

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

The meeting was held at the DoubleTree Hotel in Rockville, Maryland on Tuesday, May 2, 2006. The Chairperson, George Machiedo, MD, presided.

CSSMRB members present

George Machiedo, MD
Robert Anderson, MD
Warren Browner, MD, MPH
John Feussner, MD, MPH, FACP
Barry Davis, MD, PhD

Michael Domanski, MD
Theodore Karrison, PhD
David Cohen, MD

Ad hoc members

Emily Blumberg, MD
Bertrand Jaber, MD

John Lake, MD (via teleconference)

VACO ORD Staff present:

Timothy O'Leary, MD, PhD (via teleconference)
Grant Huang, MPH, PhD
Bridgett Baer
Karen Hood
Kelli Potter

CSP Staff present:

Stuart Warren, JD, PharmD

Dr. Timothy O'Leary, Acting Director, Clinical Science Research & Development Service and Dr. Grant Huang, Deputy Director, Cooperative Studies Program (CSP), opened the General Session of the Cooperative Studies Scientific Merit Review Board (CSSMRB) at 8:30AM. Participants were welcomed and thanked for contributing their expertise in reviewing the proposals. Comments were made that the strength of CSP research is tied to the strong review process that CSSMRB provides. An update of CSP and other VA Office of Research & Development activities was given.

Dr. Huang announced that Dr. Ira Katz had resigned from the CSSMRB. Dr. Katz accepted a position in the VA Central Office as Deputy Chief of Mental Health. Also, Dr. Robert Anderson was presented with a certificate of appreciation for his eight-year service on the committee.

Jonathan Gurland, from the Office of General Counsel, then conducted an Ethics Training session for the review board.

Afterwards, a discussion on prioritizing CSP Letters of Intent (LOIs) was held. Suggestions were solicited from the CSSMRB on how to strengthen and prioritize the types of studies submitted to CSP for consideration. Among the comments:

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- The Board commented that the basic goals of the LOI process should remain in focus: 1) to maximize the number of veterans reached; and 2) to maintain diversity in the diseases and ailments represented in research proposals.
 - The coordinating centers should be instructed to be both advocates for proposals but also to be more discerning and demanding about the quality of proposals before they are sent on to the CSSMRB.
 - Coordinating centers might lend further statistical and methodological help to proposals at the LOI stage, to improve study design.
 - It might be useful to empanel a group of experts to review proposals at the LOI stage rather than use ad hoc reviewers with differing standards.

A discussion about elements that might be emphasized as part of an upcoming CSP Coordinating Center recompetition was held. The Board proposed that onsite visits to the coordinating centers might be useful in obtaining insights to how research activities would be conducted, involving local leadership, and to better understand the local support and environment. The Board agreed on the merit of holding onsite visits.

The study review portion of the meeting was begun with Dr. Machiedo explaining the review process: the reviewers would meet in a closed session and give brief synopses of their comments on the proposals before the Board; study teams (proponents) are then brought in to make brief presentations to the Board; proponents are apprised of reviewer comments by Dr. Huang; and an interactive discussion with the CSSMRB follows. An Executive Session with only CSSMRB members follows to discuss recommendations for the study.

The review portion of the meeting progressed as scheduled. There was one new study and two midterm/extension requests reviewed at the meeting.

New Submission:

CSP #564 "Preemptive Therapy versus Prophylaxis for CMV in Liver Transplant Recipients"

Midterm/Extension Review:

CSP #424 "Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation"

CSP #530 "Intensive vs. Conventional Renal Support in Acute Renal Failure"

The next CSSMRB meeting is scheduled for October 17-18, 2006.

The meeting concluded at 3:20 PM on May 2, 2006.

Respectfully submitted,

George Machiedo, MD
Chair CSSMRB
