

**Department of Veterans Affairs
Office of Research and Development
Clinical Science Research and Development Service
Minutes of the Cooperative Studies Scientific Merit Review Board**

The meeting was held at the Holiday Inn Silver Spring on May 11, 2005. The Chairperson, George Machiedo, MD, presided.

Members present:

George Machiedo, MD
Robert Anderson, MD
Warren Browner, MD, MPH
Ira Katz, MD

Marie Diener-West, PhD
Michael Domanski, MD
David Cohen, MD

Ad hoc members:

Sheryl Kelsey, PhD
Barry Davis, MD, PhD
Greg Larsen, MD
David Good, MD
Nina Schooler, PhD

VACO ORD Staff present:

Stephen Fihn, MD, MPH, FACP
Brian Schuster, MD, FACP
Grant Huang, MPH, PhD
Bridgett Baer
Jacqueline Quarles
Karen Hood

CSP Staff Present:

Cindy Howell, CCRA
Colleen Cantillon, MPH
Robert Ringer
Mike Sather

Dr. George Machiedo, Committee Chairperson, convened the Open Session of the Cooperative Studies Scientific Merit Review Board (CSSMRB) at 8AM. He welcomed the committee members and introduced Jonathan Gurland from the Office of General Counsel. Mr. Gurland provided an overview of ethics/conflict of interest regulations pertaining to the committee members as special government employees.

Dr. Grant Huang then introduced Dr. Stephen Fihn, Acting Chief Research and Development Officer (CRADO) and Dr. Brian Schuster, Director, Clinical Science Research and Development Service (CSR&D). Drs. Fihn and Schuster provided a brief update on the VA Office of Research and Development (ORD), and the Cooperative Studies Program (CSP).

Dr. Fihn informed the group that Dr. John Perlin has been officially confirmed as the new Undersecretary for Health. Dr. Perlin has extensive knowledge and is a strong supporter of research, has served as the acting CRADO for several months and has spent some time with the NIH. He is a PhD trained scientist with experience in genetics.

Dr. Fihn explained that the "Friends" situation had a tremendous impact on CSP and management is looking at the possibility of establishing a national non-profit foundation

to make it easier to conduct the larger joint trials. He also mentioned that several other legal/technical issues in the collaborations with industry were being worked out.

Dr. Fihn shared the news that Lynn Cates of the PRIDE group has been working hard to get a national IRB. There is currently no example of a centralized IRB in the country, although there is a pilot underway at the NCI. The inefficiencies of dealing with multiple, heterogeneous IRBs in multi-center clinical trials is recognized nationally. Although this will require negotiations with local IRBs, having a centralized IRB would greatly enhance the conduct of CSP trials.

Overall, it was a good year for CSP with a number of major papers being published. Dr. Fihn stated the importance of keeping high caliber studies in the pipeline and expressed appreciation for the committee's hard work.

Dr. Schuster echoed the appreciation for the committee's efforts and thanked Dr. Fihn for his active support for CSP while serving as Acting CRADO.

Dr. Schuster announced that several CSP leadership positions have been filled. Dr. Javaid Sheikh is now the Director (no longer Acting), Palo Alto CSPCC. Dawn Provenzale, MD, MHSc, has been selected as the Director, Durham ERIC. Bridgett Baer joined CSRD as an Administrative Officer and Karen Hood is staying on as Finance Officer for CSP.

Dr. Schuster reiterated Dr. Fihn's comment on keeping high caliber studies in the pipeline stating that CSP has a few studies waiting that are the kinds of studies that will impact patient care.

After Drs. Fihn and Schuster's updates, Dr. Huang introduced the new members to the committee. The committee provided positive feedback about receiving the submissions on CD and the inclusion of voting cards for each submission.

Dr. Machiedo opened the review phase of the meeting for consideration of three new studies, one resubmission, and one midterm/renewal review.

New Submissions:

- CS #558 "Robotic Assisted Upper Limb Neurorehabilitation in Stroke Patients"
Principal Proponent: Albert Lo, MD, PhD
- CS #557 "VA CARDS – Coronary Artery Revascularization in Diabetes Study"
Principal Proponents: Masoor Kamalesh, MD & Thomas Sharp, MD
- CS #555 "Long-Acting Injectable Risperidone in the Treatment of Schizophrenia"
Principal Proponents: Robert Rosenheck, MD & John Krystal, MD

Resubmission:

- CS #501 "VA Biorepository Trust"
Principal Proponent: Louis Fiore, MD, MPH

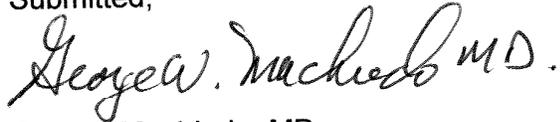
Midterm/Renewal Review:

CS #478 "CSP DNA Bank"

Principal Proponent: Philip Lavori, PhD

The review portion of the meeting progressed as scheduled. The next meeting being scheduled for November 2-3, 2005. The meeting concluded at 5PM.

Submitted,

A handwritten signature in black ink that reads "George Machiedo MD." The signature is written in a cursive style with a large initial 'G' and a long, sweeping underline.

George Machiedo, MD
CSSMRB Chairperson