

**THE U.S. DEPARTMENT OF VETERANS AFFAIRS
NATIONAL RESEARCH ADVISORY COUNCIL (NRAC)
Minutes of the Meeting of September 26, 2002**

Members Present:

Colonel Aaron X. Butler (USMC, Ret.)	John R. Feussner, M.D., M.P.H.
Dudley S. Childress, Ph.D.	David Korn, M.D.
Charles H. Epps, Jr., M.D.	George W. Rutherford, M.D. (Chair)

Members Excused:

Marie A. Bernard, M.D.	Patricia A. Grady, Ph.D.
Dan G. Blazer, M.D., Ph.D.	Spero M. Manson, Ph.D.
Gordon H. DeFriese, Ph.D.	Louis M. Sherwood, M.D.

VA Staff:

James F. Burris, M.D., Acting Chief Research and Development Officer (CRADO) and NRAC Designated Federal Official
Marsha Goodwin, Acting Chief Consultant, Geriatrics & Extended Care Strategic Healthcare Group
Laurent S. Lehmann, M.D., Chief Consultant for Mental Health, Office of Patient Care Services
E. William Judy, MSHA, Director of Operations, Office of Research and Development (ORD)
John A. Bradley, Director of Finance, ORD
Louis Fiore, M.D., Deputy Director, Massachusetts Veterans Epidemiological Research and Information Center, VAMC Boston, MA
J. Joseph Gough, Program Manager, Cooperative Studies Program
Karen Scott, Special Assistant and Committee Manager, ORD
Carla DeSpain, Staff Assistant, ORD

1. Call to Order. The meeting of the Department of Veterans Affairs (VA) National Research Advisory Council (NRAC) was held at the Hyatt Dulles, in Herndon, VA, September 26, 2002. Dr. George W. Rutherford, Council Chairman, called the meeting to order at 8:30 a.m.

In accordance with the provisions of Public Law 92-463, the meeting was open to the public.

2. James F. Burris, M.D., VA's Acting Chief Research and Development Officer (CRADO), welcomed the group and gave an update on two issues previously reported to the NRAC.

- Legislation that will establish bioterrorism centers has passed both Houses of Congress and is pending final approval. The legislation will authorize \$20 million per year over five years for the establishment of four centers within VA. If this legislation is passed, the Office of Research and Development (ORD) will likely play a role in their establishment and management, the extent of which has yet to be developed.
- The VA Human Research Protection Accreditation Program has remained in hiatus throughout the summer, and is expected to restart in November. The National Committee for

Quality Assurance (NCQA) has posted Version 2.0 of the accreditation standards on the NCQA website (www.ncqa.org) for public comment until October 4. After finalizing the standards and establishing a schedule for subsequent surveys, review of accreditation applications will resume in late November and on-site surveys are expected to resume in mid to late January 2003.

3. Minutes. The minutes of the June 20, 2002, meeting were accepted without objection.
4. Old Business. The NRAC Operating Procedures, which were approved at the June 20, 2002 meeting, were distributed for information. Also included in members' information packets was a listing of the Top 25 Universities (ranked by NIH support) in fiscal year (FY) 2000 compared with the ranking of the respective universities' VA affiliates. A list of the Top 25 VA facilities (by total VA funding) was also distributed for comparison.
5. New Member and Reappointments. Dr. Rutherford welcomed Dr. Feussner as the newest member of the NRAC. Secretary Principi appointed Dr. Feussner following his recent retirement from VA. Three members – Col. Butler, Dr. Childress, and Dr. Korn – were recently reappointed for four-year terms. Dr. Rutherford was reappointed Chairman for one year, to coincide with his term as a member.
6. Cooperative Studies Program DNA Bank Study. Dr. Louis Fiore, Deputy Director, Massachusetts Veterans Epidemiological Research and Information Center (MAVERIC), VAMC Boston, MA, presented an overview of the state of current technology, including genomics, gene expression studies, and proteomics, in DNA banking. Dr. Fiore is part of a Task Force appointed to study whether VA should be a player in this arena and, if so, to determine the appropriate mode of operation. If funding for this initiative is approved, it can be initiated within an estimated six-month period. Among the many complex issues involved with this topic are the ethical and social concerns, particularly with regard to regulatory initiatives such as the Health Insurance Portability and Accountability Act (HIPAA).

The NRAC expressed strong support for this initiative and agreed that it is an excellent opportunity for VA and a reasonable investment for the research program. Members suggested that an NRAC member might serve on the Task Force in an ad hoc capacity to follow the issue as it progresses.

7. Update on CRADO Recruitment. Mr. E. William Judy, Director of Operations, ORD, gave an update on the status of recruitment for a new CRADO. The vacancy was advertised in five widely read scientific journals (including *Science*, *NEJM* and *JAMA*) and on three web sites with an application deadline of August 16, 2002. A Search Committee chaired by Dr. Rutherford and consisting of seven members was appointed. VHA Management Support forwarded credentials for 15 qualified candidates to ORD for review and ranking by the Search Committee. The applicants were rated on seven factors: policy development, program management, budget formulation, research agenda development, leadership ability, research dissemination/promotion, and research experience. Based on scores submitted by the Search Committee, three top candidates were identified and forwarded to the Under Secretary for Health for consideration. The Under Secretary for Health, Acting Deputy Under Secretary for Health, and Acting CRADO

will interview the three candidates, and forward a recommendation to the Secretary by late October. The Secretary's approval and appointment is expected by the end of November.

Members suggested that Dr. Rutherford, as chairman of the Search Committee, be invited to participate in the interviews of the top three candidates. Dr. Burris will request to the Under Secretary for Health that Dr. Rutherford be included in interviews.

8. Update on Financial Issues. Mr. John A. Bradley, Director of Finance, ORD, gave an overview of the fiscal year 2004 budget submission and an update on NIH indirect support. Actual dollar amounts in the FY04 budget submission are embargoed, but the request allows for intramural project funding level with the anticipated FY03 budget. The major change in this submission is the realignment of Veterans Equitable Resource Allocation (VERA) funds to the research budget and an allocation of about 5% for support of infrastructure improvements such as equipment, information technology, and minor construction. If the VERA funds are realigned to research, it is unclear what mechanism will be used to distribute the funds to the field. VERA funding is approximately equal to the research appropriation. The funds will not be used for additional research projects, but rather for their intended purpose of funding clinician salaries (thus helping to ensure protected time for research) and appropriate facility and administrative cost support.

The NRAC members strongly favored ORD retaining management of and accountability for the VERA funds, if they are moved to the research budget. Retaining control of distribution of funds to the field is vital to ensuring protected time for investigators and adequate support for research program infrastructure.

With regard to the issue of NIH indirect support, the Subcommittee on Oversight and Investigations, House Veterans Affairs Committee, has expressed strong support for VA obtaining support for indirect costs of research from the National Institutes of Health (NIH) for the administration of NIH grants at VA medical centers. At two recent hearings, the Subcommittee has asked NIH to meet with VA staff and negotiate an appropriate rate. Despite this Congressional support, the ORD's efforts to reach agreement with NIH have failed. The Office of Management and Budget (OMB) is convening a meeting on October 1 for representatives of both agencies, and will serve as arbitrator on this issue.

9. Overview of VA Geriatric Research, Education and Clinical Centers. Ms. Marsha Goodwin, Acting Chief Consultant, Geriatrics & Extended Care Strategic Healthcare Group, Office of Patient Care Services, gave an overview of the Geriatric Research, Education and Clinical Centers (GRECCs). The GRECC program was established in 1975, and there are currently 21 GRECCs primarily at individual VA medical centers. In addition to the education and clinical aspects of the GRECCs, each center has a research component focused on a specific area of geriatrics and gerontology. The GRECCs combine fundamental research, applied clinical research, and health services studies to translate research "from bench to bedside." GRECC staff have generated nearly \$64 million in research funding annually, primarily from extra-VA sources. The GRECCs were the first of the research, education and clinical centers to be established, and have served as the model for future "RECCs" including the Mental Illness Research, Education and Clinical Centers (MIRECCs).

10. Remarks by Leo S. Mackay, Jr., Ph.D., Deputy Secretary of Veterans Affairs. Dr. Mackay gave an overview of steps taken recently by the Secretary to set priorities for health care services for veterans with 50% or greater service-connected illness or disability. This policy modifies the concept of open enrollment and is necessary due to fiscal constraints imposed by the rapid increase in numbers of veterans enrolled in the VA health care system and Homeland Security needs. He also discussed two additional priorities:

- *Emergency Preparedness Centers:* as previously discussed by Dr. Burris, these centers will be established following passage of pending legislation. They have the potential to bring VA's large integrated health care system into the forefront of Homeland Security with regard to research, education and clinical preparedness for events involving biologic, chemical, nuclear, or conventional weapons of mass destruction.
- *Historically Black Colleges and Universities:* Dr. Mackay recently attended a meeting at the White House at which VA's involvement with Historically Black Colleges and Universities (HBCU) was discussed. The Deputy Secretary expressed his disappointment at the low level of support from research for such collaborations, compared to support in the training and education arenas at VA. He urged the NRAC to discuss ways to increase VA research involvement in this area.

Following his remarks, Dr. Mackay welcomed Dr. Feussner to the NRAC and presented him with a Certificate of Appointment.

11. Overview of Mental Illness Research, Education and Clinical Centers. Dr. Laurent S. Lehmann, Chief Consultant for Mental Health, Office of Patient Care Services, presented an overview of the Mental Illness Research, Education and Clinical Centers (MIRECCs). The MIRECCs were originally proposed by Dr. Kenneth Kizer, former Under Secretary for Health, and were established by Public Law in the mid-1990s. There are currently a total of eight MIRECCs, the first ones being funded in 1997. In terms of research, the MIRECCs are involved in various aspects of mental health including schizophrenia, post traumatic stress disorder, dementia, and substance abuse. Several MIRECCs are tied to the Quality Enhancement Research Initiative (QuERI). Modeled after the GRECCs, the MIRECCs also offer innovative treatments in the mental health arena, and are actively engaged in training and education programs.

12. Overview of VA's Research Portfolio and Update on Recently Funded Studies. Dr. Burris presented an overview of the VA's research portfolio. Functionally, VA research funding is distributed primarily through investigator-initiated research (69%), with the remainder funding clinical trials (13%), career development (7%), centers of excellence (7%), special initiatives (3%), and service directed research (1%). Scientifically, the portfolio is distributed among Designated Research Areas (DRAs), a mechanism originally proposed by the Research Realignment Advisory Committee (RRAC) in 1996 to strengthen the alignment between VA's research and patient care missions. There were originally 9 DRAs focusing on the high priority health care needs of veterans: acute and traumatic injury, aging and age-related changes, chronic diseases, health services and systems, mental illness, military and environmental exposures, sensory disorders and loss, special (underserved, high risk) populations, and substance abuse and

addictive disorders. Using this methodology, 99% of VA-funded research has been tied to a DRA as being directly related to veterans' health concerns. The ORD has found, however, that using the "chronic disease" DRA to classify the majority of funded projects has not provided sufficient information for analytical and planning purposes. Therefore, the "chronic disease" DRA has been broken into various specific medical specialties (e.g., cancer, heart disease, lung disorders, etc.) to better describe the vast array of research funded by VA. A breakdown of FY02 funding, by DRA, was presented.

If the FY04 budget increases beyond inflation, there are several areas of research targeted by ORD for expansion, including quality improvement (primarily through the QuERI program), diseases of the brain, special populations, chronic diseases, terrorism, and emerging pathogens.

Finally, a list of research projects approved for funding in the Spring 2002 review cycles of all services was distributed (Attachment A), along with a list of currently funded centers and Research Enhancement Award Programs (REAPs) (Attachment B). The NRAC expressed interest in seeing these lists expanded to include DRA assignments in the future.

13. Overview of VA Cooperative Studies Program. Mr. Joe Gough, Program Manager, Cooperative Studies Program (CSP), summarized CSP programs and activities. The primary objective of CSP is to improve the quality of VA health care through clinical trials and epidemiology studies. Previously a part of Medical Research Service, CSP became a separate research service during Dr. Feussner's tenure as CRADO. Funding, both appropriated and leveraged, has increased significantly over the past six years to its current allocation of \$59 million. CSP currently has 25 active clinical trials, three of which are large multi-site studies and the remaining 20 are single-site epidemiology trials. Seven additional trials are currently in planning. The CSP portfolio covers cardiovascular disease, mental health/substance abuse, cancer, general and cardiac surgery, infectious disease, neurology, renal disease, spinal cord injury, and other disorders. Major challenges for the future of CSP include dealing with "hyper regulation" with regard to human subjects protection, obtaining appropriate recognition for studies by Congress and the media, continuing collaborations with other Federal agencies including the NIH, dealing with intellectual property, and translating research findings to VA clinical practice.

14. Discussion. Members discussed two agenda items, and plans for future meetings.

- *Financial Issues/VERA* – With regard to management of and accountability for VERA funds if they are realigned to the research budget in FY04, the NRAC supports the assignment for management/allocation of the funds to the ORD. Dr. Feussner will draft a letter from the NRAC (for review and consideration by members) to the Secretary recommending this strategy.
- *HBCUs* – With regard to increasing research support of HBCUs, a number of ideas were discussed, but members urge proceeding cautiously to avoid a diversion from the primary research mission dedicated to high priority health care needs of veterans. The ORD will compile data on minority institutions that are also VA affiliates and this matter will be discussed at a future meeting.

- *Future Meetings* – Members expressed interest in meeting at a VA medical center in the future in order to learn about the research program from the field perspective. Three meetings will be held in FY03, with the first being in the January/February timeframe. Tentative issues for the next meeting include an introduction to the new CRADO, Homeland Security issues, and the FY03 budget. The NRAC also expressed interest in looking at the portfolio in depth at future meetings, perhaps by splitting it into groupings of DRAs, with the intent of having substantive discussions regarding the overall content and identifying any gaps that may exist.

There were no additional issues pertaining to VA research addressed by the Council.

The meeting adjourned at 2:40 p.m.

I hereby certify that, to the best of my knowledge, the foregoing minutes are an accurate and complete record of the substance of the meeting.

James F. Burris, M.D.
Designated Federal Official
National Research Advisory Council

George W. Rutherford, M.D.
Chairman
National Research Advisory Council

These minutes will be formally considered by the Council at its next meeting, and any corrections or notations will be incorporated in the minutes of that meeting.