

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 L'Enfant Plaza Hotel, Washington, DC, on Tuesday, November 24, 2009. The Chair, George Machiedo, MD, presided.

CSSEC Members Present:

George Machiedo, MD - Chair
Barry Davis, MD, PhD
Theodore Karrison, PhD
Sheryl F. Kelsey, PhD

Karl Kieburtz, MD, MPH
Laura Mauri, MD, MSc
John Powers, MD

Other Attendees Present:

Robert Gatchel, PhD, ABPP
Rowland Hazard, MD

VA Staff Present:

David Burnaska
Grant Huang, MPH, PhD

Timothy O'Leary, MD, PhD
Kelli Potter

Study Proponents Present: see attached agenda

Dr. Machiedo opened the general session at 8:35 AM. Dr. O'Leary, VA Deputy Chief Research and Development Officer and Director, CSR&D, provided welcoming remarks and thanked participants for their time and effort. He commented that VA's research budget continues to grow, and noted the competing demands for research addressing the needs of recent Veterans as well as the aging Veteran population.

Dr. O'Leary mentioned recent papers in the *New England Journal of Medicine* and other high impact journals by CSP investigators, and pointed out that the recently approved study on Vietnam era women Veterans, CSP #579, was highlighted on the VA internet homepage. He also remarked that funding the highest quality science undergoing rigorous peer review remains the core value of the CSP.

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, Deputy Director, CSP, asked members to sign the certification form stating that they completed the ethics training.

Dr. Huang announced that Dr. O'Leary has been officially appointed as Deputy Chief Research and Development Officer. He mentioned that Peter Peduzzi, PhD, Director, CSP Coordinating Center, West Haven, CT, is retiring at the end of the year, and that

Ying Lu, PhD, has been named Director of the CSP Coordinating Center in Palo Alto, CA.

Dr. Huang closed the public session of the meeting at 9:35 AM to begin the study review portion. Dr. Machiedo explained the review process to members: the reviewers would 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 by Dr. Huang and asked to make brief presentations and responses to the Committee; an interactive discussion with the CSSEC ensues. A closed Executive Session follows to discuss recommendations for the proposal and to score it.

Committee members were reminded that the proceedings and recommendations pertaining to the review of research proposals are considered to be privileged and confidential information. Dr. Huang asked members to sign the conflict of interest form.

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

New Submission:

CSP #581 “Pharmacotherapy and Integrative Behavioral
Treatment for Chronic Low Back Pain”

The meeting concluded at 12:35 PM on November 24, 2009.

Submitted,

A handwritten signature in black ink, appearing to read "G Machiedo", written in a cursive style.

George Machiedo, MD
Chair CSSEC

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

November 24, 2009

L'Enfant Plaza Hotel
480 L'Enfant Plaza, SW
Washington, DC 20024

Tuesday, November 24

- 8:30 – 9:00 AM Opening of General Session & Welcoming Remarks
Timothy J. O'Leary, MD, PhD
Deputy Chief Research & Development Officer
Director, Clinical Science R&D Service
- 9:00 – 9:30 AM Annual Ethics Training
Jonathan Gurland
Office of General Counsel
- 9:30 – 9:45 AM Overview of Review Procedures
George Machiedo, MD
CSSEC Chair
- 1st Proposal** **CSP #581 – “Pharmacotherapy and Integrative Behavioral
Treatment for Chronic Low Back Pain”**
- 9:45 – 10:00 AM **Briefing Session**
- 10:00 – 10:15 AM **Study Proponent Presentation**
Robert Kerns, PhD – Principal Proponent
Daniel Clauw, MD – Consultant
Peter Guarino, PhD – Biostatistician
Peter Peduzzi, PhD – CSPCC Director
- 10:15 – 11:00 AM **CSSEC Review**
- 11:00 – 11:15 AM **Executive Session**
- 11:15 – 12:15 PM Advice and Guidance for Scientific Planning and Proposals
- 12:15 PM **MEETING ADJOURNMENT**