The meeting was held at the American Association of Airport Executives (AAAE) Conference Center, 601 Madison Street, Alexandria, VA, on Wednesday, December 13, 2017. The Chair, John H. Alexander, MD, MHS, presided.

CSSEC Members Present:
John H. Alexander, MD, MHS – Chair
William Cushman, MD
Barry Davis, MD, PhD
Deborah Grady, MD, MPH
Hermes Florez, MD, PhD
Theodore Karrison, PhD
Renee Martin, PhD

Other Attendees Present:
John Powers, MD
Gary Wynn, MD

VA Staff Present:
Grant Huang, MPH, PhD – Designated Federal Official (DFO)
Timothy O’Leary, MD, PhD
Kelli Potter
David Burnaska, MPA
Rachel Ramoni, DMD, ScD
Kristina Nord, MPH

Study Proponents Present: see attached agenda

Dr. Alexander called the meeting to order at 8:33 AM and welcomed the attendees. He then led a round of introductions.

Dr. Huang, Acting Director, CSP, also welcomed the attendees and thanked them for their time and effort. He noted that the three proposals under review were quite different than the traditional CSP study proposals, reflecting CSP’s move to push the envelope more with innovative approaches to doing science. He announced that CSP #577, “Colonoscopy vs. Fecal Immunochemical Test in Reducing Mortality from Colorectal Cancer (CONFIRM)”, reached 50,000 participants and is the largest CSP interventional study to date. He then discussed some ongoing activities within CSP, including a Request for Applications (RFA) with the National Cancer Institute (NCI) for VA sites to enroll into NCI clinical trials—likening it to an extension of the Network of Dedicated Enrollment Sites (NODES) concept. He explained that while about 10 sites will be awarded, CSP received 54 Letters of Intent. He then introduced Dr. Ramoni, VA’s Chief Research and Development Officer.

Dr. Ramoni thanked the attendees and remarked that she hopes to see if some components of this review process can translate to the review processes of the other VA research services. She noted that clinical trials in the VA are getting much more attention, including from the VA Secretary, with many requests from industry to
collaborate. She explained that Central Office is looking at ways to make clinical trial start-up easier and more efficient, and also looking at ways to potentially co-fund trials with industry for VA to then receive a substantial discount on drugs down the road. In addition, central office is examining ways to better implement research findings in the healthcare system.

Dr. Ramoni outlined her top three priorities for VA research: 1) improve access to high quality clinical trials, 2) improve the real world impact of VA funded studies, and 3) transform VA data into a national resource. She asked committee members to consider whether the studies under review are the most important studies to undertake, not just whether they are excellent studies. A discussion of issues around the implementation of research findings followed. Attendees also suggested possibilities for revamping the size and format of study proposals.

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 reminded participants to sign their Conflict of Interest forms and briefly discussed other meeting logistics. He closed the public session of the meeting at 9:25 AM to begin the study review portion.

The study review portion of the meeting proceeded as indicated on the attached agenda with one new submission, one resubmission and one mid-term submission reviewed.

**New submission:**
CSP #2016 “Adaptive Clinical Trial for Insomnia in Veterans with PTSD (ACTIVe-PTSD)”

**Resubmission:**
CSP #2012 “Prediabetes Prospective Observational Study (PreDOS)”

**Mid-term:**
CSP #592 “Efficacy and Safety of ICD Implantation in the Elderly”

The meeting concluded at 2:35 PM on December 13, 2017.

Submitted,

John H. Alexander, MD, MHS
CSSEC Chair
Wednesday, December 13, 2017

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

8:45 – 9:00 AM  Overview of Review Procedures  
John H. Alexander, MD, MHS  
CSSEC Chair

1st Proposal  
CSP #2012 – “Prediabetes Prospective Observational Study (PreDOS)”

9:00 – 9:15 AM  Briefing Session

9:15 – 9:30 AM  Study Team Presentation  
Jennifer Lee, MD, PhD – Principal Proponent  
Mihaela Aslan, PhD – Study Biostatistician  
John Concato, MD, MPH – CSPEC Director  
Mei-Chiung Shih, PhD – CSPCC Acting Director

9:30 – 10:15 AM  CSSEC Review

10:15 – 10:30 AM  Executive Session

10:30 – 10:45 AM  BREAK

2nd Proposal  
CSP #592 – “Efficacy and Safety of ICD Implantation in the Elderly” – Pilot Study Review

10:45 – 11:00 AM  Briefing Session

11:00 – 11:15 AM  Study Team Presentation  
Steven Singh, MD – Study Chair
Michael Wininger, PhD – Study Biostatistician
Gary R. Johnson, MS – CSPCC Acting Director

11:15 – 11:45 AM  CSSEC Review
11:45 – 12:00 PM  Executive Session

12:00 – 12:30 PM  LUNCH

3rd Proposal  CSP #2016 – “Adaptive Clinical Trial for Insomnia in Veterans with PTSD (ACTIVe-PTSD)”

12:30 – 12:45 PM  Briefing Session
12:45 – 1:00 PM  Study Team Presentation
John H. Krystal, MD – Principal Proponent
Bruce K. Chow, MS – Study Biostatistician
Mei-Chiung Shih, PhD – CSPCC Acting Director

1:00 – 1:45 PM  CSSEC Review
1:45 – 2:00 PM  Executive Session

2:00 – 3:30 PM  Follow-up Review Discussion

3:30 PM  MEETING ADJOURNMENT