Martin, PhD  
John Powers, MD

**Other Attendees Present:**

Hermes Florez, MD, PhD  
Warren S. Joseph, DPM (via teleconference)

James Rawn, MD

**VA Staff Present:**

Grant Huang, MPH, PhD – Designated  
Federal Official (DFO)  
David Burnaska

David LaBarca  
Timothy O’Leary, MD, PhD  
Kelli Potter

**Study Proponents Present:** see attached agenda

Dr. Alexander called the meeting to order at 8:31 AM and welcomed the attendees.

Dr. Huang, Acting Director, CSP, provided an overview of the agenda. He explained that David Atkins, MD, MPH, Director of the Health Services Research and Development Service within ORD, is now the acting Chief Research and Development Officer (CRADO). He noted that a search for a permanent CRADO is underway. He also informed the committee that Jennifer Lee, MD, has been appointed the Deputy Under Secretary for Health for Policy and Services and that she is very interested in research and will be a good advocate for the program. Dr. Huang described the ongoing budget discussions and stated that CSP’s budget will likely remain strong. He reminded participants to complete their conflict of interest forms and briefly discussed other meeting logistics. He and Dr. Alexander then led a round of introductions.

Dr. Huang next provided a broad overview of CSP. He described the program’s infrastructure, study development and scientific review processes, current portfolio of studies and program management initiatives. Dr. Alexander commented that the overview will allow the committee to understand better how a study proposal fits into the universe of CSP studies and activities. In addition, he suggested that CSSEC could help inform CSP leadership and study teams on directions and trends in clinical trials to improve study development and conduct.

A discussion of potential improvements in CSP processes ensued. Members raised the possibility of issuing a targeted Request for Applications (RFA) for CSP studies or inserting language about CSP into existing RFAs to help expand awareness of the program. Members also discussed the possibility of involving a mentee in study development to help grow future study chairs. The idea of having a Corporate Data Warehouse observational study become more standard in planning efforts to help demonstrate feasibility was thought to be a best practice and encouraged. In addition, CSSEC members talked about ways to promote more innovative biostatistical and trial methodologies and approaches. It was also suggested that CSP staff work with CSSEC members to develop a list of common errors and assumptions that were later not supported in study proposals to help improve submissions prior to CSSEC review. CSSEC welcomed opportunities to convey messages to CSP planning committees not to assume that established or "old" ways for planning studies would be more acceptable for scientific review. Rather, CSSEC is looking for more innovative approaches to known common problems in clinical trials, especially knowing the capabilities of CSP and VA in general.

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 ensues. 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 10:45 AM to begin the study review portion.

The study review portion of the meeting proceeded as indicated on the attached agenda with two resubmissions reviewed.

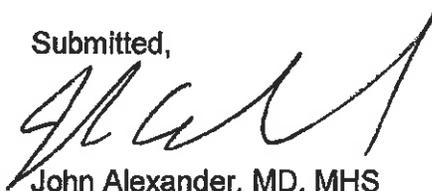
*Resubmissions:*

CSP #599            "Transfusion Trigger After Operations in High Cardiac Risk Patients (TOP)"

CSP #2001           "Investigation of Rifampin to Reduce Pedal Amputations for Osteomyelitis in Diabetics (VA Intrepid)"

The meeting concluded at 2:15 PM on June 29, 2016.

Submitted,



John Alexander, MD, MHS  
CSSEC Chair

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

June 29, 2016

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

**Wednesday, June 29, 2016**

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

8:45 – 10:15 AM    Program Updates & Discussion  
*Grant Huang, MPH, PhD*  
*Acting Director, Cooperative Studies Program*

10:15 – 10:30 AM	<b>BREAK</b>
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10:30 – 10:45 AM    Overview of Review Procedures  
*John Alexander, MD, MHS*  
*CSSEC Chair*

**1<sup>st</sup> Proposal**            **CSP #2001 – “Investigation of Rifampin to Reduce Pedal Amputations for Osteomyelitis in Diabetics (VA Intrepid)”**

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

11:00 – 11:15 AM    **Study Team Presentation**  
Mary T. Bessesen, MD – Principal Proponent  
Sheldon Brown, MD – Co-principal Proponent  
Gheorghe Doros, PhD – Study Biostatistician  
John Hermos, MD – Study Director  
Kelly Harrington, PhD – Study Director  
Ryan Ferguson, ScD, MPH – CSPCC Director

11:15 – 12:00 PM    **CSSEC Review**

12:00 – 12:15 PM    **Executive Session**

12:15 – 12:45 PM	<b>LUNCH</b>
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**2<sup>nd</sup> Proposal**      **CSP #599 – “*Transfusion Trigger After Operations in High Cardiac Risk Patients (TOP)*”**

12:45 – 1:00 PM      **Briefing Session**

1:00 – 1:15 PM      **Study Team Presentation**  
Panagiotis Kougias, MD – Principal Proponent  
Zhibao Mi, MD, PhD – Study Biostatistician  
Kousick Biswas, PhD – CSPCC Acting Director

1:15 – 2:00 PM      **CSSEC Review**

2:00 – 2:15 PM      **Executive Session**

2:30 PM              **MEETING ADJOURNMENT**