

**Department of Veterans Affairs
National Research Advisory Council (NRAC) Meeting**

**131 M Street NE, Washington, D.C. 20002
Office of Research and Development
Middleton Conference Room (Room 23)
February 22, 2012**

Meeting Notes

Members Present

Blanck, Ronald
Bonham, Ann
Butler, Aaron
Donoghue, John
Korn, David
Laine, Christine
Wenzel, Richard

Member Not Present

Kelch, Robert

Invited Guests

Gurland, Jonathan
Waxman, Stephen

VA Staff Present:

Atkins, David
Barnaby, Laurie
Birdsall, Holly
Cates, Lynn
Crow, Janet
Cuccherini, Brenda
Dorn, Patricia
Eisen, Seth
Hannon, Peggy
Hammond, Timothy
Iveljic, Suzana
Jaeger, Robert
Kalasinsky, Victor
Kupersmith, Joel
O'Leary, Timothy
Ommaya, Alex
Przygodzki, Ronald

Dr. Richard Wenzel, Chair called the meeting to order at 9:30 a.m. Welcome and introduction of everyone in attendance.

Annual Ethics Training - Jonathan L. Gurland, Esq., OGC

"Ethics Training for Special Government Employees" was presented to the seven NRAC members and one invited guest in attendance. Contact information was given as well as guidance on financial disclosure, conflict of interest, definitions of 'direct and predictable effect' and 'particular matter', exceptions, prohibited compensation, side switching, standards of conduct, restrictions on teaching, speaking and writing; gifts; and charitable fundraising, and other laws and regulations including the Hatch Act. "General Principles of Ethical Conduct" was distributed.

Office of Research and Development Update – Joel Kupersmith, M.D.

Dr. Kupersmith provided an overview highlighting ORD's mission and strategic goals and highlights of our 85 year history with recent accomplishments including deep brain stimulation in Parkinson's disease, being listed among the Secretary's 16 Transformational Initiatives, recipient of 5 Telly Awards, and the launch of Million Veteran Program (MVP). Dr. Kupersmith went over the Presidential Directive on Peer Review, including the recent additional language defining federally mandated guidelines for peer review processes. Dr. Kupersmith advised members that in light of this, a VA guideline is in the process of being developed and is being handled by the Scientific Integrity Committee.

Dr. Kupersmith noted that the ORD budget is comprised of four parts: research, medical care, federal resources (i.e. NIH), and non-federal resources (i.e. industry). Dr. Kupersmith commented on the importance of keeping stakeholders informed and connected to developments within ORD and that a communications strategy, based on survey results, will be developed to help in this regard. Dr. Kupersmith shared survey results from stakeholders revealed a strong support of genomics projects and VA research in general.

Dr. Kupersmith did confirm that within the last two years, ORD received more visibility on important projects. Members agreed that communications should focus on internal communications to reach researchers and clinicians, NIH, collaborators, stakeholders, and Veterans. Dr. Kupersmith commented that he believes VA Research Week events held nationwide are beneficial and noted that last year, approximately 230 people attended the annual forum held in Washington D.C.

Gulf War Research Strategic Plan 2012 – 2016 – Victor Kalasinsky, Ph.D.

Dr. Kalasinsky provided an overview of the Gulf War Research Strategic Plan 2012 - 2016: background information such as Gulf War research funding FY 2001-2010, the committee

structure for planning, and then the timeline, outline, working groups for the planning, Finally he addressed implementation and asked the NRAC for guidance as he described some of the specific recommendations from the Working Groups that would require significant changes in policy or procedures within ORD.

It was stated that ORD needs to couple the Strategic Plan with an operational plan that will allow VA to do everything possible for the Veteran. It is essential that no GWVs feel that their particular problem is low priority.

It was suggested that ORD needs to continue to support investigator-initiated research projects as well as service-directed projects to ensure the proper balance in the research portfolio.

The following recommendations were made by the Council for each sub-section of Section 5:

5.1 Symptomatic and Specific Treatments:

Treatments should be the focus of the GW research portfolio.

ORD should increase the number of clinical trials.

NRAC noted there does not appear to be a need for any additional infrastructure to increase the treatment trials.

5.2 Databases and Continued Surveillance:

Much of the proposed work involves combining and archiving existing databases in a central location, but this sort of activity should only be done if there is a specific research question to be answered.

Databases constructed prospectively, however, should be compatible with one another. The MVP could be used as a model for other databases.

5.3 Establish an Evidence-Based Case Definition of Chronic Multisymptom Illnesses in Gulf War Veterans:

ORD should proceed with developing a consensus definition for chronic multisymptom illness.

ORD should try to accomplish this within 12 to 18 months.

VA should not endorse an interim definition. Instead, if researchers need to use a case definition, they should identify and justify their choice.

5.4 Genetics/Genomics/Systems Biology:

The specimens from CSP #585 and MVP should be used for genetic/genomic studies.

5.5 Biomarkers:

A carefully defined phenotype is necessary for appropriate biomarker research.

NRAC noted this section outlines many possible projects; given the number of projects, prioritization will have to be done.

5.6 Animal Models:

Research involving animals should focus on treatments.

Animal models should be selected based on their appropriateness for GWV treatments.

5.7 Improve Coordination with Stakeholders:

New information technology methods should be used to accomplish many of the coordination recommendations in the draft GWR Strategic Plan (virtual communication, accessibility). Brief reports summarizing research accomplishments should be targeted to specific audiences.

5.8 Translation Research Findings into Science:

Once sufficient evidence of successful trials exists, the QUERI program staff will work with Gulf War researchers to implement a plan to translate the research into clinical practice.

LUNCH BREAK

Welcome New Members - VA Chief of Staff John Gingrich

Chief of Staff (COS) Gingrich welcomed the new NRAC members and thanked them for their service. He advised the Council that VA and Department of Defense have challenges ahead as 1 million new Veterans enter the system over the next 5 years. New legislation dictates that 100% Veterans leaving active service go through TAP in transition which will contribute to the influx of enrollees. Since 2009 when he joined the VA, one of his goals has been to change the perception of VA research; he continues to address where we need to be when the current enlistees are 60 years old. Mr. Gingrich proclaimed the Million Veteran Program to be “phenomenal” and will work to ensure that the Office of Research and Developments (ORD) projects are aligned with VA priorities with focused research and development and investing in infrastructure. Certificates of Appointment were issued to four new NRAC members: Drs. Blanck, Bonham, Donoghue, and Laine.

Programmatic Review: VA Medical Research & Development –Joel Kupersmith, M.D., Timothy O’Leary, M.D., Ph.D.; Holly Birdsall, M.D., Ph.D.

Dr. O’Leary noted that research funding is aligned with VA healthcare costs for chronic care and that the research and clinical portfolios differ with a large investment in deployment-related conditions and rehabilitation. He discussed ORD’s principles of resource allocation and metrics used to monitor outcomes. In closing the overview, Dr. O’Leary asked the committee for their advice on the relationship between research funding and clinical funding and asked them to share their thoughts on metrics for assessing research effectiveness (if they believe there are other criteria ORD should be using that we currently are not using.) Dr. Kupersmith asked if ORD should look at portfolio gaps or should they look to future high rewards projects? NRAC feedback included:

- 1) *Answer questions clinicians need answers to the most;*
- 2) *Survey clinicians as physicians are surveyed;*
- 3) *Develop a research portfolio that is balanced with creative discovery along with scientific questions doctors, nurses, and patients need answered. This creates a balance between top down directives and the creative scientific process.*
- 4) *Justify increased funding as helping Veterans and as VA initiatives being carried out.*

Communications - Suzana Iveljic, M.B.A.

Ms. Iveljic announced that ORD and research offices at VAMCs across the nation are planning activities to observe VA Research Week April 23-27, 2012. The fifth annual Research Forum will be held at VACO on April 26, 2012. The theme "Caring for Veterans through Discovery and Collaboration" will emphasize translation of research discoveries into advancements in health care, acknowledgement of the vital role of Veterans in research, engaging stakeholders (VSOs, academic affiliates, and non-profits) that contribute to caring for Veterans, and recognizing VA investigators.

RR&D Pilot Research Program Modifications – Patricia Dorn, Ph.D.

Dr. Dorn requested input from the members on modifications to the Rehabilitation Research & Development (RR&D) Pilot Study Program. She asked that they review her handout which discussed the need to modify the Program, what the Program provides, presented a comparison of the current and modified programs, review criteria and scoring guidelines, along with a pilot program critique. Members were asked to contact her directly at patricia.dorn@va.gov with comments.

3:50 p.m. Public Discussion

4:00 p.m. Adjournment