

**Department of Veterans Affairs (VA)**  
**Office of Research and Development (ORD)**  
**Clinical Science Research and Development Service (CSR&D)**  
**Minutes of the Cooperative Studies Scientific Evaluation Committee (CSSEC)**

The meeting was held at the Sheraton Suites Old Town Alexandria, Alexandria, VA, on Thursday, July 12, 2012. The Chair, Karl Kieburtz, MD, MPH, presided.

**CSSEC Members Present:**

Karl Kieburtz, MD, MPH – Chair  
John Alexander, MD, MHS  
Daniel Clauw, MD  
William Cushman, MD

Barry Davis, MD, PhD  
Theodore Karrison, PhD  
Sheryl F. Kelsey, PhD  
Laura Mauri, MD, MSc

**Other Attendees Present:**

Gary Bond, PhD  
Sheila Fesko, PhD

William Lawson, MD, PhD

**VA Staff Present:**

David Burnaska  
Theresa Gleason, PhD  
Grant Huang, MPH, PhD – Designated  
Federal Official

Timothy O’Leary, MD, PhD  
Kelli Potter  
Sunil Sen-Gupta, PhD

**Study Proponents Present:** see attached agenda

Dr. Kieburtz opened the general session at 8:30 AM and welcomed the participants. Dr. O’Leary, VA Deputy Chief Research and Development Officer, and Director, CSR&D, thanked the participants for their help and effort. He commented that the efforts of CSSEC have helped VA to conduct exceptional research studies that have changed clinical practice. He explained that while the VA research budget grew substantially several years ago, it has been relatively flat for the past few years, making the Committee’s recommendations extremely important in determining where to dedicate the limited resources.

Dr. O’Leary mentioned that the CSP statistical coordinating centers will likely be ISO 9001 registered in the near future. He described the Network of Dedicated Enrollment Sites (NODES) pilot initiative that seeks to provide efficiencies and economies of scale for CSP studies by establishing stable units of knowledgeable clinical research personnel who are primed and ready to conduct CSP clinical trials. He noted that 10 pilot sites have been identified. He also provided an update on the Million Veteran

Program (MVP) stating that 72,000 Veterans have enrolled to date and that 10 new sites will soon be added for enrollment. In addition, he mentioned that results from the Prostate cancer Intervention Versus Observation Trial (PIVOT) will soon be published and that several studies that CSSEC recently reviewed will soon be launching.

Dr. Huang, Deputy Director, CSP, also thanked the participants. He noted that there will be several studies to review at the next fall and spring CSSEC meetings and described a few of them. He then announced that Dr. Mauri's term on CSSEC has ended, thanked her for her participation and presented her with a certificate of appreciation.

Jonathan Gurland from the VA Office of General Counsel conducted the annual ethics training for CSSEC members. He described the roles of Special Government Employees, and discussed ethics laws and standards of conduct. Dr. Huang reminded members to complete the conflict of interest form.

Dr. Kiebertz thanked the participants for their time and effort and explained the review process to the members: 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 9:45 AM to begin the study review portion.

The study review portion of the meeting proceeded as scheduled, with two new submissions reviewed.

*New Submissions:*

CSP #588                    "Randomized Endo-Vein Graft Prospective (REGROUP) Trial"

CSP #589                    "Evidence-Based Supported Employment for Veterans with Posttraumatic Stress Disorder: A Multisite Randomized Controlled Trial"

The meeting concluded at 1:15 PM on July 12, 2012.

Submitted,



Karl Kiebertz, MD, MPH  
Chair CSSEC

**DEPARTMENT OF VETERANS AFFAIRS  
CLINICAL SCIENCE RESEARCH AND DEVELOPMENT SERVICE  
COOPERATIVE STUDIES SCIENTIFIC EVALUATION COMMITTEE (CSSEC)  
AGENDA**

July 12, 2012

Sheraton Suites Old Town Alexandria  
801 North Saint Asaph Street  
Alexandria, VA 22314

**Thursday, July 12, 2012**

8:30 – 8:45 AM      Opening of General Session & Welcoming Remarks  
*Timothy J. O’Leary, MD, PhD*  
*Deputy Chief Research & Development Officer*  
*Director, Clinical Science R&D Service*

8:45 – 9:15 AM      Annual Ethics Training  
*Jonathan Gurland*  
*Office of General Counsel*

9:15 – 9:30 AM      Overview of Review Procedures  
*Karl Kieburtz, MD, MPH*  
*CSSEC Chair*

**1<sup>st</sup> Proposal**            **CSP #589 – “Evidence-Based Supported Employment for Veterans with Posttraumatic Stress Disorder: A Multisite Randomized Controlled Trial”**

9:30 – 9:45 AM      **Briefing Session**

9:45 – 10:00 AM    **Study Team Presentation**  
Lori L. Davis, MD – Principal Proponent  
Tassos C. Kyriakides, PhD – Study Biostatistician  
Peter Guarino, MPH, PhD – CSPCC Director

10:00 – 10:45 AM    **CSSEC Review**

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

11:00 – 11:15 AM	<b>Break</b>
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**2<sup>nd</sup> Proposal**      **CSP #588 – “Randomized Endo-Vein Graft Prospective (REGROUP) Trial”**

11:15 – 11:30 AM    **Briefing Session**

11:30 – 11:45 PM    **Study Team Presentation**  
Marco Zenati, MD, MSc – Principal Proponent  
Michael Gaziano, MD, MPH – Consultant  
Joseph Collins, ScD – CSPCC Director

11:45 – 12:30 PM    **CSSEC Review**

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

12:45 PM              **MEETING ADJOURNMENT**